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MSc. Pharmaceutical Science

FINAL YEAR PROJECT

astellas

Validation Summary Report & Risk Assessment of

AICL (KP) LIMS

LABWARE

(LabWare LIMS Version 5.0.2)

Project Name: Validation Summary Report & Risk Assessment of AICL (KP) LIMS

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This project is submitted as part of the requirements for the award of MSc. Industrial Pharmaceutical Science and is the work of the candidate.

Definitions & Acronyms

Any abbreviations required for use and understanding of this document are listed below;

Definition/Acronym	Description
CDS	Chromatography Data System (Waters Empower)
DQ	Design Qualification
Installation Qualification (IQ)	Documented verification that a system is installed according to written and pre-approved specifications.
LIMS	Laboratory Information Management System. The application being implemented is LabWare LIMS by LabWare, Inc.
VP	Validation Plan
AICL (KP)	Astellas Ireland Co., Ltd. (Kerry Plant)
Operational Qualification (OQ)	Documented verification that a system operates according to written and pre-approved specifications throughout all specified operating ranges.
Performance Qualification (PQ)	Documented verification that a system is capable of performing or controlling the activities of the processes it is required to control or perform, according to written and pre-approved specifications, while operating in its specified operating environment.
SDLC	System/Software Development Lifecycle
FDS	Functional Design Specification
MES	Manufacturing Execution System
DBA	Database Administrator
UAT	User Acceptance Testing
Unit Testing	A process used to validate that individual units of source code are working properly prior to testing the finished solution as a whole.
Validation	Establishing documented evidence, which provides a high degree of assurance, that a specific process will consistently produce a product meeting its predetermined specification and quality attributes.
ODBC	Open Database Connectivity
DR	Disaster Recovery
DRP	Disaster Recovery Plan
BCP	Business Continuity Plan
Req. No.	URS Requirement Number
Requirement	Description of the Requirement
Conf	Configured in the system (Y/N). 'No', meaning this functionality is part of the LabWare LIMS Pharma 2.1a template while Yes refers to built in functionality (e.g. coding from LW or LIMS Power Users) or OTS functionality which operate in accordance to system settings (e.g. business rules or password settings).
RT	Risk Type; Business, Compliance or both.

Definition/Acronym	Description
Potential Failure	Description of the failure.
Effect of Failure	Effect of the failure on the patient.
S	Severity to the patient, 1 being no impact on patient, 5 being patient will suffer some impact and 10 being patient's life will be threatened.
O	Likely hood of Occurrence within a year. 1 being happens less than once per year, 5 being once per year and 10 being happens once in 3 months
D	Likely hood of detection 1 being more than one mechanism for detection by company systems, 5 being only one mechanism for detection by company systems, 10 – will not be detected by company systems.
Risk	The level of risk calculated using the formula S x O x D
VA	Vendor Assessment
SCR	Source Code Review
'-' In the OQ column	Means testing may be performed as part of the OQ.
SA	System Administrator
Comment\Justifications	Comment or justification for additional or reduced testing.
Mitigating Action(s)	Actions or measures implemented as part of the Risk Assessment in order to mitigate the risk associated with a requirement.

Abstract

LabWare LIMS is a full-featured, configurable, enterprise Laboratory Information Management System (LIMS). LIMS is a computerised system used to manage laboratory samples, equipment, results, workflow, users, and results and to generate reports. At AICL the LIMS system has a bi-directional interface with the Waters Empower Chromatography Data System and with SAP.

The purpose of this report is to give a general overview of all the different aspects of validation required to introduce a LIMS computerised system into AICL. In this project I will detail specifically the risk assessment as this is an area of increasing importance with the regulators/inspectors and relatively new within the pharmaceutical industry. It details the items identified as 'high risk' from the FMEA and how these items were controlled and validated.

At the time of this report being generated, the LIMS system has been introduced for use in the 'live' environment, but some of the existing modules of the system are still being developed i.e. stability samples and alert alarms monitoring.

An external audit performed on the LIMS system post go-live is also detailed highlighting the non-conformance issues that arose during review of the system.

In this project, validation of the AICL (KP) LIMS was executed. The key results showed that the AICL (KP) LIMS is qualified. Also a lot of important lessons learned throughout the duration of the project are highlighted.

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Chapter 1 - Introduction

This report summarizes the validation and risk assessment carried out on AICL (KP) LIMS which was introduced to Astellas Ireland Company Ltd (AICL).

1.1 What is LIMS?

LabWare LIMS is a full-featured, configurable, enterprise Laboratory Information Management System (LIMS). LIMS is a computerised system used to manage laboratory samples, equipment, results, workflow, users, and results and to generate reports. At AICL the LIMS system has a bi-directional interface with the Waters Empower Chromatography Data System and with SAP.

.2 Scope of the Project

This scope of the validation includes the LabWare LIMS software being designed for use by the Chemistry & Microbiology labs and related process areas within the AICL Kerry Plant (KP). The facilities include;

Chemical Testing within the Chemistry Laboratory including;

- Raw Material & Packaging Materials Testing
- In-Process Testing
- Finished Product Testing
- Packaged Finished Product Testing
- Utilities Testing

Microbiological Testing within the Microbiology Laboratory including;

- Raw Material Testing
- Environmental Monitoring Testing
- Personnel Monitoring Testing
- Finished Product Testing

- Utilities Testing
- Finished Product Stability Studies
- Raw Material & Finished Product Sampling
- LIMS Servers & Oracle Database Installation Qualification
- LIMS Client Installation on Empower & User Computers
- LabWare LIMS – Waters Empower Interfacing
- LabWare LIMS – SAP interfacing

Validation also covers the installation of the systems infrastructure which includes the Production and Test environments. Validation has been documented as outlined in this validation plan.

.3 Aims and Objectives

This is a computerised system with the goal of replacing many of the paper based recording processes used within the QC Laboratories. The aim of this report is to demonstrate that AICL (KP) LIMS is validated in accordance with Validation plan (VP), to detail the risk assessment performed and then to authorise the release of the computerised system for operational use in the live environment.

1.4 Validation of a Computerised System

A general model of a computerised system is depicted in Figure 1. [1]

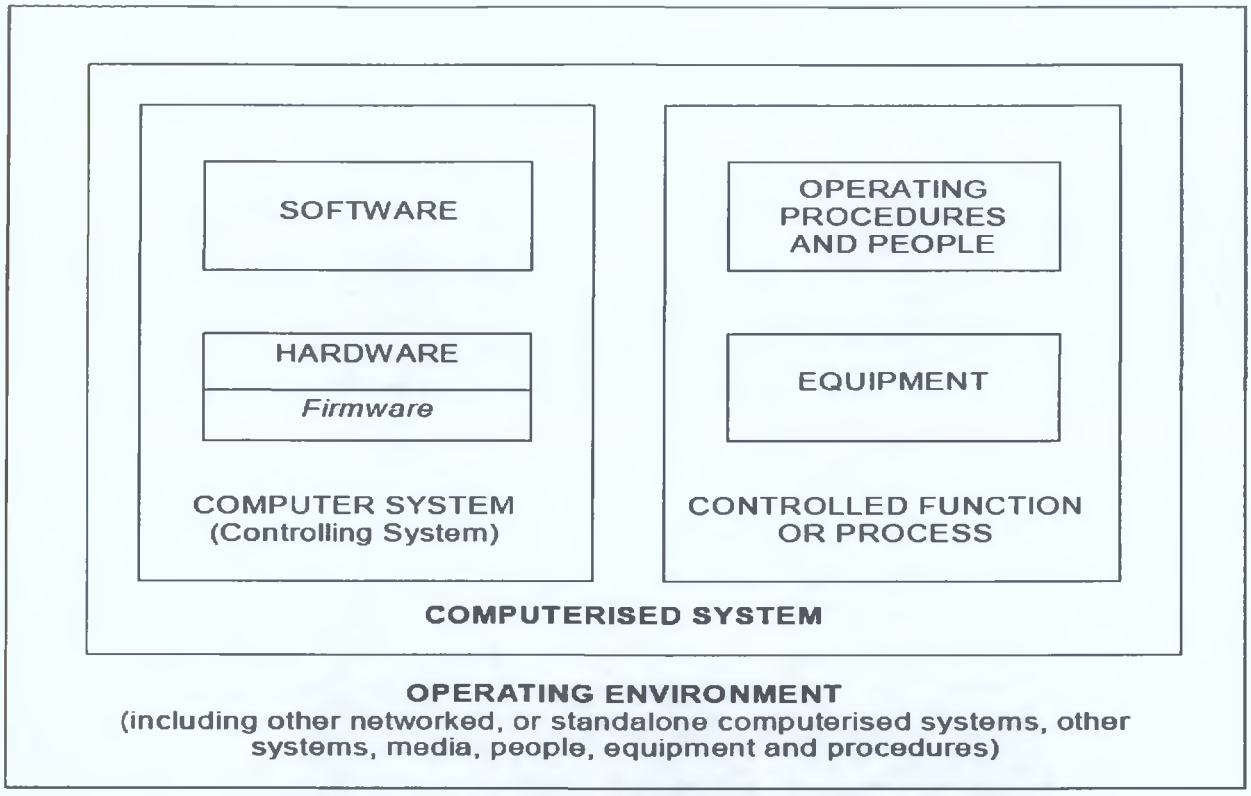

Figure 1: Model of a Computerised System

A computerised system in a GLP environment consists of computer hardware and software, which forms the computer system. The degree of validation required for computerised systems vary depending on the types of systems i.e. simple or complex software.

LabWare LIMS is intended for use in regulated laboratories and is consistent with the principles outlined by GLP, GALP, cGMP, and ISO 9000. LabWare LIMS is designed in accordance with GAMP and ISO 9000-3 guidelines and operates in such a way that:

- allows configuration instead of programmed customizations;
- contains internal configuration-change-control auditors;
- all raw data modifications are audited;

- configuration can be centrally maintained;
- permits language and terminology translations without compiling source code;
- supports database configuration changes without compiling source code;
- conforms to the requirements for a "Closed System" as defined by 21 CFR Part 11;
- GAMP 5 Guidelines define as a "Category 4 - Configurable Software Package".[2]

For this project the extent of validation requirements was based on GAMP 5. GAMP represents Good Automated Manufacturing Practices and is a software process automation group that operates within the International Society of Pharmaceutical Engineers (ISPE).

AICL (KP) manufactures pharmaceutical product for the US, EU, Japanese and rest of world countries and is governed by their retrospective inspection authorities thus the LIMS system must meet all their requirements as regard computerised systems and GMP requirements.

.5 Roles and Responsibilities

A LIMS project team was established within AICL (KP). The roles and responsibilities are outlined in Table 1 below:

Role	Title
Project Sponsor (PS)	Head of Quality
Project Manager (PM)	Project Engineer
System Owner (SO)	QC Manager, Technical
Sub System Owner (QC)	QC Manager, Micro & Lab Analysts

Role	Title
Sub System Owner (QC)	QC Manager, Chemistry
QA Manager (QA)	Compliance Manager
QA Representative (QA)	QA Validation Contractor
Validation Coordinator (Eng)	Validation Coordinator
Project Owner (PO)	PTG Manager
Validation Engineer (VE) x3	Validation Engineer
Project Engineer (PE)	Project Engineer
LabWare Consultant (LW) x3	LabWare Engineer
IT Support (IT)	Head of IT
IT Support (IT)	Sogeti - IT Service Delivery Manager
IT Support (IT) x2	Sogeti - Infrastructure Engineer
IT Support (IT)	Sogeti - Snr. Infrastructure Engineer
IT Support (IT)	Sogeti - Infrastructure Engineer
IT Support – Oracle DBA	Sogeti - Oracle DBA
IT Support (PFH)	Infrastructure Engineer (PFH)
LIMS System Administrator	QC Coordinator
Power Users (PU) x2	Quality Control Chemist
Power Users (PU)	Laboratory Analyst
Power Users (PU)	Quality Control Microbiologist
LabWare Consultant (LW)	LabWare Engineer (SAP)

Role	Title
LabWare Consultant (LW)	LabWare Engineer (Empower)
QC Co-ordinator	System Tester
Chemist	System Tester
Chemist	System Tester

Table 1: Roles and Responsibilities

Project Sponsor

The Sponsor was responsible for signing off the project's budget and ensuring the business receives the planned benefit. Key responsibilities included;

- Ensuring that the business objectives for the project were correct.
- Ensuring that all senior managers knew what the project was trying to deliver to the business and actively supporting the project in their daily actions during the duration of the project.
- Provide support to the Project Manager.
- Form relationships with the LabWare Directors in order to aid problem escalation, increase communication channels and crosscheck understanding of the project's progress.

Project Manager

The project manager was responsible for the following:

- Managing the project scope including user-requirements, business objectives and project deliverables.
- Assigning tasks, resources to all team members including the consultant and monitoring their successful completion.
- Ensuring all planning, monitoring and quality control requirements were being adhered to.
- Ensuring all infrastructures were in place including computers, network, instrument cables and access to laboratory staff as required.

- Resolving any conflicts or problems through facilitation or involvement of the sponsor, etc.
- Providing status reports to the Sponsor and LabWare management team.
- Ensuring that the required regulatory compliance material for the system was produced, GMP, the Validation Plan and Validation Lifecycle managed and maintained.
- Ensuring that the scope of the project was adhered to, and that it was not allowed to increase to the point where the project was negatively affected.
- Review/approval of validation test protocol documentation.

LIMS Administrator

The LIMS administrator was responsible for the following:

- Implementing the majority of the project with advice and knowledge transfer from LabWare Consultant.
- Leading user reviews, assisting with testing, and correction of any error identified.
- Training end-users and maintaining the skills of Power Users.
- Assist power users in the roles along with test protocol execution.

Power Users

The Power users were responsible for the following;

- Setting up and testing static data, co-ordinating user reviews and testing.
- Configuration of the system.
- Unit testing and code review.
- Creating LIMS functionality.
- Discussing implementation issues with the Project Manager and LabWare personnel.
- Training end users.

Validation Engineer

Key responsibilities included;

- Co-ordination of the validation process in acceptance with AICL (KP) procedures.
- Setting up and testing static data, co-ordinating user reviews and producing the necessary test scenarios and data.

- Ensuring all documents were created and the validation was completed correctly.
- Co-ordination and preparation of test protocols with input from the power users.
- Assess Data Migration validation requirements from legacy system(s) to new LIMS system.
- Evaluation of validation requirements including areas of new equipment, Change Controls and new requirements.
- Maintain User requirement specification and validation plan throughout the project lifecycle.
- Review of validation test protocol documentation.

Validation Co-ordinator

The Validation Co-ordinator was responsible for the following;

- Co-ordination of the validation process in accordance with AICL (KP) procedures.
- Providing QA representatives with information regarding the validation status and approach.
- Liaising with the Project Manager on critical validation issues.
- Technical review and approval of all project protocols.
- Updating validation documents to support validation engineer, if required.

IT Support

IT support was required for maintaining the server, database and network. This person was also required to provide help on interfacing to internal IT systems. Key responsibilities included:

- Initial hardware set-up.
- Qualification of hardware.
- Operating System and Database accounts and access.
- Setting up the database instance.
- Optimisation and backup of Database.
- Diagnosing and correcting hardware problems.
- Discussing issues related to interfacing LabWare LIMS to internal systems.

LabWare Consultant

The LabWare Consultant(s) were experienced LIMS professional. The Consultant took the lead during the early stages of the project and then fell back into a more coaching / consultative role as the core team starts to own the LIMS. The key responsibilities of the Consultant included:

- Training the LIMS Administrator and Power Users.
- Providing consultancy throughout the project as requested by the Project Manager.
- Undertaking specific tasks agreed with the project manager, e.g. producing the conceptual system.
- Assisting Power Users with static data set-up.
- Assisting LIMS Administrator with Reports Creation.
- Liaison with LabWare USA for customisations when required.
- Liaison with Regulatory Compliance Resources.

QA Representatives

The Quality Assurance Representative was responsible for the following:

- Assure compliance with appropriate regulatory, business, technical, and user requirements.
- Provide support for the creation, independent review and approval of all deliverables.
- Quality review/approval of all project protocols, both Vendor and AICL (KP).

System Owner

The System owner was responsible for the following:

- Review of project protocols, both Vendor and AICL (KP).
- Provided support for the creation and execution of all validation protocols.
- Provided support for ensuring user requirement specifications are being met.
- Support the design review process of the configured LabWare LIMS.
- Update validation documents to support validation engineer, if required.
- Review, approval and execution of validation test protocol documentation.

Project Engineer

Key responsibilities included;

- Co-ordination and preparation of test protocols with input from the power users.
- Co-ordination and preparation of validation documents as required under the guidance of the validation engineer.

System Tester

The System Tester along with Power Users and are made up of QC Personnel and were responsible for the following;

- Assessing configuration of the system as per the URS.
- Unit testing and code review.
- Test protocol execution.
- Review of validation test protocol documentation.
- Assisting Validation Engineers in generation of validation documentation, if required.
- Generation of new Standard Operating Procedures (SOP's) associated with LIMS and updating existing SOP's to introduce new procedures generated by the introduction of LIMS.
- Training end users.

My role within the project was a system tester. I was brought into the project after its initiation to give additional support to the core project team. As I was the QC technical co-ordinator at the time of the project, I was only able to assist the project team on a part time basis.

Chapter 2 - Methodological Details

A variety of on-site methodologies were employed for the successful implementation and validation of the LIMS system. These methodologies included the validation SOP's to identify validation requirements and these also give guidelines on validations document requirements and contents. These are generated in compliance with GAMP, Annex 11 on computerised systems, PIC/S guidance and 21 CFR guidance. A risk assessment was also performed on the system using FMEA tools, descriptions of these are given below in greater detail.

2.1 Validation Documentation Requirements

Validation Lifecycle as defined by GAMP for commercially available configurable software is outlined in Figure 2.

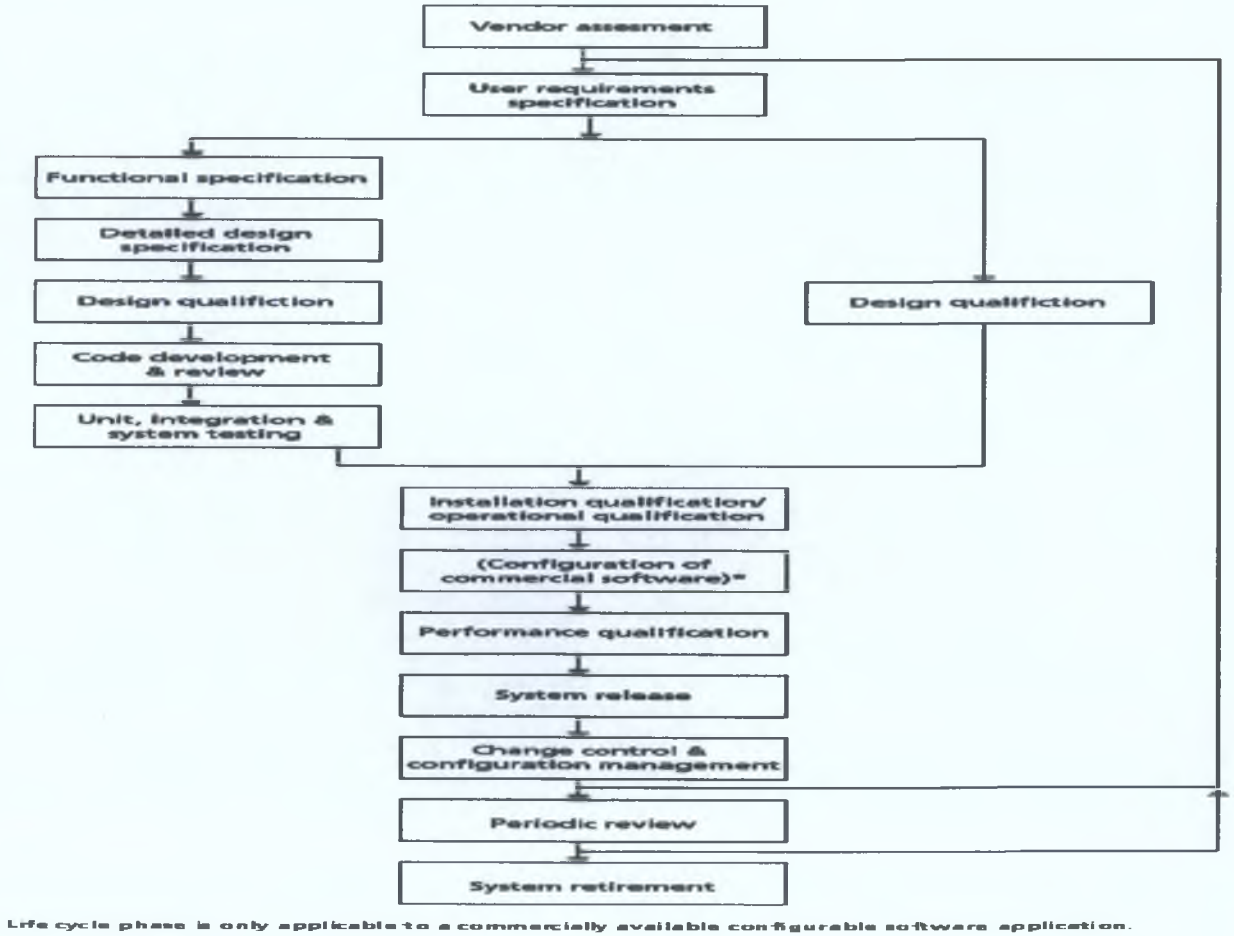

Figure 2: Validation Lifecycle

2.2 Risk Assessment and FMEA Techniques

This Risk Analysis was performed on the LIMS URS to determine the risk involved when using the LIMS system within production. The task was performed as part of a review meeting in which the validation engineer along with a representative of the Engineering, Quality Assurance, Quality Control Departments collaborate and assess the potential risk of the system to the patient. Consideration was also made in the comments section with regard to the risks associated from either a business or compliance perspective where it was applicable. This consideration and others such as those requirements which require actions to mitigate a risk were also detailed as regard additional testing required as part of the assessment.

.2.1 Approach

Various levels of configuration have been performed on the system. The approach to which a requirement was deemed to be configured or not relied on the experience of the subject matter expert and his/her knowledge of how the various requirements where either 'off the shelf' (OTS) or built/configured into the system. In cases where a requirement was deemed OTS, requiring configuration but did not required additional coding, then this requirement were deemed configured. As such these types of configuration are tested in the form of configuration verification and depending on the risk level they may also be functionally tested through User Acceptance Testing (UAT).

Analysis built in to the system are categorised as of three types i.e. complex, non-complex and non-complex but performing a calculation to generate GMP related data. All of these types of data are tested to a high level by the Subject Matter Experts (developers) through Unit Testing. These are also tested at a functional level through UAT and where the risk level is deemed 'high' they are repeated in OQ & PQ. Testing of the system through UT & UAT is leveraged with regard to OQ/PQ testing where the risk level is low.

2.2.2 Failure Mode and Effect Analysis

A failure modes and effects analysis (FMEA) is a procedure for analysis of potential failure modes within a system for classification by severity or determination of the effect of failures on the system. It is widely used in manufacturing industries in various phases of the product life cycle and is now increasingly finding use in the service industry. Failure causes are any errors or defects in process, design, or item, especially those that affect the customer, and can be potential or actual. *Effects analysis* refers to studying the consequences of those failures.

The risks analysis identifies the potential failures of each requirement and then an assessment of the effects of the failure is applied to the patient's safety.

2.2.3 Risk Level and Testing

The risks analysis uses the following parameters; severity, occurrence & detection, which have a points rating of 1 to 10 as defined within GAMP refer to Tables 2, 3 and 4.

Hazardous without warning	Very high severity ranking when a potential failure mode effects safe system operation without warning	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe system operation with warning	9
Very High	System inoperable with destructive failure without compromising safety	8
High	System inoperable with equipment damage	7
Moderate	System inoperable with minor damage	6
Low	System inoperable without damage	5
Very Low	System operable with significant degradation of performance	4
Minor	System operable with some degradation of performance	3
Very Minor	System operable with minimal degradation of performance	2
None	No effect	1

Table 2: FMEA Severity

PROBABILITY of Failure	Failure Prob.	Ranking
Very High: Failure is almost inevitable	>1 in 2	10
	1 in 3	9
High: Repeated failures	1 in 8	8
	1 in 20	7
Moderate: Occasional failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
[illegible]	[illegible]	3
[illegible]	[illegible]	2
[illegible]	[illegible]	1

Table 3: FMEA Probability

Detection	Likelihood of DETECTION by Design Control	Ranking
Absolute Uncertainty	Design control cannot detect potential cause/mechanism and subsequent failure mode	10
Very Remote	Very remote chance the design control will detect potential cause/mechanism and subsequent failure mode	9
Remote	Remote chance the design control will detect potential cause/mechanism and subsequent failure mode	8
Very Low	Very low chance the design control will detect potential cause/mechanism and subsequent failure mode	7
Low	Low chance the design control will detect potential cause/mechanism and subsequent failure mode	6
Moderate	Moderate chance the design control will detect potential cause/mechanism and subsequent failure mode	5
Moderately High	Moderately High chance the design control will detect potential cause/mechanism and subsequent failure mode	4
High	[illegible]	3
Very High	[illegible]	2
Almost Certain	[illegible]	1

Table 4: FMEA Detectability

Multiplication of these parameters results in a numeric value which identifies the risk as high, medium or low. Based on our analysis we deemed that any risk less than 125 points are low risk, greater than 125 and less than 249 would be medium and greater than 249 deemed high risk. Unit testing will be performed on the entire system during development. Using this logic, the appropriate testing was determined using the following table 5;

Risk Level	Configured	Testing Actions
< 125	N	Testing Not Required however it may be performed if deemed applicable.
< 125	Y	UAT
>125 <249	N	Testing Not Required however it may be performed if deemed applicable. (e.g. high business/compliance risk)
>125 <249	Y	UAT, OQ (justification may be made to not perform the OQ testing)
> 250	*	UAT, OQ, PQ (Mitigate the risk required.)

Table 5: FMEA Testing Requirements

* A Non-Configurable requirement that is not high risk should not exist.

Note: Where a user requirement is configured and non-configurable then configured shall take precedence.

Chapter 3 - Results

The results generated as part of this project are different types of validation documentation. These are divided into two different sections; Validation Documentation generated and the Risk Assessment and FMEA Outcome.

3.1 Validation Documentation Generated

The following documents were generated as part validation lifecycle of the LIMS computerised system.

3.1.1 Vendor Assessment

A Vendor Site Audit of LabWare Ltd., Knut ford, United Kingdom was performed. LabWare provided full supplier audit facilities and adopted a very open approach. This audit demonstrated that the LabWare Quality Management System met AICL (KP)'s requirements. The scope of the vendor audit included a review of a number of the test cases and software enhancement modules to be installed at AICL (KP) for the purpose of delivering all the requirements of the URS as defined in the VP. A traceability matrix highlighting all the testing performed for the released LabWare LIMS version 5 has been successfully completed by LabWare. The AICL (KP) vendor audit concluded that LabWare Inc. operates a mature, effective quality management system that includes the elements necessary for projects directly managed from the UK. The LIMS system is a Configurable Off-the-Shelf (COTS) System; the core software has been tested by the Vendor prior to release. A vendor assessment report has been generated detailing the AICL's acceptance of this vendor testing and their quality management systems. AICL deemed it appropriate not to retest the entire product after installation at AICL and leveraged the vendors testing with our own. AICL tested the configuration of the system and any additional functionality implemented in order to meet the user requirements specification.

3.1.2 System Impact

The System Impact Assessment was documented in accordance with Computerised System Impact Determination and Validation Approach Guidelines. The LIMS system was deemed to be a 'high impact' system and the validation strategy has been developed to reflect this.

The impact of the LIMS on IMPCON is considered low as it does not replace the system. The IMPCON system performs a number of tasks including label print which will be replaced by the SAP implementation while the printing of the Certificates of Analysis will be performed through LIMS. Interfacing components supplied by LabWare were used to interface to the Waters Empower and SAP systems. These interfaces have been previously qualified by LabWare and their impact was considered as low.

3.1.3 Validation Plan

The Validation Plan was documented in accordance with internal SOP, 'Guideline for the Production of a Validation Plan'. The purpose of this document is to define the validation strategy for the implementation of the LabWare Laboratory Information Management System (LIMS) Software in Astellas Ireland Co., Ltd., Kerry Plant (KP). The validation approach takes account of GxP, safety and business needs. This validation strategy has been developed following the requirements of AICL (KP) Site Validation Master Plan.

3.1.4 User Requirement Specification

The LIMS User Requirements Specification was documented as per SOP 'Guideline for the generation of a URS'. The URS gives system requirements as defined by the company. Each requirement is defined as GMP Yes/No. There are no conflicts between any requirements. The URS contains functional and non-functional requirements including functionality, effectiveness, maintainability, security, deliverables, timelines and usability. Although the URS is generated independently of the vendor the document is agreed upon

by both parties. Since its creation it has been revised to version 2 after review with the vendor in the form of a formal Gap Analysis and updated as required after DQ to clarify and remove requirements.

3.1.5 Functional Design Specification

The vendor manuals identified the functionality of the configurable system and therefore no FDS document was produced as part of this validation and traceability was mapped between the User Requirement and LabWare Manuals. This has been documented in the Traceability Matrix.

3.1.6 Configuration Specification

The LIMS Configuration Specification documents the current configuration of the LIMS. Changes to the configuration of the system were captured at various milestones in the OQ and PQ qualification phases and documented as a revision to the Configuration Specification document. The document details the Application, Client, User and Database Specifications for the Production (Live) LIMS. The current release of the system at generation of this report is revision 2.

3.1.7 Design Qualification

A Design Qualification Report was produced as per SOP 'Systems Design Qualification'. DQ was performed using the trace matrix which identifies the traceability between the URS and Design Document then details requirements not implemented prior to system testing OQ or PQ. The DQ objectives which have not been met are detailed in the DQ Report and are summarised as follows; there are no outstanding critical user requirements remaining and the remaining requirements do not impact adversely on the system validation.

The majority of LIMS Crystal Reports provided by the vendor have been used. The content of the Microbiology & Stability trending reports will be assessed after PQ testing as trending data was not sufficient during testing.

ABSS has not been created as on further review a System Description Document has been concluded to be adequate due to the fact the system was configured and no customisation was carried out.

Changes to the Test Plan were not carried out as on review and during use no further clarification or revision was deemed necessary. The test plan outlined the testing required as outlined in Figure 3.

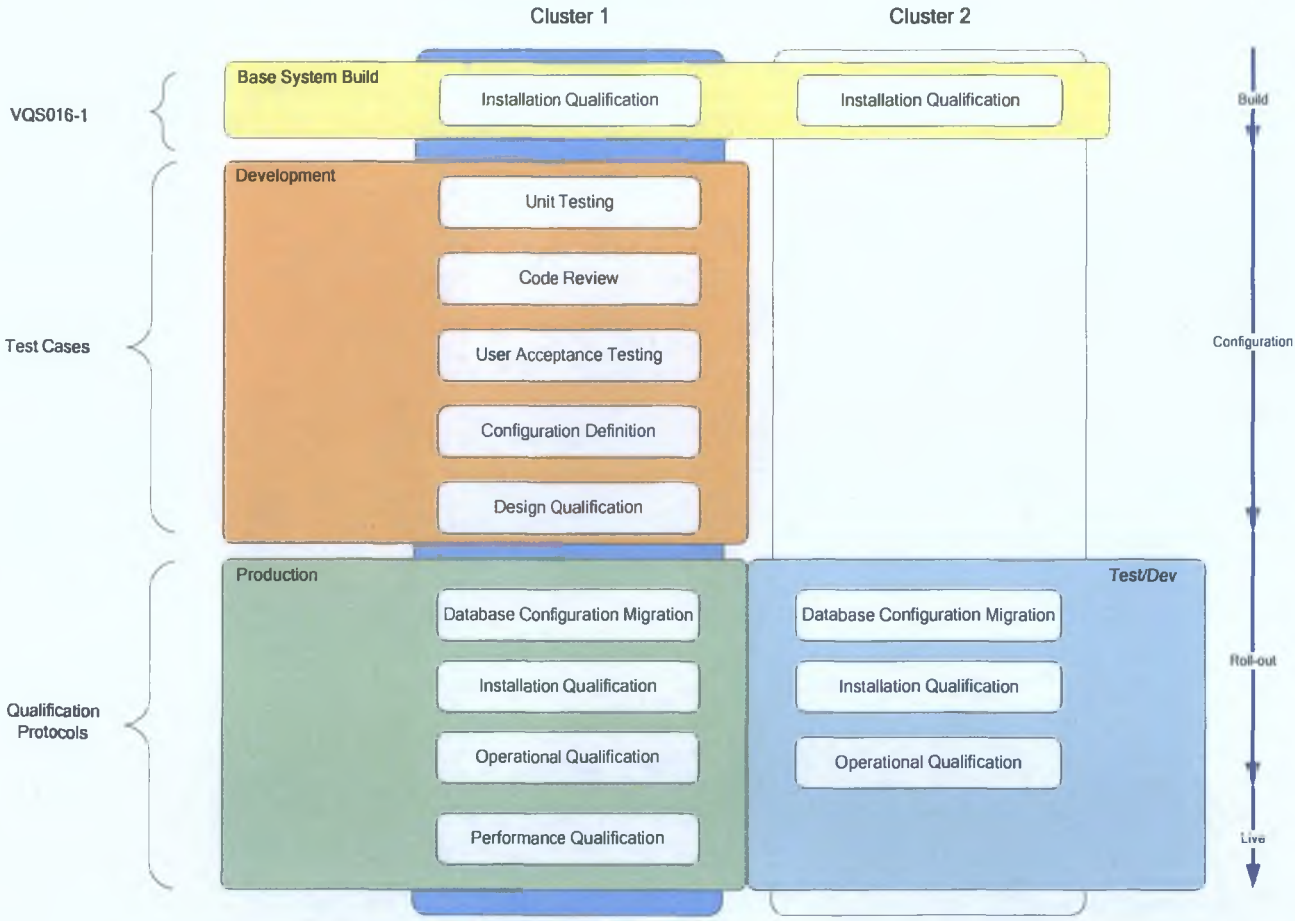

Figure 3: Test Plan Lifecycle

3.1.8 Installation Qualification (IQ) Protocols

Two systems Production and Test are installed at AICL (KP). Installation of the system may be divided into a number of key component installations; Servers, Clients and Software. Installation instructions are documented in the vendor's installation manuals and

white paper documentation. They were revised and have been documented as part of the IT Department documentation; 'LabWare Installation Work Instructions. Empower installation has been documented as per 'Empower Installation Work Instruction'. All installation qualifications have received final post approval.

3.1.8.1 Hardware

A specific Change Control 'IQ of the Production and Test Environments' details the IQ of the Production and Test Environments. IQ was performed on both nodes of the production server and the one node of the test server. Server Configuration Specifications are documented within the IT Department as follows; LIMS PROD Server and LIMS TEST Server.

During the configuration of the system it was decided to build in the production environment as this would be the final location of the completed system. During the configuration phase the production environment was referred to as the development environment. Prior to initiating the OQ the development environment was evaluated to check for any changes implemented as part of the configuration.

Clients were installed under Change Control also. The 'IQ for IT Systems' change control, covers the installation of the initial client. All LIMS client installations including images were performed.

3.1.8.2 Software

LabWare Software is installed using compiled software through a software installer. Modification maybe made to the various directories during installation as part of the installation configuration. Common client files, report and worksheet directories were located on a separate file share.

Installation of the LabWare application was performed by LabWare consultants on the Production Environment as per the installation manual. This was performed under the supervision of the IT Department and Validation Engineer. Qualification of the software was performed using AICL (KP) documentation derived from the official LabWare IQ documents. Installation of the LIMS Client software is documented.

The second major component of the LIMS is the Database Management System. Oracle was selected as it is robust and remains a market leader having various utilities for backup and restore. It is also the same version used for the Waters Empower CDS therefore main homogeneity within the system.

Databases are made up of two parts; the database scheme and data. The LabWare LIMS database schema is distributed in MS Access format. Initial development was performed on MS Access and then once the servers and oracle software were qualified the database scheme and data was migrated to the Oracle Database using the Database Migration Tool utility (DBMT) provided and performed by LabWare on site at AICL (KP). Additional configuration was performed on the database at this time and the remaining configuration was performed in this development.

Other software installed as part of the system include; Microsoft Windows 2003 Enterprise, LabWare LIMS Version 5.0.2 (Pharma Template 2.0a), Oracle 10g Database Management Software (Enterprise Edition), MacAfee Antiviral Software (IT017-2 Virus Checker Configuration Specification), Adobe Professional, Crystal Reports and North West Analytical, Intel/JEPG Viewer & SAP data link libraries. These were installed and qualified as part of the Client and Server IQ's.

All IQ testing has been completed and all acceptance criteria have been achieved. There were no critical deviations. Non-critical deviations are all closed.

3.1.9 User Acceptance Test (UAT)

User Acceptance Testing was performed to pre-test the systems configuration prior to release of the system for OQ testing. Unit testing was performed on small units of a system while UAT is performed on configured functionality or on multiple units in defined functional processes. UAT was used to assess the system against the user requirements and expectations, to dry run the test scripts as the UAT's would become the OQ testing protocol modules and finally to highlight any issues with the configured system in an informal setting. This reduces the number of deviations in the OQ testing phase. Issues were detailed as a result of UAT in the testing track. Issues were resolved while configuration of the system continued in parallel. UAT tests increase the overall confidence in the system prior to OQ. UAT traceability has been included in the Test Matrix as this testing is a requirement under the Functional Risk Assessment.

UAT consisted of two main types of testing; configuration verification and functional testing. Configuration verification is testing whereby setting configured in the 'off the shelf' systems, in-built functionality or data setups were tested. Functional testing includes testing of processes or product related constructs which were built into the system to meet the day to day routine requirements of the QC laboratories.

96 Configuration and Functional UAT's were performed and completed as part of the pre-testing. This included a SAP-LIMS pre-integration test. These were executed and received approval while any remaining issues outstanding prior to commencing the OQ were documented as part of a memo to the project documentation, 'review of the UAT Issues' which has been attached to the Server IQ Change Control. On completion of the UAT testing the initial AICL (KP) LIMS Traceability Matrix was documented.

Note: Control of the configuration build was performed using two project documents; System Build Tracker version 3 which listed product related constructs for OQ1 build. The remaining product related constructs required in the final build were documented in System Build Tracker version 4 and these were used in the data upload for the OQ2

update. Unit testing, ownership and release of these constructs have been documented and controlled using these documents. Refer to the Test Plan for further information on control of the validation testing and logging of issues and deviations[7].

3.1.10 Operational Qualification (OQ) Protocols

Operation Qualification was conducted in two phases. Due to the large amount of configuration required a strategy was devised to allow testing and configuration of the system in parallel. During configuration in the development phase a large percentage of the system's static data and functional processes had been implemented and tested through UAT. OQ was split into two phases; OQ1 which would validate the configuration already pre-tested in UAT while OQ2 would validate any new configuration implemented after OQ1 completion. OQ testing was performed in the PROD database instance while a second database DEV2 was used to configure the remaining constructs required for the finalised system. The system used to conduct the OQ1 testing was captured as Configuration Specification Revision 0. Both databases (Production & DEV2) existed on the Production Environment and the LabWare Changes Manager Utility was used to transfer constructs from the Development to the Production Database.

Testing performed on Production database instance which resulted in deviations was assessed and where the deviations required a system change, the changes were implemented and tested in the development instance of the LIMS prior to being implemented in the Production instance.

Prior to initiation of OQ testing on the Production Environment a review was performed to assess any changes that may have been made to the system as part of the Development and Configuration phases.

OQ1 was detailed in an OQ1 Master Protocol which listed the modules to be executed in order to validate the system. Due to the large complex size of the system the qualification was broken into smaller more manageable modules. These modules are based on the UAT's and are distinct data verification, product, process or functional tests. A number of additional modules were added to this list in order to complete the validation. Modules

were added to the master list for retesting as required, others were new modules and a number of modules were removed from OQ1 testing and placed into the OQ2 testing phase.

In order to facilitate the system build and testing OQ2 was started once OQ1 Testing was completed but prior to final approval. An impact assessment was performed on system changes to assess any potential issues with this strategy i.e. moving into OQ2 prior to OQ1 final approval and the migration of data into the system for OQ2.

An initial informal impact assessment deemed that a number of OQ1's were required to be re-executed. This impact assessment was produced after commencing OQ2 however initial analysis was performed using the System Build Tracker version 4 which identified new and updated constructs to be added to the system for OQ2.

Uploading of the constructs defined in System Build Tracker version 4 was performed under Change Control, 'Migration and Setup of OQ2TEST for OQ2 Testing'. A copy of the PROD database instance was backed up and documented in a revision of the Configuration Specification - AICL (KP) LIMS Release 1.

OQ2 were performed in the same format as OQ1 where an OQ2 Master Protocol was approved detailing the OQ2 Modules required for qualification of the system. A number of additional modules were added to this in order to complete the validation. Where deviation required changes to the system that could impact on the validated status of a construct additional testing was performed. Testing in OQ2 concentrated on the new or updated constructs. Where testing was already performed in OQ1 modules, or retesting of one/more constructs in OQ2 tests were required then reduced testing was performed or retested in the OQ2 modules.

Empower Testing was performed on the Empower Backup Server as detailed in 'Empower VLAN Configuration'.

'OQ1 & OQ2 Close out Assessment for PQ' documents the status of the system on commencement of the PQ1.

OQ1 includes all the functional testing of the system and therefore the system should operate as intended in a limited capacity. OQ2 modules not complete prior to PQ1 were put on hold. A copy of the PROD database was copied to the Test Environment following provisional approval of the IQ for IT System and installation of the then current version of the Application Specification.

'Migration of OQ2 testing to OQ2TEST Database in LIMS TEST Environment' documents the set up the OQ2TEST instance of the Production Database which was used to perform the remaining OQ2 Module testing on the Test Environment. This migration allowed the continuation of PQ1 testing on the PROD LIMS database instance in a limited capacity i.e. any products identified for PQ would require OQ2 module final approval. Testing was recommenced on OQ2TEST, an identical copy of the PROD system to completion.

The OQ2 tests were complete on the OQ2TEST instance and final approval of these remaining constructs were uploaded into PROD for release to PQ2. A copy of the PROD database instance was backed up and documented in a revision of the Configuration Specification - AICL (KP) LIMS Release 2.

SAP-LIMS OQ testing was performed on a development instance of the LIMS. SAP-LIMS integration was also documented as part of the SAP 'Validation Plan' and Validation Report, 'KP Val Status Go-Live'. These are maintained as part of the SAP validation documentation. This approach was taken as the Go-Live date for SAP was in advance of the LIMS. The SAP Project Team needed to do pre-integration testing of the system prior to their Go-Live however no validated version of LIMS could be included in the testing at this time.

On completion of the OQ testing the AICL (KP) LIMS Traceability Matrix was updated.

3.1.11 System Rollout

A number of remaining actions were performed prior to releasing the system in to the Production Environment as a LIVE system. These included database connectivity, client and labels printer checks. The loading of item codes, analysis (MIC Code) External ID configurations, units of measure and suppliers static data to the system for SAP integration was documented in the Change Control. The reconfiguration of Environmental Monitoring programs and installation of Label Printers within the production environment, documented in the Change Control.

The IT Department were responsible for the roll out of the LIMS software either by installing on current client such as Empower or installing new LIMS Imaged clients as per SOP. Checks have been performed by the IT Department on all LIMS clients and ODBC setups confirmed.

Label Printers have been installed along with scanners. This has been performed under change control, and documented in 'IQ for IT Systems' which has Final Approval status.

A system cutover checklist was performed prior to Go-Live and attached as Attachment to the PQ Testing Change Control.

'Second Data Load to the LIMS Database Instance' was created to document the final uploading of data to the system for full go-live in PQ2. This includes a number of SAP-LIMS data verification checks with regards Item codes only.

Due to the parallel validations in a number of separate database instances a final system check was performed prior to PQ2. This included verification that the Production and Test Environments were configured correctly and all remaining development systems removed from Production.

On completion of the system clean up and review of all non-validated systems were removed from the Production Environment. A Server Environment review was performed prior to fully Go-Live (PQ2). This along with the creation of the Test & Dev LIMS instances has been document in the 'Server Change Control'.

3.1.12 Performance Qualification (PQ) Protocols

PQ testing was performed in two phases to allow for limited testing of the system and to identify any remaining problem which may remain within the system prior to going to full release of the system.

PQ1 identified a number of products in the Chemistry and Microbiology laboratories for testing over a defined period. Testing was completed successfully showing that the system could perform as required.

SAP-LIMS PQ testing was performed prior to the PQ2 on the PQTEST instance of the LIMS. This has been documented as part of 'Data Uploading to LIMS Database Instances for Go-Live'. SAP-LIMS integration was also documented as part of the SAP Validation Plan. A separate LIMS database instance PQTEST was used for this testing. Ten SAP-LIMS PQ Test Protocols covering various integral processes were tested. SAP was introduced to live production environment during PQ1. This has been controlled and documented under provisional approval to the site Change Control and SAP Change Control.

PQ2 has been documented in Change Control 'Initiation of LIMS PQ2 Phase'. PQ2 is a monitoring period whereby the legacy paper based system is maintained by management for reference while being removed from the Laboratory environments. On completion of the PQ2 monitoring period a report/memo was generated highlighting any observation and recommendation and concluding the PQ study findings. No issues were generated during PQ2.

All PQ testing has been complete and all acceptance criteria have been achieved. There were no critical deviations. Non-critical deviations are all closed.

3.1.13 Change Control Management

'LIMS Change Management' SOP is in place to manage changes within the LIMS on completion of the validation.

'SAP Change Control Procedure' has been put in place to control any changes in SAP. Prior to implementation of these changes the Key User will identify any potential issues with the LIMS System Administrator.

Change Control Management was conducted in accordance with SOP. As this document is the site wide change management procedure it shall take president over all other system specific change management procedures. This includes Empower Change Control Management.

3.2 Risk Assessment and FMEA Outcome

The outcome of the FMEA risk assessment is detailed in Appendix 1. A number of high risk items have been highlighted in Table 6 below and will be included in the Risk Assessment discussion section.

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-8	It shall have the ability to average / aggregate results where required.	N,Y	C	Software Error, Incorrect Configuration	Incorrect data generated. No result returned.	10	3	10	300	x	x	x		x			Ensure all calculation are executing correctly.
SF-10	It shall have the ability to automatically generate results from calculations	Y	C	Not configured correctly.	Results generated without complete data or not at all.	10	5	10	500	x	x	x		x			Check configuration of the results trigger prior to or after complete data entry.
SF-11	It shall have the ability to perform statistical calculations. For Example:	Y	C	Not configured correctly.	Incorrect data generated. No result returned.	10	3	10	300	x	x	x		x			Check configuration of the results calculations.
5	It shall have the ability to handle reporting of second stage / additional analysis (e.g. Content Uniformity 20 Additional Units, Dissolution S2 stage analysis).	Y	C	Not configured correctly.	No 2nd stage testing result returned.	10	3	10	300		x	x		x			Check configuration of the results calculations.
1	It shall have the ability to generate the FPP with a list of all relevant data from the testing of the GRN material	Y	C	Not configured correctly.	Can't generate the FPP	10	8	10	800		x	x		x		Compliance issue.	Check configuration of the system during testing.
4	It shall have the ability to print out a summary table detailing all results for a stability time point or multiple time points. This data shall include:	Y	C, B	Configure of the report.	Invalid, incorrect or incomplete data on the report.	10	3	10	300	x	x	x		x	x		Confirm the batch detail on the report for all results.
	§ Material Name								-								
	§ Material Code								-								
	§ Batch number								-								
	§ Stability Conditions								-								
	§ Tests								-								
	§ Results for each test at the current time point								-								
	§ Results to date for each test at each time point								-								
	§ Specifications for each result								-								
	§ Approved By Information								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	§ *Date of approval*					1	1	1	1								
SF-104	It shall have the ability to assign different statuses, other than Quarantine, to a batch. The following statuses are to be included:	Y	C	Not configured correctly.	Incorrect status given to a batch	10	3	10	300								
	§ Restricted (Partial) Approval					10	1	1	10								
	§ Approved								-								
	§ Rejected								-								
1	It shall have the ability to associate / link the following for a batch upon its initiation	Y	C	Not configured correctly.	Wrong specs associated to batch. The batch is not tested correctly. Incomplete or invalid data.	10	3	10	300								All product specifications are required to be checked prior to go-live.
	§ Material Name																
	§ Material Code																
	§ Batch Number																
	§ Test Specifications																
9	It shall have the ability to enable the user to accept or reject data entries prior to committing the data to the LIMS.	N	C	Software Error	User doesn't have the ability to check data before committing it to the database. Incomplete or incorrect data.	10	3	10	300	x	x	x		x			Peer review in place.
SF-192	It shall have the ability to generate stability data tables for all batches on stability based on batch number and stability conditions	N	C	Software Error	Can't view the report, incorrect data displayed.	10	3	10	300	x	x	x		x		Used to decide shelf life of the product.	Check configuration of the system during testing.
DS-6	It shall have the ability to interface to the Empower System to enable the user to repeat or rerun a test and then capture additional or reprocessed results from Empower.	Y	C	Empower Projects incorrectly mapped.	Incorrect data.	10	3	10	300		x	x		x	x		High degree of testing, Configuration verification needs to be performed.
DS-9	It shall have the ability to interface with the Empower system and import results	Y, N	C	Empower Projects incorrectly mapped.	Incorrect data imported. No results imported.	10	3	10	300	x	x	x		x			High degree of testing, Configuration verification needs to be performed.

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
DS-13	It shall have the ability to interface with the ERP system to communicate change of batch status.	Y	C, B	SAP-LIMS fields incorrectly mapped.	Incorrect or no approvals status transferred	10	5	8	400	x	x	x		x			Configuration Verification checks required. SAP will be performing its own setup checks. It will be covered in the SAP OQ and additional LIMS OQ, PQ if required at that time. Procedure need to be put in place as part of change control for changes to the LIMS and SAP configuration specifications. An implementation process for configuration changes between LIMS/SAP needs to be put in place.
[illegible]	The LIMS system shall be a closed system, of open architecture, with a secure mechanism for access.	Y	C	Infrastructure and access is not configured incorrectly.	LIMS operation and security compromised.	10	3	10	300					x		Link to DS-29	Verify that the alarms and monitoring systems are functioning as expected. VLAN - ensure change control has been assessed and closed out. Review configuration specification. Verify IT security procedures are in place.
[illegible]	The system shall support authority checks (e.g. identification code and password) to ensure that only authorized individuals can	N	C	Software Error	System is not secure.	10	3	10	300	x				x		Linked to DS-28	As above.
	o Electronically sign a record																
	o Access the operation or computer system input or output device																Ensure the IT vendor audit is in place and that all high criticality LIMS related issues are resolved.
	o Alter a record																
	o Perform the operation at hand																
DS-30	It shall be possible to specify the structure of the password regarding:	Y	C	Not configured correctly.	System is not secure.	10	3	10	300	x	x	x		x			Verify through configuration verification, testing or protocol control.
DS-32	The user shall be forced to change the password at first log-in	Y	C	Not configured correctly.	System is not secure.	10	3	10	300	x		x		x			Include in Administrative LIMS SOP.

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
DS-35	After a specifiable number of failed attempts to execute an electronic signature, access for that user shall be locked	Y	C	Failure attempts limit not configured correctly.	Can still execute an e-sig, e-sig compromised by other user	10	3	10	300	x		x		x			Verify through configuration verification and testing.
DS-37	It shall be possible to define a time limit for automatically lock out a user when the user has not been active in the system for a specifiable time (minutes and/or seconds)	Y	C	Lock out time not configured correctly.	System is not secure.	10	3	10	300	x		x		x		Desktop is set to lock at 15 mins.	Verify through configuration verification and testing.
DS-38	User access to the data shall only be possible from the LIMS application	Y	C	LIMS & DB security not configured correctly.	System is not secure.	10	3	10	300	x		x		x			Procedure or test required to secure LIMS and proprietary database.
[illegible]9	The system shall support that the data in the system are restricted to different users	Y	C	Not configured correctly.	User may have access to pertinent data regarding other system processes.	10	3	10	300	x	x	x		x			Verify tests, folders & sampling through configuration verification and testing.
[illegible]5	System administration privileges shall be separated from routine usage to prevent use of privileged account, when not required	Y	C	Not configured correctly.	The system administrator could perform a task which is not part of their Job description.	10	3	10	300			x		x		Ensure that the SA roles perform only SA tasks. Linked to DS-40	Implements guidance in an SOP
[illegible]7	The batch, the batch samples and the batch results shall be approved by different users, with different rights.	Y	C	Not configured correctly.	User can perform an approval action which they shouldn't have i.e. release of a test, sample or batch.	10	3	10	300		x	x		x		High compliance issue.	Needs to define each of the users in an SOP and have this approved by management.
DS-80	The system shall force passwords to be periodically changed and enable identification/passwords to be inactive without losing the record of their historical use	Y	C	Not configured correctly.	System security maybe compromised.	10	3	10	300	x		x		x			Verify through configuration verification and testing.
DS-101	The system shall have the ability to record modifications to master data such as test specifications.	N	C	Software Error	No auditing of data.	10	3	10	300	x		x		x			Administrative controls required for new users and roles assigned.
C-3	The system should detect and record application errors.	N	C	Software Error.	Errors not detected and recorded. Potential data corruption.	10	3	10	300	x	x	x					Procedure to review error log periodically required.
A-1	The system shall be available for use 24 hours per day, 7 days per week, 365 days per year (excluding times for essential maintenance, backup procedures, etc.)e.g. 24hrs x 7 days	N/A	B	System maintenance without notice.	Data loss or corruptions.	10	3	10	300`						x		Procedures need to be put in place so that maintenance is planned. QC need control over maintenance not IT.

Table 6: Risk Assessment and FMEA Outcome

Chapter 4 - Discussion

All testing required as detailed in the validation plan has been completed. Items remaining include additional testing not yet implemented which are documented in DQ. These include Reports, Alert Alarms implementation and Stability. The alert alarm investigations configuration and a number of reports did not meet the expectations of the users and will be implemented at a future time. A number of stability related product specifications and analysis constructs have yet to be configured and validated.

4.1 Validation Documentation

All the items of validation documentation highlighted in the Results section 3, give documented evidence that the LIMS system has been validated to its predetermined requirements. Figure 4 below maps the relationship between the key specifications and qualification elements as the LIMS system was designed, built and tested.

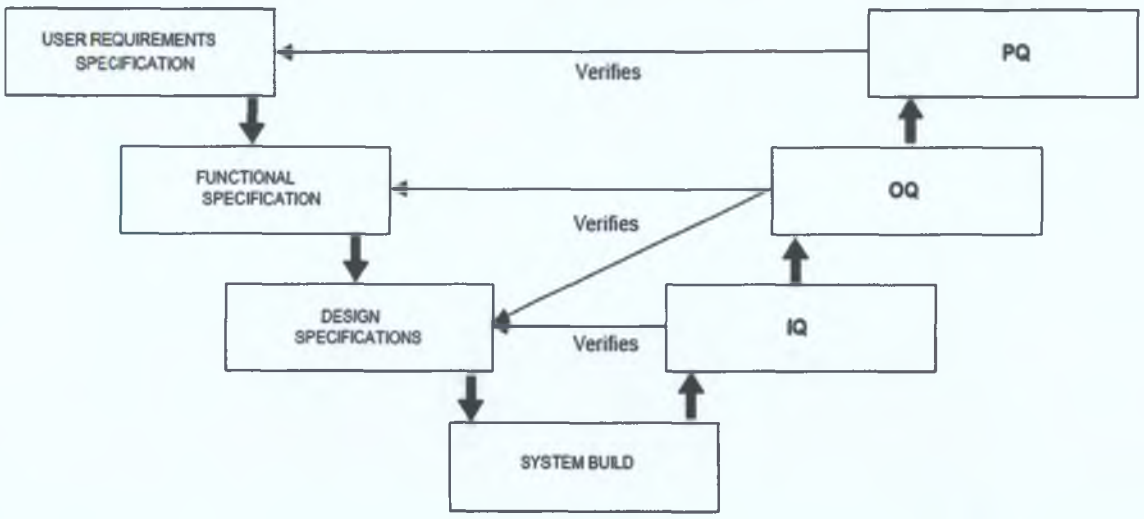

Figure 4: Relationships in Validation Documentation

4.2 Risk Assessment & FMEA

A number of high risk requirements were identified and selected for discussion from the risk assessment section 2.2.

The requirements SF-8, SF-10 and SF-11 all deal with the system's ability to aggregate results, perform statistical analysis and perform defined calculations on results. All these functions are essential to the systems performance as these calculations and results are used within the system to generate certificates of analysis for the products and also are the basis of the approval of all raw materials and finished products. Extensive validation was performed on these calculation including source code review, unit testing, user acceptance testing and operational qualifications. Many of these calculations would also have been included in the PQ of the system.

SF-15 is a requirement for triggering additional analysis mainly for Content Uniformity, Dissolution testing and also a number of microbial tests. In this case the results may not fulfil all the requirements of first stage testing and may need additional analysis carried out and the overall results of all the different stages of testing to be reported. As there are many different conditions for triggering additional analysis all these conditions were outlined and tested in the validation (UT, UAT, and OQ). All these results were checked to ensure they meet all the conditions manually as part of review of testing to ensure all results were compliant.

FPP is finished product packed, FPP cert of analysis results may be an amalgamation of results of the finished product batch, GRN material and the FPP results combined. This requirement is outlined in SF-41. To ensure this requirement was fulfilled UT, UAT and OQ testing was carried out. FPP cert's of analysis do not have to be generated on LIMS and may be generated manually if required.

System Requirements' SF-74 and SF-192 are specific to the Stability Module which is still under development.

SF-104 specifies the requirement of assigning different status to a batch. This function is a necessity to control the status of material within QC. Different statuses include quarantine, approval, rejected, partial approval and restricted approval. This is an EU GMP requirement for all material within the company.

SF-121 deals with linking specific documents to a batch upon initiation. These include material codes and specifications links. If these links are incorrect a batch of material may be linked to the incorrect specifications, and the incorrect tests may be assigned to the batch also. Extensive validation was applied to this requirement including UAT, OQ and PQ.

SF-149 deals with the Empower CDS system and the acceptance of results prior to committing to LIMS. In some cases chromatography may need to be reprocessed or re-run or repeated within QC. As a result of this the analyst and another analyst (checker) review the chromatography prior to committing the results to LIMS. Commitment of results to LIMS from Empower includes a manual trigger/step once the results are confirmed to be valid. DS-6 and DS-9 also deal with the Empower CDS and the ability of LIMS to interface with the system and report results. Empower mappings were carried out and verified in UAT and OQ's.

LIMS must also have the ability to interface with SAP to communicate the change of batch status on SAP when a batch status is changed on LIMS. A substantial amount of validation took place on the SAP-LIMS interface as both systems were being introduced and validated at the same time. Validation included OQ and PQ's including both systems. Batch status on SAP may be changed manually on SAP in the event of a failure of the two systems communicating.

DS-28 and DS-29 are IT requirements for the LIMS system. These include that is should be a closed system with secure access and should have the ability to support authority checks. It was ensured that the alarm and monitoring functions as required, that the system is on the VLAN and that the system is governed by IT security procedures.

DS-30, DS-32, DS-35, DS-37, DS-38, DS-49, DS-55, DS-57 and DS-80 all deal with system security, passwords, system access, privileges and rights as governed by 21 CFR guidance. Configuration verification and testing were carried out on these requirements and these are also detailed in the LIMS Management SOP.

The LIMS system contains controlled specifications, due to this DS-101 requires the need of the system to be able to record changes to master data such as specifications. Only LIMS users with certain access rights have the ability to change specifications. Also any changes made to controlled items in LIMS are routed through an approval system where they require approval from QC and QA management, similar to that of controlled paper documents. A Document Change Request is associated with the paper specifications that are still in place will also highlight the need to update and approve the relevant LIMS specifications and records all the reasons for revision.

C-3 is a requirement for the system to detect and record system errors. This will highlight any issues with the system so they can be resolved easily.

A-1 details the system availability, the system needs to be available 24 hours a day, 7 days a week. There are procedures in place for remedial actions in the event of LIMS unavailability, i.e. paper data sheets etc.

4.3 Audit Findings

A compliance audit was performed on site by an external agency. This audit focused on aspects of design, development, validation, implementation and routine maintenance and control of the LIMS and SAP systems. The aim of the audit was to confirm compliance of the approach to design, validation and implementation of the computerised system with the requirements of EU Guide to GMP and 21 CFR, these defining the requirements of the EU and US regulatory systems. Compliance with the current best practice standard of GAMP 5 was also reviewed.

Non compliances with current GMP are categorised as critical, major and other, to reflect the categorisations that are typically used by regulatory agencies. A critical GMP non-compliance is a GMP failure that indicates a significant risk that the product could or would be harmful to a patient, or a failure that has produced a harmful product. A major non-compliance is a non-critical failure which contravenes the conditions of the manufacturers licence to a significant extent, or relates to a failure by the Qualified Person to carry out their legal responsibilities, or relates to changes in the operation of the company that have not been notified to, or agreed with the IMB. GMP non-compliances that are classified as 'other' reflect departures from the GMP that are not considered critical or major. It should be noted that a number of major or other non-compliances might collectively be considered by the regulatory authorities to constitute critical or major non-compliances respectively.

A report was generated after the audit highlighting that there was 3 Other GMP deficiencies and 5 Major GMP deficiencies and no Critical GMP deficiencies. These are highlighted below.

4.3.1 Other GMP Deficiencies

Observation: A deviation occurred during testing where failure to append screen shots to test documentation occurred. However no formal deviation was raised relating to this.

Recommendation: Formal deviation to be documented for this failure.

Observation: A second stage testing was observed in the screen shot however this was not defined in the test script, and no clarification was entered on the test script.

Recommendation: It is recommended that a clarification be recorded on the validation documentation relating to the observation of second stage testing on the screen shot and not on the test script.

Observation: the LIMS change history does not provide a good audit trail as reasons were not recorded for a number of changes, 'no reason specified' was recorded automatically by the LIMS System.

Recommendation: it is recommended that reasons for change be recorded to ensure that the change history provides a full audit trail. It is recommended that the system be reviewed in relation to silent prompts to allow reasons for change to be entered by the user where appropriate. It is further recommended that the accuracy of the automated and silent prompts be established and that this verification work be documented as an addendum to the LIMS Validation.

4.3.2 Major GMP Deficiencies

Observation: The validation approach of the vendor selection was reviewed. AICL carried out a vendor audit as part of their validation. In the design of the validation activities after vendor selection, AICL had leveraged on software validation that had been completed by the vendor, however it was not always possible that the vendor validation was in place and available relating to each of these leveraged elements.

Recommendation: It is recommended that AICL review the white paper used to support leveraging validation from the vendor to confirm the validity of AICL's confidence in the leveraging that was carried out.

Observation: Two of the URS items ranked at 300 during the risk assessment were reviewed. However no validation was identified for the various activities and no validation testing had been carried out. This contravenes the risk assessment where a risk level of >250 was identified as requiring validation.

Recommendation: It is recommended that the risk assessment be reviewed with respect to scoring levels and the ability of AICL to demonstrate appropriateness of validation activities.

Observation: It was noted when an initial result was entered into the system, the flag that was assigned in the history table varied between "enter result" and "modify result". Standard functionality in LIMS system was to flag any modification that occurred. However, in these instances this flag was not activated. While activation of the modification flag is not an issue in this case, the allocation of a modification statement to the initial entry of a test result is of concern as it confuses the history record. This was confirmed to be a known bug in the LIMS system, but procedures had not been put in place to manage this system error in routine implementation. Similarly it could not be confirmed if there were other known bugs within the system which had the potential to impact on GMP compliance.

Recommendation: It is recommended that a procedure be defined for dealing with the known bug in the LIMS system. It is also recommended that a documented review be carried out to identify if there are bugs within the LIMS system that are known and for which work around and controls are required for day to day implementation, to ensure GMP compliance.

Observation: Electronic records and electronic signatures assessment was carried out and had received provisional approval. It was noted that the handover of the LIMS system to the live environment had been carried out while this aspect of validation had not been completed.

Recommendation: it is recommended that the rationale for proceeding with the cutover to the live LIMS system in advance of completion of the ERES validation be documented.

Observation: Complete performance testing and challenge testing were not carried out as part of the LIMS Validation programme. For example, performance testing to include timing and response, and testing performance under expected load conditions. Challenge testing such as hardware fault tolerance tests and stress tests were not carried out. While a system description was available, the age of the hardware was not recorded to provide a baseline and to facilitate evaluation of the validation testing performed in relation to an overall system challenge.

Recommendation: It is recommended that an additional performance testing and challenge testing be carried out on the LIMS system. It is further recommended that key information relating to hardware in place for performance of the validation programme be documented in relation to the overall system challenge e.g. age of individual pieces of hardware.

Chapter 5 - Conclusion

In this project, validation of the AICL (KP) LIMS was executed. The key results showed that the AICL (KP) LIMS is qualified. Installation has been completed successfully and all the hardware and software are available for use. OQ has been completed successfully with all LIMS modules qualified. It has been installed as per AICL (KP) requirements. The system is operational and performing as per the user requirements.

A number of remaining actions/recommendations need to be performed arising from the external audit performed just prior to this report being generated.

Stability to be implemented along with updates to LIMS reports. Implementation of the Alert Alarm Investigations in LIMS has been temporarily suspended.

This validated state will be maintained by the LIMS System Administrator(s) and Power Users in cooperation with the QC Department. Changes to the system will be controlled as per SOPs.

As such a large project has never been undertaken by the QC Department at AICL to date, there were a number of valuable lessons learned during the LIMS project. LIMS was a very large project and the extent of the validation required to implement this project was enormous. The initial scope of the project underestimated this, and as a result additional resources had to be allocated to the project, which lead to additional costs.

The power users were given initial training on LabWare LIMS and then had to develop source codes, create analysis specific to AICL which was a hard task as all power users were QC based with no computer programming background or previous LIMS experience, while LabWare Consultants were on site for defined periods during the project there was

little on hand expertise for the power users, thus increasing the time required for the power users to configure the system.

As LIMS was being validated at the same time as SAP and were introduced to the 'live environment' at the same time, there were a lot of problems associated with the SAP-LIMS interface and linking of data. This was due to changes being made to one system and not being communicated to the other project team in an efficient manner as both projects were under development.

The extent of validation documentation required to verify the system was functioning as required was also under-estiminated along with extensive time consuming review's required by 3 different departments on each document.

As a result of the implementation of LIMS at AICL, the QC Department have gained valuable experience in validation of computerised systems, along with project management.

Chapter 6 – References

External References

1. PIC/S, Good Practices for computerised systems in Regulated GxP environments
2. www.labware.ie
3. Eudralex Volume 4: Good Manufacturing practice (GMP) guidelines.
4. 21 Code of Federal Regulations (CFR).
5. GAMP 5 Guidance.
6. GAMP Good Practice Guide: Validation of Laboratory Computerised Systems

Internal References

7. Systems Design Qualification SOP
8. LIMS Change Management SOP
9. SAP Change Control Procedure SOP
10. Change Control SOP
11. Guidelines for Production of a Validation Plan SOP
12. Guidelines for the documentation of User Requirements SOP
13. General Requirements for the Preparation, Execution and Approval of Validation Protocols and Structuring of OQ and PQ Protocols SOP
14. Installation Qualification SOP
15. Computerised System Impact Determination and Validation Approach SOP
16. Requirements Design Testing Traceability SOP
17. Computerised Systems Vendor Audit SOP

Chapter 7 – Appendices

1. Risk Assessment & FMEA Outcome.

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
PR-3	The system environment should inform the user about the version used and the actual environment such as Production, Test or Development	Y	C	ODBC Setup	Execute actions on incorrect system i.e. test performed in the Production environment rather than the Test.	10	3	5	150			x	x				
PR-5	The system shall enable date/time synchronization to a timeserver.	Y	C	W32 Time and Time Server have incorrect time. W32 Time and Time Server has configured incorrectly.	Time Stamp between system incorrect and possible conflict.	1	5	10	50				x				
PR-6	The system shall support special characters and where special characters are printed that printer shall be capable of print such characters as required.	Y	C	Not configured correctly on Client. Printers can use special characters	Special characters not printed.	1	1	1	1				x				
PR-7	The systems shall support to work with bar codes for data entry.	N	B	Software Error	Barcode scanning not possible.	1	1	1	1	x							
PR-8	It shall be capable to refresh the display of data to the user via a user interface either manually or automatically at a predefined rate.	Y	B	Not configured correctly.	Data not refreshed as required.	1	1	1	1	x	x						
SF-2	It shall be possible to migrate data into the LIMS system by manual entry	N	B	Terminal failure.	Can use system.	1	1	1	1	x							
SF-4	It shall be possible to export data to Microsoft Excel	N	B	Software Error	Can't export data.	1	1	1	1	x							
SF-5	In the event of system failure an alert notification shall be sent to the System Administrator and/or IT e.g. computer alarm, interlocks, PSU Failure, Storage Disk Failure email alerts	Y	C	Active Xpert software not configured properly - to include LIMS Server	Alert not created	1	1	5	5			x	x			High business issue.	
				Active Xpert software not working properly	Alert not created	1	1	5	5				x				
SF-6	In the event of storage disk failure an alert notification shall be sent to the System Administrator and/or IT	Y	B	Not configured correctly.	No notification sent.	1	3	10	30				x	x			Check that systems and SOP are in place.
SF-7	It shall be possible to create custom calculations within the application e.g. specific calculations or algorithms required by the system	N	C	Software Error	Can't create custom calculations.	1	1	1	1	x							
SF-8	It shall have the ability to average / aggregate results where required.	N,Y	C	Software Error, Incorrect Configuration	Incorrect data generated. No result returned.	10	3	10	300	x	x	x		x			Ensure all calculation are executing correctly.

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-9	It shall have the ability to enable an authorised user define calculations	N/A	C	Implemented without authority	Incorrect results.	10	1	10	100								CC in place for changes and SOP referring to SA
SF-10	It shall have the ability to automatically generate results from calculations	Y	C	Not configured correctly.	Results generated without complete data or not at all.	10	5	10	500	x	x	x		x			Check configuration of the results trigger prior to or after complete data entry.
SF-11	It shall have the ability to perform statistical calculations. For Example:	Y	C	Not configured correctly.	Incorrect data generated. No result returned.	10	3	10	300	x	x	x		x			Check configuration of the results calculations.
	§ Linear Regression calculations	Y							-								
	§ Correlation Factor calculations	Y							-								
	§ Population Mean	N							-								
	§ Population Relative Standard Deviation	N							-								
SF-14	It shall have the ability to allow the manual entry of test results	N	C	Terminal failure.	Can use system.	1	1	1	1	x							
SF-15	It shall have the ability to handle reporting of second stage / additional analysis (e.g. Content Uniformity 20 Additional Units, Dissolution S2 stage analysis).	Y	C	Not configured correctly.	No 2nd stage testing result returned.	10	3	10	300		x	x		x			Check configuration of the results calculations.
SF-16	It shall have the ability to enable filtering of data through the following search criteria:	Y	B	Not configured correctly.	Can't filter or search	1	1	1	1	x							
	§ Batch Number								-		x						
	§ Stability Conditions								-		x						
	§ Packaging Configuration								-		x						
SF-17	It shall have the ability to create additional search criteria options	Y	B	Not configured correctly.	Can't create additional search	1	1	1	1	x							
SF-26	It shall have the ability to enter free text comments relating to deviations for a batch by an authorised user.	Y	C	Not configured correctly.	Can't add test comment	1	1	1	1	x	x	x				Compliance issue.	
SF-30	It shall have the ability to generate the batch COA with results and usage decision.	Y	C	Not configured correctly.	Can't send results and usage decision.	1	1	1	1	x							
SF-31	It shall have the ability to print out COA	N	C	Software issue, update performed	Can't Print	1	3	1	3	x	x	x				Compliance issue.	
				Report won't open in adobe					-								
				No Printer setup or connected					-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
				Report not present on server					-								
SF-32	It shall have the ability to enter free-text into the COA to make any additional comments as deemed necessary.	Y	C	Not configured correctly.	Can't add a CoA Note.	1	3	1	3	x	x	x				Compliance issue.	
SF-36	It shall have the ability to automatically include all relevant testing data from the batch into the FPP batch.	Y	C	Not configured correctly, user input.	No CoA. Incorrect batch linked.	10	3	5	150		x	x		-		Compliance issue.	
SF-41	It shall have the ability to generate the FPP with a list of all relevant data from the testing of the GRN material.	Y	C	Not configured correctly.	Can't generate the FPP	10	8	10	800		x	x		x		Compliance issue.	Check configuration of the system during testing.
SF-42	It shall have the ability to link the official shipping COA with the company details and logo	Y	C	Not configured correctly.	Logo and company details not displayed in the final CoA	10	3	1	30		x	x				Compliance issue.	
SF-43	It shall have the ability to identify batches with any change control and/or protocol procedure either through manual identification.	Y	C	Not configured correctly.	Can't identify batches.	1	1	1	1		x	x				Batch record is stamped therefore high detection.	
SF-44	It shall have the ability to contain storage durations for retain samples based on regulatory requirements and generate a report when samples have been stored beyond this requirement	N	C	Software Error	Storage conditions and duration not displayed. Can't query LIMS inventory manager.	10	1	1	10	x	x						
SF-45	It shall have the ability to generate/update a work schedule detailing the testing that needs to be performed for a material	N	C	LEAN process	Tests not Scheduled	1	3	1	3							No associated risk.	
SF-46	It shall have the ability to enable entry of free-form text to describe deviations associated with a process or a procedure	Y	C	Not configured correctly.	Free form text field not displayed,	10	3	1	30	x	x						
SF-47	It shall have the ability to accept skip lot testing.	Y	C	Not configured correctly.	Malfunction in the skip lot testing process.	3	3	10	90	x	x	x				Business issue.	
SF-49	It shall have the ability to generate a alert alarm notice and corrective action investigation for the Water systems which will specify	Y	C	Not configured correctly.	Alert alarm report not generated.	10	3	1	30	x	x	x				Creation of the Alert Alarm investigation is a manual process.	
	§ Sampling Point					5	1	1	5								
	§ Result					10	1	1	10								
	§ Corrective Action Details								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-51	Procedures shall be put in place to ensure that updates to a BOM in the ERP system which effect the LIMS (i.e. material codes) are managed through change control.	N/A	C	Procedure is not in place	Updates not made to the system.	1	3	1	3	x	x					Confirm through DQ, CC. Business risk.	
SF-52	The system shall report the name and number of all templates which have undergone modification within a given period of time.	N	C	Software Error	Can't review changes to the system.	1	1	1	1	x	x					Compliance risk. Part of CC. Configuration Manager can perform this task if require. OTS.	
SF-53	It shall have the ability to create a protocol study or analysis request containing the following information:	Y	C	Not configured correctly.	Incomplete data.	1	3	10	30	x	x	x		x		Compliance issue.	
	§ Protocol Description																
	§ Associated Document Numbers																
	§ Associated Change Control Numbers																
	§ Free-form text for the description of protocol procedures																
	§ Associated Equipment/Locations for cleaning																
	o Sampling points																
	o Frequency of cleaning																
	o Tests																
	o Free-form text to define a sample needed for cleaning																
	§ Associated Batches																
	o Material Name																
	o Material Code																
	o Batch Number																
	o Tests																
	o Test Methods																
	o Test Specifications																
SF-54	It shall have the ability to manually amend the tests to be performed on a batch associated with a protocol	N	C	Software Error	Can't modify a protocol.	1	1	1	1	x	x	x				Compliance issues.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-55	It shall have the ability to halt the continuation of a protocol study until it has received approval for execution.	Y	C	User input	Protocol executed without approval.	1	3	1	3	x	x	x				Compliance issues.	
SF-57	It shall have the ability to allow for additional samples to be added to the protocol study	N	C, B	Sample can be added to a protocol due to a software issue	Can add samples to a protocol	10	3	1	30	x	x	x		x	x	High compliance issues.	
SF-59	It shall have the ability to specify the specifications to be applied to a batch associated with a protocol	N	C	Software Error	Can't specify the specifications to be applied to a batch associated with a protocol	1	1	1	1	x	x						
SF-61	It shall have the ability to allow cessation of a protocol during its lifetime	N	C	Software Error	Can't close the protocol.	1	1	1	1	x	x						
SF-62	It shall have the ability to define associated equipment (CTC) on the application for stability batches. This shall include the ability to define the equipment with the following information: § Equipment Name § Temperature set point § Humidity set point § Current contents of CTC chamber	Y	C	Not configured correctly, CTC could be wrongly configured, Samples place in wrong CTC.	Incorrect information about an analysis. Invalid results possible both positive and negative.	3	3	5	45	x	x	x		x		High compliance issues.	
SF-63	It shall have the ability to create a unique stability study detailing time points and set points for the study during its lifetime	N,Y	C	Software Error	Can't define a study. Study not setup correctly.	7	3	1	21	x	x	x		x		High compliance issues.	
SF-64	It shall have the ability to define the tests required within a stability study at each time point during its lifetime	Y	C	Not configured correctly.	Wrong study Conditions. Invalid results possible both positive and negative.	7	3	1	21	x	x	x		x		High compliance issues.	
SF-65	It shall have the ability to change the stability study by adding/removing time points as required	N	C	Software Error	Can't add/remove tests.	1	1	1	1	x	x						
SF-66	It shall have the ability to manually input the list of stability tests onto the application	N	C	Software Error	Can't input test results.	1	1	1	1	x	x	x		x		High compliance issues.	
SF-67	It shall have the ability to manually define / create a unique batch for a stability study within the application	Y	C	Not configured correctly.	Can't manually define / create a unique batch for a stability study.	1	1	1	1	x	x						
SF-68	It shall have the ability to create a stability data sheet on the application detailing the container numbers for the batch	Y	C	Not configured correctly.	Incorrect container numbers recorded against the container.	7	3	5	105		x	x				Compliance issues.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-69	It shall have the ability to log the stability samples onto the LIMS inventory and link these samples to the assigned CTC	N	C	Software Error	Can't link the samples to the CTC.	1	3	1	3	x	x	x				Requires the users to have configured the CTC's correctly but the ability is OTS.	
SF-71	It shall have the ability to generate a report listing all of the stability batches to be sampled between a date range. The report should include:	N	C	Reports Adobe	Can't report but can go in by other means	1	1	1	1	x	x	x		x		High compliance issues. Run the reports.	
	§ Material Name								-								
	§ Material Code								-								
	§ Batch Number								-								
	§ Planned date of removal from CTC								-								
	§ Time point								-								
	§ Conditions (temperature and humidity)								-								
SF-72	It shall have the ability to indicate on the system which container numbers for a stability batch were removed from the CTC at each time point	Y	C	Configuration, User input.	Invalid or incomplete data.	7	3	5	105		x	x		x		Linked to SF-68	
SF-73	It shall have the ability to assign testing of the stability batch to multiple groups of users based on the types of test specified for the stability study.	Y	C	Configure of the study, folder configuration.	Sample not tested	10	1	3	30			x				Compliance issue.	
SF-74	It shall have the ability to print out a summary table detailing all results for a stability time point or multiple time points. This data shall include:	Y	C, B	Configure of the report.	Invalid, incorrect or incomplete data on the report.	10	3	10	300	x	x	x		x	x		Confirm the batch detail on the report for all results.
	§ Material Name								-								
	§ Material Code								-								
	§ Batch number								-								
	§ Stability Conditions								-								
	§ Tests								-								
	§ Results for each test at the current time point								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	§ Results to date for each test at each time point								-								
	§ Specifications for each result								-								
	§ Approved By Information								-								
	§ Date of approval					1	1	1	1								
SF-75	It shall have the ability to enable the grouping of multiple stability studies into a defined, named stability project.	N	C	Software Error.	Can't group studies.	1	1	1	1	x		x				Compliance issue.	
SF-76	It shall have the ability to define, create and modify a stability project containing various stability batches during their time on stability	N	C	Software Error.	Can't create or alter studies.	1	1	1	1	x		x				Linked to SF-75	
SF-77	It shall have the ability to create, modify and save templates which can be used for further stability studies.	N	C	Software Error.	Can't create or alter studies templates.	10	1	1	10	x		x				Linked to SF-75	
SF-78	It shall have the ability to close out a stability study before its due date	N	C	Software Error.	Can't close out a study before it's complete.	10	1	1	10	x		x				Compliance issue.	
SF-79	It shall have the ability to capture Environmental Monitoring material preparation details:	Y	C	Not configured correctly.	Field not entered	1	3	7	21			x		x		High compliance issues.	
	§ Date Prepared.								-								
	§ Prepared By.								-								
	§ Media Lot Numbers.								-								
	§ Media Expiry Dates.								-								
	§ Confirmation of Media QC Acceptance Check.								-								
SF-80	It shall have the ability to capture Environmental Monitoring sampling information:	Y	C	Not configured correctly.	Field not entered or function can't be performed, result not entered	1	3	7	21			x		x		High compliance issues.	
	§ Date of Monitoring.								-								
	§ Monitoring Location ID Number (unique).								-								
	§ Type of monitoring at ID location, Settle Plate, Contact Plate, Air Sample Plate, Finger-Dab Plate, and Garment Monitoring Contact.								-								
	§ Operator Performing Monitoring, specific monitoring shall								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	be capable of being grouped for sampling information.																
	§ Sampling Times (From: hh:mm – To: hh:mm), shall be able to group specific monitoring for sampling information and also able to record for individuals as Air-Sample Plates have to be recorded individually.								-								
	§ Highlight when a sample or series of grouped samples are ready for completion								-								
SF-81	It shall have the ability to capture Environmental Monitoring sampling information where continuous monitoring during a process is performed	Y	C	Not configured correctly.	Can record it terminal	1	3	7	21	x		x		x		High compliance issues.	
SF-82	It shall have the ability to record comments during Environmental Monitoring sampling for the acknowledgement of a damaged sample requiring re-sampling and testing.	Y	C	Not configured correctly.	Can't record comment	1	3	7	21	x		x		x		High compliance issues.	
SF-84	It shall have the ability to capture Environmental Monitoring test data:	Y	C	Not configured correctly.		1	3	7	21	x		x		x		High compliance issues.	
	§ Record date of incubation.								-								
	§ Record time of incubation.								-								
	§ Record incubator used for grouped items.								-								
	§ Record person incubating.								-								
	§ Record time and date of reading of results as grouped items.								-								
	§ Record individual results for all test items in specific format.								-								
	§ Record person reading the results as grouped items.								-								
	§ Comments, as required.								-								
	§ Provide a field whereby identification results can be recorded for specific non-compliant recoveries								-								
SF-85	It shall have the ability to record results for additional Environmental Monitoring	N	C	Software Error.	Can't group studies.	1	1	1	1	x	x						

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-87	It shall have the ability to capture the different sampling information in Production:	Y	C	Not configured correctly.	As per listed requirements.	-	-	-	-			x		x		High compliance issues.	
	§ For Personnel monitoring it shall be able to list the activities performed associated with that sample/samples	Y	C	Not configured correctly.	Can't list activities. Incomplete data.	1	3	7	21								
	§ For Environmental monitoring it shall be able to list the Production activities associated with that sample/samples	Y	C	Not configured correctly.	Can't list activities. Incomplete data.	1	3	7	21								
SF-89	It shall have the ability to generate an OOS Notice (Alert/ Alarm Notice) report.	Y	C	Not configured correctly.	Can't generate an Alert Alarm or OOS report.	1	1	1	1	x	x						
SF-90	It shall have a definable Environmental Monitoring OOS report format with the following details:	Y	C	Not configured correctly.	No report generated.	10	3	1	30	x	x	x				Creation of the Alert Alarm investigation is a manual process.	
	§ Sample Locations for corrective action																
	§ Follow-up questionnaire of routine corrective actions																
	§ Sections for entry of free-form text for follow-up on non-routine corrective actions																
	§ Section for report approval/sign-off																
SF-91	It shall have the ability to create a daily schedule for environmental monitoring based on appropriate production activities	Y	C	Not configured correctly.	Can't create samples or wrong schedule created	1	5	1	5			x		-		High business requirement.	
SF-94	It shall have the ability to select & specify that only certain locations apply for re-monitoring as the need arises	Y	C	Not configured correctly.	Can't re-monitor. Incomplete data.	1	3	3	9		x	x		-		High business requirement.	
SF-95	It shall have the ability to capture second stage testing of Capsule Production Monitoring whereby total coliform testing is performed on recoveries.	Y	C	Not configured correctly.	Can't capture second stage testing. Incomplete data.	1	3	1	3		x	x		-		High business requirement.	
SF-97	It shall have the ability to configure label content and layout as required in accordance with changing requirements	N	C	Software Error	Can't modify the label content.	1	3	1	3	x	x						
SF-98	It shall have the ability to generate bar coded labels with an appropriate printer.	N	B	Software Error	Can't print barcodes.	1	1	1	1	x	x						

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-99	It shall have the ability to generate configurable labels for laboratory samples containing definable information already maintained within the LIMS application.	N	C	Software Error	Can't print a label with information from the system.	1	1	1	1	x	x						
SF-100	It shall have the ability to generate sampling labels with the following information for raw materials:	Y	C	Not configured correctly.	Incomplete label or wrong information on label.	10	3	7	210	x	x	x		x		High compliance risk.	
	§ Material Name								-								
	§ Material Code								-								
	§ Batch number								-								
	§ Container number (e.g. Container 1 of 6)								-								
SF-101	It shall have the ability to manually select/input a batch number for the generation of stability batch sample labels. These labels shall include the following information:	Y	C	Not configured correctly.	Incomplete label or wrong information on label.	10	3	7	210	x	x	x		x		High compliance risk.	
	§ Material Name								-								
	§ Material Code																
	§ Batch Number								-								
	§ Stability conditions								-								
	§ Date sample placed on stability								-								
	§ Container Number								-								
SF-102	It shall have the ability to print additional labels as required.	N	B	Software Error	Can't print additional labels.	1	1	1	1	x	x						
SF-104	It shall have the ability to assign different statuses, other than Quarantine, to a batch. The following statuses are to be included:	Y	C	Not configured correctly.	Incorrect status given to a batch	10	3	10	300								
	§ Restricted (Partial) Approval					10	1	1	10								
	§ Approved								-								
	§ Rejected								-								
SF-111	It shall have the ability to print out bar-coded unique labels with clearly visible environmental monitoring location identification numbers for	Y	C	Not configured correctly.	Incomplete label or wrong information on label.	7	3	3	63		x	x				Linked with SF-100	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	each monitoring location test in a pre-defined monitoring program.																
SF-114	The environmental monitoring labels shall be able to be reissued for a monitoring point for additional monitoring of the same location and this shall enable the system to identify that it will have additional sampling data and results to capture.	N	C	Software Error	Can't add addition samples or print for the additional samples. Can't retest. Incomplete data.	1	1	1	1	x	x	-				High business requirement.	
SF-121	It shall have the ability to associate / link the following for a batch upon its initiation	Y	C	Not configured correctly.	Wrong specs associated to batch. The batch is not tested correctly. Incomplete or invalid data.	10	3	10	300								All product specifications are required to be checked prior to go-live.
	§ Material Name																
	§ Material Code																
	§ Batch Number																
	§ Test Specifications																
SF-123	The system shall have the ability to report the FFP Certificate of Analysis information. Both the finished product & packaging component results displayed along with the product specifications including;	Y	C	Not configured correctly.	Incomplete data due to report setup, Can't display data.	1	3	5	15	x	x	x		-		Compliance Issue	
	§ Material Name								-								
	§ Material Code								-								
SF-124	It shall have the ability to create a test specification for the time of release and shelf life of the product. This data shall include:	Y	C	Not configured correctly.	Tests not defined properly for a product.	1	3	1	3	x	x	x		-		Compliance Issue	
	§ Material Name																
	§ Material Code																
	§ List of Tests																
	§ Data Ranges																
	§ Test Specification Revision Date																
	§ Test Specification Revision Number																

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-125	It shall have the ability to create a new test within the application and provide sufficient detail as to how the test is to be reported within the application along with relevant specifications	N	C	Software Error	Unable to create new test or specifications.	1	1	1	1	x						This is dealt with as per change control over the operational lifetime of the LIMS	
SF-126	It shall have the ability to handle the management of multiple test specifications for different countries per packaging configuration	N	C	Software Error	Can't handle multiple specifications.	1	1	1	1	x							
SF-127	It shall have the ability to manage multiple specifications per product	N	C	Software Error	Unable to apply test specifications.	1	3	1	3	x						This functionality is covered through reports generation.	
SF-128	It shall have the ability to assign a default single specification to a stability data sheet	Y	C	Not configured correctly.	Default not assigned in stability study. No specs assigned or incorrect spec assigned. Incorrect or invalid data.	7	3	5	105		x	x		-		Compliance Issue	
SF-129	It shall have the ability to overwrite the default test specification and manually assign single or multiple test specifications	N	C	Software Error	Can't test against alternative specifications.	1	1	1	1	x	x						
SF-131	It shall have the ability to automatically link the Test Specifications to the individual Material Code for a batch	Y	C	Incorrect configuration of the lot template, incorrect product specification against material codes.	Batch release to the wrong specification. Incorrect or invalid data.	10	3	7	210		x	x		x		Need to check prior to go-live. High compliance risk.	
SF-136	It shall have the ability to create different layouts for the different types of data sheets lite.	Y	C	Not configured correctly.	Configuration failure in crystal. Datasheet lite not printed as per configuration specification.	1	3	1	3		x	x				High business requirement.	
SF-139	It shall have the ability to manually print out the data sheets with all associated data	N		Software Error	Can't manually print out the data sheets with all associated data.	1	1	1	1	x							
SF-140	It shall have the ability to create / store all specifications for each Environmental Monitoring location.	Y	C	Incorrect configure of the program, incorrect p-spec against the samples in the location.	Samples release to the wrong spec for a location. Incorrect or invalid data.	10	3	7	210	x	x	x		x		Checking al specifications prior to go-live.	
SF-141	It shall have the ability to compare recorded results to preset specification limits and identify non-compliances for Environmental Monitoring.	N	C	Software Error	Specifications not applied or applied incorrectly.	1	1	1	1	x	x					Linked to SF-148, 150 for on screen alert for OOS of data.	
SF-142	It shall have the ability to set tightened specifications for	Y	C	User doesn't assign tighter specs, or they	Tightened specification not applied. Incorrect	10	3	7	210	x	x	x		x			

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	environmental monitoring of Aseptic Area Personnel Monitoring on Fill Days			are not configured as part of the program.	or invalid data.												
SF-143	It shall have the ability to set looser specifications for environmental monitoring of Aseptic Area Personnel Monitoring on non-fill days	Y	C	User doesn't assign tighter specs, or they are not configured as part of the program.	Tightened specification not applied. Incorrect or invalid data.	1	3	7	21	x	x					Tested to be performed as part of SF-142.	
SF-148	It shall have the ability to compare the obtained data and results against pre-defined specifications and apply the required logic to determine the success / fail of the test	N	C	Software Error	Specification not applied. Incomplete data.	10	3	5	150	x	x	x		x		Link to SF-141. Specification check required.	Peer review in place.
SF-149	It shall have the ability to enable the user to accept or reject data entries prior to committing the data to the LIMS.	N	C	Software Error	User doesn't have the ability to check data before committing it to the database. Incomplete or incorrect data.	10	3	10	300	x	x	x		x			Peer review in place.
SF-150	It shall have the ability to alert the user during data entry of invalid or out of specification entries prior to committing the data to the LIMS.	N	C	Software Error	User not notified of OOS data prior to commit. Incomplete or incorrect data.	10	1	10	100	x	x						Peer review in place.
SF-152	It shall have the ability to enable new results to supersede incorrect results within the LIMS application if a reprocessing procedure is performed. The original incorrect results shall be maintained on the application for review if required	N	C	Software Error	Can't update system.	1	3	1	3	x	x						
SF-153	It shall have the ability to enable new results to supersede incorrect results within the LIMS application if a rerun procedure is performed. The original incorrect results shall be maintained on the application for review if required	N	C	Software Error	Can't update system.	1	3	1	3	x	x						
SF-154	It shall have the ability to enable new results to supersede incorrect results within the LIMS application if a repeat procedure is performed. The original incorrect results shall be maintained on the application for review if required	N	C	Software Error	Can't update system.	1	3	1	3	x	x						

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SF-156	It shall have the ability to allow an authorised user to designate a result that does not meet specification as invalid due to an invalid analysis. This procedure shall employ the use of electronic signatures and the use of free form text to enable justification for invalidating the result.	N, Y	C	Software Error	Can't modify a result. An electronic signature is not applied. An unauthorised user could access the system. No audit reasons or justification assigns for an update. Terminal error in most cases.	1	3	1	3	X	X	X				High compliance issue.	
SF-157	It shall have the ability to enable additional testing for investigation purposes on generation of an OOS result	N	C	Software Error	Can't perform additional testing. Incomplete analysis.	1	1	1	1	X	X						
SF-158	It shall have the ability to distinguish between approved data and data that has been deemed invalidated.	N	C	Software Error	Can't distinguish between approved data and modified data. Data review could be compromised.	10	1	10	100	X	X	X				This is used as a visual aid for review and therefore testing of icon needs to be performed.	
SF-159	It shall have the ability to alert an approved checker that there is a batch available on the system once the analyst who performed the test has accepted the results.	Y	C	Not Configured correctly.	Batches for peer review not displayed properly in folders.	1	3	1	3		X	X				High business requirement.	
SF-160	It shall have the ability to enable an approved checker to confirm the acceptance of the data.	N	C	Software Error	Can't approve results.	1	1	1	1	X	X						
SF-161	It shall have the ability to alert an authorised approver that there is a batch available on the system for approval once all tests have been performed and checked.	Y	C	Not Configured correctly.	Batches for approval not displayed. Batches can't be approved.	1	3	1	3	X	X	X				High business requirement.	
SF-162	It shall have the ability to enable an authorised person to make approval decision on data generated for a batch, pertaining to their functional role.	N	C	Software Error	Can't control privileges.	10	1	1	10	x	x					Linked to DS-59	
SF-163	It shall have the ability to enable an authorised person to trigger a	N	C	Software Error	Can' add additional testing. Incomplete	1	1	1	1	x							

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	reprocess/repeat procedure for any data generated for a batch.				data.												
SF-166	It shall have the ability to enable a QP to log the release of a batch.	N/A															
SF-171	It shall have the ability to allow approval/rejection of samples in a protocol.	N	C	Software Error	Can't control the approval or rejection of samples in a protocol.	1	1	1	1	x	x	x				High compliance requirement.	
SF-172	It shall have the ability to update a system inventory for approved samples.	N	C	Software Error	Can't update the system inventory.	1	1	10	10	x	x					Linked to SF-161	
SF-177	It shall have the ability to print off a report detailing the sampling schedule for all stability studies	N	C	Software Error	Can't view the sampling schedule, incorrect schedule displayed.	1	1	10	10	x	x	x				Linked to SF-161	
SF-178	It shall have the ability to generate a monthly stability report with the following information:	Y	C	Software Error	Can't view the schedule report, incorrect schedule displayed.	1	3	10	30	x	x	x				Linked to SF-161	
	§ Material Name								-								
	§ Material Code								-								
	§ Batch Number								-								
	Planned date of removal from CTC								-								
	§ Time point								-								
	Conditions (temperature and humidity)								-								
	Required analytical tests								-								
SF-179	It shall have the ability to print out a monthly summary report of all Environmental Monitoring data consisting of a table of results for the following:	N	C	Software Error	Can't view the schedule report, incorrect schedule displayed.	1	1	10	10	X	X	X				Checked as part of reports.	
	§ Personnel Monitoring Data for:								-								
	o Capsule Area								-								
	Ampoule Area								-								
	o Microbiology Laboratory								-								
	§ Environmental Monitoring Data for:								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	o Capsule Area								-								
	o Ampoule Area								-								
	o Microbiology Laboratory								-								
SF-180	It shall have the ability to generate a trend report of Environmental Monitoring data, which has the ability to group data under specific categories and/or specific locations i.e. room, person, microbial type.	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
SF-181	It shall have the ability to generate a trend report of Environmental Monitoring data for a definable fixed period of time	N?	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Checked as part of reports.	
SF-182	It shall have the ability to provide graphical depiction of trending of Monitoring data.	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
SF-183	It shall have the ability to generate a trend report of water system testing data utilising both Microbiological and Chemical data	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
SF-185	It shall have the ability to sort data by Material Codes and to be able to filter by multiple codes	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
SF-188	It shall have the ability to provide tabulated trending data for all materials per year	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
SF-189	It shall have the ability to graph all numerical data on the LIMS system for trending purposes	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
SF-190	It shall have the ability to generate statistical control charts in order to provide results in real time once the results have been created on the system	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
SF-192	It shall have the ability to generate stability data tables for all batches on stability based on batch number and stability conditions	N	C	Software Error	Can't view the report, incorrect data displayed.	10	3	10	300	x	x	x		x		Used to decide shelf life of the product.	Check configuration of the system during testing.
SF-193	It shall have the ability to generate graphical depictions of stability data for all batches on stability based on batch number and stability conditions	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Check as this functionality is used across other configured reports.	
SF-194	It shall have the ability to tabulate, trend and graph multiple batches	N	C	Software Error	Can't view the report, incorrect data	1	1	10	10	x	x	x				Compliance requirement.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
					displayed.												
SF-195	It shall have the ability to tabulate, trend and graph by packaging configuration	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
SF-198	It shall have the ability to generate monthly / annual stability schedule with the following information:	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Link to SF-71	
	§ Material Name																
	§ Material Code																
	§ Batch Number																
	§ Stability Conditions																
	§ Time point																
	§ Status																
	§ Tests																
	§ Date placed in CTC																
	§ CTC Removal Date for each time point																
SF-211	It shall have the ability to report the inventory held within Retain Stores.	Y	C	Not configured correctly.	Can't view or incorrect data displayed.	1	1	10	10	x	x					Linked to SP-44	
SF-212	It shall have the ability to add columns to existing tables. These columns are to contain additional data stored within the LIMS application that have not been expressly defined in other requirements	N	C	Software Error	Can't add column for reporting. Incomplete data reported.	1	1	1	1	x							
SF-223	It shall have the ability to use e-mail functionality to send reports generated by the LIMS system	N	C	Software Error	Can't send report via email.	1	1	1	1	x	x	x				Compliance requirement.	
SF-224	It shall have the ability to create Environmental Monitoring summary reports for the following:	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
	§ Summary of non-compliant results for a series of grouped rooms/ grouped locations for a specific day.	N							-								
SF-225	It shall have the ability to create Environmental Monitoring summary reports for the following	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	§ Summary of non-compliant results for Personnel for a specific day								-								
SF-226	It shall have the ability to create Environmental Monitoring summary reports for the following	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
	§ Monthly monitoring report defining monitoring locations (Environmental and Personnel), date of monitoring and recoveries obtained at same (omitting preparation, sampling and testing data)								-								
SF-227	It shall have the ability to create Environmental Monitoring trend reports for the following	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
	§ Trend graph report for recoveries at an individual location over a specific time-period.								-								
SF-228	It shall have the ability to create Environmental Monitoring trend reports for the following	N	C	Software Error	Can't view the report, incorrect data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
	§ Trend graph report for recoveries at grouped locations over a specific time-period.								-								
SF-229	It shall have the ability to create Environmental Monitoring summary reports for the following	N	C	Software Error	Can't view the report, incorrect monitoring data displayed.	1	1	10	10	x	x	x				Compliance requirement.	
	§ Summary of non-compliant results for specific locations or grouped locations over a specific time-period.								-								
SF-230	It shall have the ability to provide an approval section to all reports generated by LIMS	Y	C	Configuration, Software Error	Can't view the report, approval data not displayed.	1	3	1	3	x	x	x				Compliance requirement.	
DS-1	The system shall have the ability to interface with an ERP System	N	B	Software Error	Can't perform disposition. Can create a lot which won't affect the user.	1	3	1	3	x	x					Linked to DS-13	Must have a manual system in place if the SAP system is offline. Need a control system in place to notify the users if LIMS/SAP are not interfacing.
DS-2	It shall have the ability to manually enter all data in the event that an interface with ERP is not available upon installation of the LIMS application	N	B	Software Error	Can't create a lot.	1	3	1	3		x	x				If alarm comes back to LIMS stating that SAP is down can we still disposition	This will be performed as part of SAP go-live.

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
																as Lot. A contingency plan for the LIMS needs to be in place.	
DS-4	The system shall have the ability to interface directly with Waters Empower chromatography management system on a real-time basis.	N	B	Software Error	Can't interface to Waters Empower CDS.	1	3	1	3	x	x					Link to SF-131, DS-6	Manual entry of results to LIMS requires a Business Contingency Plan.
DS-6	It shall have the ability to interface to the Empower System to enable the user to repeat or rerun a test and then capture additional or reprocessed results from Empower.	Y	C	Empower Projects Incorrectly mapped.	Incorrect data.	10	3	10	300		x	x		x	x		High degree of testing, Configuration verification needs to be performed.
)S-9	It shall have the ability to interface with the Empower system and import results	Y, N	C	Empower Projects incorrectly mapped.	Incorrect data imported. No results imported.	10	3	10	300	x	x	x		x			High degree of testing, Configuration verification needs to be performed.
)S-13	It shall have the ability to interface with the ERP system to communicate change of batch status.	Y	C, B	SAP-LIMS fields incorrectly mapped.	Incorrect or no approvals status transferred	10	5	8	400	x	x	x		x			Configuration Verification checks required. SAP will be performing its own setup checks. It will be covered in the SAP OQ and additional LIMS OQ, PQ if required at that time. Procedure need to be put in place as part of change control for changes to the LIMS and SAP configuration specifications. An implementation process for configuration changes between LIMS/SAP needs to be put in place.
DS-17	It shall have the ability to link with external files/documents (for example .pdf, .jpeg, Excel files, Word files) and create a link to the COA	N	C	Software Error	Can't view link or can't open linked file/document.	1	1	1	1	x	x						
DS-20	Users shall have the ability to interface with the application from computers at multiple points throughout the AICL facility.	N	B	Software Error or Network Failure.	Can't access LIMS at multiple points.	1	1	1	1	x	x					Tested implicitly as part of the PQ.	
DS-26	The system shall use a standard interface (which follow Microsoft Windows Graphical User Interface	N	C	Software Error	System function not displayed as per the privileges	1	1	1	1	x	x					Linked to DS-59	

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	(GUI) conventions) and display only those functions permitted by the current logged in user's profile and privileges.				configuration. Can't perform tasks.												
DS-28	The LIMS system shall be a closed system, of open architecture, with a secure mechanism for access.	Y	C	Infrastructure and access is not configured incorrectly.	LIMS operation and security compromised.	10	3	10	300					x		Link to DS-29	Verify that the alarms and monitoring systems are functioning as expected. VLAN - ensure change control has been assessed and closed out. Review configuration specification. Verify IT security procedures are in place.
DS-29	The system shall support authority checks (e.g. identification code and password) to ensure that only authorized individuals can	N	C	Software Error	System is not secure.	10	3	10	300	x				x		Linked to DS-28	As above.
	o Electronically sign a record																
	o Access the operation or computer system input or output device																Ensure the IT vendor audit is in place and that all high criticality LIMS related issues are resolved.
	o Alter a record																
	o Perform the operation at hand																
DS-30	It shall be possible to specify the structure of the password regarding:	Y	C	Not configured correctly.	System is not secure.	10	3	10	300	x	x	x		x			Verify through configuration verification, testing or protocol control.
	o Required length								-								
	o Character types and character combination								-								
DS-31	It shall not be possible to re-use any of a specifiable number of previous passwords	Y	C	Not configured correctly.	System security compromised.	3	3	10	90	x		x		x			
DS-32	The user shall be forced to change the password at first log-in	Y	C	Not configured correctly.	System is not secure.	10	3	10	300	x		x		x			*Include in Administrative* LIMS SOP.
DS-33	It shall be possible to define a time limit for when a user is forced to change password (days)	Y	C	Time limit not configured correctly.	System security compromised.	3	3	10	90	x		x		x			
DS-34	After a specifiable number of failed attempts to log-in, access for that user shall be locked.	Y	C	*Fail limit not configured* correctly.	Security prone to breached	10	3	5	150	x		x		x			Verify through configuration verification and testing.

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
DS-35	After a specifiable number of failed attempts to execute an electronic signature, access for that user shall be locked	Y	C	Failure attempts limit not configured correctly.	Can still execute an e-sig, e-sig compromised by other user	10	3	10	300	x		x		x			Verify through configuration verification and testing.
DS-37	It shall be possible to define a time limit for automatically lock out a user when the user has not been active in the system for a specifiable time (minutes and/or seconds)	Y	C	Lock out time not configured correctly.	System is not secure.	10	3	10	300	x		x		x		Desktop is set to lock at 15 mins.	Verify through configuration verification and testing.
DS-38	User access to the data shall only be possible from the LIMS application	Y	C	LIMS & DB security not configured correctly.	System is not secure.	10	3	10	300	x		x		x			Procedure or test required to secure LIMS and proprietary database.
DS-40	The system administrator shall only have access to administrative tasks	Y	C	Not configured correctly.	Users have additional privileges. System is not secure.	10	3	10	300	x		x		x		Ensure DS-60 is implemented.	Verify through configuration verification and testing.
DS-41	It shall be possible to review the possible information about each user of the system	N	C	Software Error	Unable to view user history.	1	3	10	30	x		x				Access logs & audit trails are in place. Linked to SF-95	
	o When the user access was activated																
	o When the user access was deactivated																
	o Group privileges																
	o User access status																
DS-42	It shall not be possible to delete system users. Instead, the user account is deactivated	N	C	Software Error	User deleted.	1	1	10	10	x		x		x		High compliance issue.	Procedure needs to maintain this user and store the password in case it's ever required.
DS-43	The system shall ensure that each identification code is unique	N	C	Software Error	Username not unique.	10	1	10	100	x							
DS-44	Attempts to login by an authorised user shall be recorded by the system	N	C	Software Error	User access not recorded.	1	1	10	10	x		x				Linked to DS-96	
DS-45	Failed login attempts by authorized users shall be detected by the system and the system administrator notified.	N	C	Software Error	User access not recorded. No alert sent.	1	1	10	10	x		x		x		High compliance issue.	
DS-46	The system shall support different levels of functional privileges	N	C	Software Error	No control over user privilege. System data is not secure.	10	1	5	50	x						Linked to DS-59 to DS-68	
DS-47	The system shall have the ability to allow control over what activities a user is allowed to perform.	N	C	Software Error	No control over user privilege. System data is not secure.	10	1	5	50	x							

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
DS-48	The system shall only allow authorised personnel to create, modify or delete records depending on functional privileges.	N	C	Software Error	No control over user privilege. System data is not secure.	10	1	5	50	x		x				Acceptance testing will verify the functional privileges required within the system.	
DS-49	The system shall support that the data in the system are restricted to different users	Y	C	Not configured correctly.	User may have access to pertinent data regarding other system processes.	10	3	10	300	x	x	x		x			Verify tests, folders & sampling through configuration verification and testing.
DS-50	It shall be possible to restrict access to user profile data in the system	N	C	Software Error	User can see information on other users.	1	1	10	10	x	x	x				High compliance issue.	Verify user profile configuration.
DS-51	A user should have access only to the privileges that is relevant to his/her work. It is predefined in the "User Profiles" (see User Profiles section DS-59 to DS-68) requirements.	N/A							-							Refer to DS-60 through to DS-68	
DS-52	The system shall allow the creation of "User Profiles", which contains the following information:	N	C	Software Error	No control over user profiles. Compliance of the system is compromised.	1	1	1	1	x	x						
	o Name								-								
	o Job title								-								
	o System privileges								-								
	o Data assigned to the user								-								
DS-53	It shall be possible to create the "User Profiles" as outlined in User Profiles section (DS-59 to DS-68)	N/A							-							Refer to DS-60 through to DS-68	
DS-54	For users that have different roles within the organisation, it shall be possible to chose between different roles at login	N	C	Software Error	Uses can't select roles.	1	1	1	1	x						should report errors like this to a SA	
DS-55	System administration privileges shall be separated from routine usage to prevent use of privileged account, when not required	Y	C	Not configured correctly.	The system administrator could perform a task which is not part of their Job description.	10	3	10	300			x		x		Ensure that the SA roles perform only SA tasks. Linked to DS-40	Implements guidance in an SOP
DS-56	It shall be possible to control the data group of a created batch, the samples created for the batch and the tasks for the created samples individually	Y	C	Not configured correctly.	User may have access to data not related to their job description or training profiles. System data is compromised.	1	3	1	3	x						Linked to DS-59	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
DS-57	The batch, the batch samples and the batch results shall be approved by different users, with different rights.	Y	C	Not configured correctly.	User can perform an approval action which they shouldn't have i.e. release of a test, sample or batch.	10	3	10	300		x	x		x		High compliance issue.	Needs to define each of the users in an SOP and have this approved by management.
DS-59	The system shall support the following User Profiles	Y	C	Not configured correctly.	User setup with incorrect access. Security compromised.	10	3	7	210	x		x		x		Verify user profile configuration.	
	1) System Administrator								-								
	2) QC Administrator								-								
	3) Head of Quality								-								
	4) QC Manager								-								
	5) QC Coordinator								-								
	6) QC Laboratory Personnel								-								
	7) Stability Administrator								-								
	8) Production Operator								-								
DS-60	The System Administrator shall have the following privileges:	Y	C	Not configured correctly.	User setup with incorrect access. Security compromised.	10	3	7	210	x		x		x		Verify user profile configuration.	
	o Enrolling new users								-								
	o Granting access rights to users								-								
	o Definition of User Profiles								-								
	o Definition of data groups								-								
	o Setting of system parameters								-								
DS-61	The QC Administrator shall have the following privileges:	Y	C	Not configured correctly.	User setup with incorrect access. Security compromised.	10	3	7	210			x		x		Verify user profile configuration.	
	o Create LIMS samples for any protocol								-								
	o Assign location to samples								-								
	o Create test specifications								-								
	o Create sampling plans								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	o Create test methods								-								
	o Define analysis templates								-								
	o Define COA								-								
	o Define batch composition								-								
DS-62	Head of Quality shall have the following privileges:	Y	C	Not configured correctly.	User's setup with incorrect access. Security compromised.	10	3	7	210	x		x		x		Verify user profile configuration.	
	o Approval analytical methods								-								
	o Approval sampling plans								-								
	o Approval specifications								-								
	o Approval/rejection of batches								-								
	o Stability study protocol approval								-								
	o Approval/rejection retest results								-								
	o Define calibrations/maintenance schedules								-								
	o Approval change calibration/maintenance								-								
	o Schedules instruments								-								
	o Manage equipment, equipment contracts and supplier data								-								
	o Assign persons to use equipment in validation phase								-								
	o Release equipment								-								
	o Update equipment documentation availability overview								-								
	o Update equipment status								-								
	o Prevent access to equipment								-								
DS-63	The QC Manager shall have the following privileges:	Y	C	Not configured correctly.	User's setup with incorrect access. Security compromised.	10	3	7	210	x		x		x		Verify user profile configuration.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	o Work assignment								-								
	o Approval/rejection of batches								-								
	o Approve analytical result								-								
	o Stability protocol approval								-								
	o Release stability time points								-								
	o Release stability studies								-								
	o Approval analytical methods								-								
	o Approval sampling plans								-								
	o Approval specifications								-								
	o Stability study protocol approval								-								
	o Approval retest results								-								
	o Approval change calibration/maintenance								-								
	o Schedules instruments								-								
	o Define calibration/maintenance schedules								-								
	o Assign persons to use equipment in validation phase								-								
	o Release equipment								-								
	o Update equipment documentation availability overview								-								
	o Update equipment status								-								
	o Prevent access to equipment								-								
DS-64	The QC Coordinator shall have the following privileges:	Y	C	Not configured correctly.	User setup with incorrect access. Security compromised.	10	3	7	210	x		x		x		Verify user profile configuration.	
	o Enter study protocol amendments								-								
	o Work assignment								-								
	o Release batches								-								
	o Approve analytical results								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	o Release stability time points								-								
	o Release stability studies								-								
	o Approval retest results								-								
	o Approval change calibration/maintenance								-								
	o Schedules instruments								-								
	o Define calibration/maintenance schedules								-								
	o Assign persons to use equipment in validation phase								-								
	o Release equipment								-								
	o Update equipment documentation availability overview								-								
	o Update equipment status								-								
	o Prevent access to equipment								-								
	o Define work								-								
	o Enter analytical results								-								
DS-65	The QC Laboratory Personnel shall have the following privileges:	Y	C	Not configured correctly.	User setup with incorrect access. Security compromised.	10	3	7	210	x		x		x		Verify user profile configuration.	
	o Define work								-								
	o Enter analytical results								-								
	o Approve analytical results – in process samples only								-								
	o Review analytical results								-								
	o Confirm analytical results								-								
	o Change incorrect results								-								
	o It shall not be possible to confirm own results								-								
Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
DS-66	The Stability Administrator shall have the following privileges:	Y	C	Not configured correctly.	User setup with incorrect access. Security	10	3	7	210	x		x		x		Verify user profile configuration.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
					compromised.												
	o Enter analytical results								-								
	o Create summary tables and graphical trends								-								
	o Create stability protocol								-								
	o Modify stability protocol								-								
	o Create stability samples for any protocol								-								
	o Approve stability results								-								
)S-67	The Production Operator shall have the following privileges:	Y	C	Not configured correctly.	User setup with incorrect access. Security compromised.	10	3	7	210	x		x		x		Verify user profile configuration.	
	o Enter sampling details								-								
	o Query batch status								-								
	o View Alert Notifications								-								
	o Enter free-form text for designated processes								-								
)S-68	The View-Only user shall have the following privileges	Y	C	Not configured correctly.	User setup with incorrect access. Security compromised.	10	3	7	210	x		x		x		Verify user profile configuration.	
	o View batch status								-								
	o Testing status								-								
	o Lab schedule								-								
DS-71	Electronic record creation, modification or deletion shall be attributable to an individual by means of audit trail	N	C	Software Error	No person associated with an action in the audit.	1	1	1	1	x		x				High compliance issue.	
DS-72	Where Electronic Records are printed to paper and both the Electronic Record and the Paper Record may be used for GXP decisions, controls shall be in place to ensure that the records are linked and maintained in a synchronised state, e.g.	Y	C	Not configured correctly.	Electronic and paper records not linked.	1	3	10	30			x				Maters data is maintained on the LIMS. Paper copies should be checked for accuracy prior to being used for reference.	Paper records from LIMS are not to be used for GMP decisions. Need SOP or training to highlight this requirement. ERES training. Execute ERES Assessment.
	o Filename								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	o Date and time								-								
	o Storage location (database)								-								
DS-74	Certificates of Analysis shall be retained as electronic records	N	C	Software Error	CoA not generated and saved as pdf.	1	1	1	1	x		x				Compliance issues. Need to check that these are created and retained. Check access restrictions, no deletion, backup procedure are in place.	
)S-75	The system shall have to ability to allow electronic signatures	Y	C	Not configured correctly.	No electronic signature applied to records.	1	3	1	3	x		x				Compliance requirement.	
)S-76	Where identification codes and passwords are used as an electronic signature, they shall be unique to the individual user	N	C	Software Error	Electronic signature not unique not enforced correctly. Data accuracy compromised. Possible security risk.	10	1	10	100	x		x				Linked to DS-43	
)S-77	Electronic signature information shall itself be an electronic record and subject to the same controls (e.g. change of a user's surname shall be audit trailed)	N	C	Software Error, Database corruption	Incomplete, incorrect or invalid data.	1	1	10	10	x							
)S-78	Electronic signatures shall employ at least two distinct identification components such as identification code and password	N	C	Software Error	Security compromised.	10	1	1	10	x		x				High compliance issue.	
DS-79	Failed attempts to execute electronic signatures shall be logged	N	C	Software Error	Failed electronic signature not recorded. Incomplete data.	1	3	10	30	x							Review of system audit trail to be proceduralized.
DS-80	The system shall force passwords to be periodically changed and enable identification/passwords to be inactive without losing the record of their historical use	Y	C	Not configured correctly.	System security maybe compromised.	10	3	10	300	x		x		x			Verify through configuration verification and testing.
DS-82	The system should not provide any ordinary means of accessing electronic signature information	N	C	Database corruption.	Incomplete, incorrect or invalid data.	1	1	1	1	x		x				Closed system so no ordinary means possible or very rare.	Change Control required to deal with this scenario. Check configuration specification of IT infrastructure.
DS-83	The system shall enforce uniqueness, prevent reallocation of	N	C	Software Error, Database corruption	Failure of uniqueness,	1	1	10	10	x						Linked to DS-43	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	electronic signature and prevent deletion of information regarding electronic signature once it has been used				reallocation and deletion.												
DS-84	Meaning of a signature shall always be displayed when an electronic signature is required.	Y	C	Not configured correctly.	Meaning of electronic signature is not display or incorrectly displayed.	1	3	1	3	x		x				High compliance issue.	
DS-86	The system should enforce that both components are entered at least at the first signing and following a break in the session.	N	C	Software Error	no password require after subsequent actions	1	3	1	1	x		x				High compliance issue.	
DS-87	A statement that the electronic signature is legally binding shall be displayed when executing an electronic signature	Y	C	Not configured correctly.	Understanding of electronic signature not display or understood by users.	1	3	1	3	x		x				High compliance issue.	
DS-88	Signed electronic records shall contain the following information associated with the signing that clearly indicates all of the following:	N	C	Software Error	No traceability on data.	1	1	5	5	x		x				High compliance issue.	
	o Printed name of the signer																
	o Date and time of execution																
	o Meaning (review, approval, responsibility, authorship etc.) associated with the signature																
DS-89	The items identified in DS-86, DS-87, DS-88 & DS-90 shall be included as part of the human readable form of the electronic record, such as an electronic display or a printout.	N	C	Software Error	Electronic record has displayed or printed in a human readable form.	1	1	1	1	x							
DS-90	The system shall ensure that signatures are linked to, or included in the electronic record to which they are applied and that signatures cannot be removed or copied by ordinary means to falsify records	N	C	Software Error	Electronic signatured is compromised, copy or removed. Compromised data.	1	1	10	10	x							
DS-91	It should not be possible to alter data linked to an electronic signature without applying a new electronic signature.	N	C	Software Error	Electronic signatured is compromised, copy or removed. Compromised data.	10	1	10	100	x		x		-		High compliance issue.	
DS-93	The system shall have the ability to record the creation/deletion/modification of a user	N	C	Software Error	No auditing of data.	1	1	1	1	x		x				High compliance issue.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
DS-94	The system shall have the ability to record the creation/deletion/modification of a user profile	N	C	Software Error	No auditing of data.	1	1	1	1	x		x				High compliance issue.	
DS-95	The system shall have the ability to record alteration to the applications system policies	N	C	Software Error	No auditing of data.	1	1	1	1	x		x				High compliance issue.	
DS-96	The system shall have the ability to record successful logon/logoff attempts	N	C	Software Error	No auditing of data.	1	1	10	10	x		x				High compliance issue.	
DS-97	The system shall have the ability to record deactivating/reactivating a user account	N	C	Software Error	No auditing of data.	1	1	1	1	x		x				High compliance issue.	
)S-100	The system shall have the ability to be backed up as per standard IT procedures and recovered in the event of a disaster.	Y	C	Disaster Recovery Procedure not in place or not effective.	Disaster Recovery Procedure not possible.	1	3	1	3					x		As per the VP	
)S-101	The system shall have the ability to record modifications to master data such as test specifications.	N	C	Software Error	No auditing of data.	10	3	10	300	x		x		x			Administrative controls required for new users and roles assigned.
)S-105	The system shall have the ability to record generation/modification of sample details by users	N	C	Software Error	No auditing of data.	1	1	1	1	x		x				Compliance requirement.	
/IT-1	The vendor shall provide a System Delivery Plan (SDP) four weeks after final vendor selection as described in section Documentation & Deliverables. This would include the following sections	N/A	C	Task not performed.	Project timelines not met.	1	3	1	3							Not a risk to the system. Risk to the Project.	
	§ Project Schedule and Work Plans								-								
	§ Functional Scope of project								-								
	§ Project Roles and Responsibilities								-								
	§ Resourcing								-								
	§ Monitoring and Reporting mechanism								-								
	§ Approach, Methodology and Standards								-								
	§ Management of inter-dependencies								-								
	§ Change Control process								-								
	§ Document Management								-								

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	§ Risks and Assumptions								-								
	§ Quality Assurance								-								
	§ Management of Costs								-								
	blank								-								
MT-2	Astellas Ireland Co., Ltd. shall review/comment/approve the SDP within four (4) weeks of receipt from the vendor	N/A	C	Task not performed.	Project timelines not met.	1	3	1	3							Not a risk to the system. Risk to the Project.	
CS-1	Vendor support for the system shall be available during Office Hours (0830-1845). This shall be subject to a Maintenance agreement being put in place	N/A	B	LabWare SLA not received and approved.	System not maintained no support for unplanned downtime.	1	10	1	10				x			Traceable in DQ/Change Control	
CS-2	An internal agreement shall be made to make sure that installation, maintenance and support (including all service packs and bug fixes) for the system could be guaranteed to an agreed service level.	N/A	B	IT SLA not received and approved.	System not maintained, no support for unplanned downtime.	1	3	1	3							DQ to verify SLA in place.	
CS-3	The supplier will understand the work processes as described in this URS and configure LIMS according to these processes as agreed with the customer. This configuration is seen as a continuous during the complete acquirement and implementation, until the complete release of the system for general use.	N/A	B	System not configured correctly.	System doesn't perform as require to the end user.	1	3	1	3								
CS-4	The LIMS supplier has to support the delivered version for at least 5 years, subject to a Maintenance agreement.	N/A	B	Not Supported	System not maintain, no support for unplanned downtime.	1	10	1	10				x			DQ to verify SLA in place.	
C-1	Selected technologies shall provide the ability to add extra CPU, memory and disk.	Y	B	Unable to upgrade the system hardware.	System can't meet business needs.	1	1	5	5				x				
C-2	A monitoring tool should detect and record hardware errors.	Y	B	Monitoring Software not implemented. Monitoring Software error,	Hardware errors not detected and recorded.	1	3	1	3				x				HP Management Console and Insight software to be installed.
C-3	The system should detect and record application errors.	N	C	Software Error.	Errors not detected and recorded. Potential data corruption.	10	3	10	300	x	x	x					Procedure to review error log periodically required.
C-4	In case of power outage the	Y	B	UPS software failure.	System shutdown	1	10	10	100	x	x	x			x	Business	Power off test done by

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	system should automatically shutdown when 10 minutes remains on UPS capacity.			Not attached to the UPS system.	immediately. Potential loss or corruption of data.											requirement.	vendor. DR needs to be proceduralised and implemented.
C-5	Backup of server should run every 24th hour	Y	B	Network down. Backup not implemented or functioning. Server/Tape space full. Backup not performed.	No backup data in case of Disaster Recovery.	1	10	1	10						x	Check to see if it is turned on	
C-6	The system should support a backup and recovery process, which will recover to the last, committed transaction before failure.	N	C	Software Error.	No Disaster Recovery procedure can be performed.	10	1	1	10						x		
C-7	The system should support disaster recovery with data not older than 24 h and a maximum lead-time from disaster to recovery of 24 h (Scope: Hardware, Software & data)	N/A	B	SLA & Backups not in place.	Can't rebuild the system in 24 hours.	1	1	1	1						x		
C-8	The supplier of the application software should offer availability to the source code.	N/A	B	No ESCROW in place.	No access to the code.	1	1	1	1	x							
C-9	The system should be protected against damage and data loss due to power failure	Y	B	UPS software failure. Not attached to the UPS system.	System shutdown immediately. Potential loss or corruption of data.	1	10	10	100	x							
A-1	The system shall be available for use 24 hours per day, 7 days per week, 365 days per year (excluding times for essential maintenance, backup procedures, etc.)e.g. 24hrs x 7 days	N/A	B	System maintenance without notice.	Data loss or corruptions.	10	3	10	300`						x		Procedures need to be put in place so that maintenance is planned. QC need control over maintenance not IT.
CRS-1	The Vendor shall have a quality management system in place	N/A	C	No QMS at vendor facility.	Systems quality and VA but under scrutiny.	1	1	1	1	x							
CRS-2	The Vendor's quality management system shall be based on recognised software standards e.g. IEEE, TickiT or equivalent e.g. energy efficiency rating	N/A	C	No QMS at vendor facility.	Systems quality and VA but under scrutiny.	1	1	1	1	x							
CRS-3	The Vendor's quality management system shall be auditable	N/A	C	Can't do the audit.	Systems quality and VA but under scrutiny.	1	1	1	1	x							
CRS-4	LIMS and Oracle should operate under Windows 2000 Server or higher version (e.g. XP)	Y	C	Windows OS not Supported	Doesn't comply with AICL network.	1	1	1	1	x			x			Business requirement.	
CRS-5	Hardware specs shall be approved by IT Operations.	N/A	C	System not configured correctly.	System doesn't perform as require to	1	3	1	3				x			Business requirement.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
					the end user.												
CRS-6	LIMS should support CITRIX technology	Y	C	None, not implemented.	Future system upgrading may be compromised.	1	1	1	1	x							
CRS-7	Oracle database version 9.2 or above shall be supported	Y	B	Upgrades of the Oracle DB would affect the LIMS Software Configuration.	System would not work properly on multiple levels and future version of Oracle may compromise the system if upgrading. Work around possible.	1	3	10	30	x			x			Business requirement.	Vendor SLA and Contract should clearly define the support for the application and life expectancy for support of the implemented version.
DD-1	All supplier documentation shall be in English.	N/A	C	Documentation is not in English.	Manuals would not be understood readily.	1	1	1	1	x					x		
DD-2	All material shall be clearly identified with appropriate identification	N/A	C	Documentation is not identified correctly.	Materials would not be readily identified.	1	3	1	3						x		
DD-3	Any document specifically raised for the project shall have an individual document number and shall clearly show its revision status after the first issue.	N/A	C	Documentation is not identified correctly.	Documentation would not be readily identified.	1	3	1	3						x		
DD-4	All documentation shall be provided in the as-built version.	N/A	C	Document is not created accurately.	Configuration specification would not be accurate.	1	3	10	30			x			x	Compliance issue.	
DD-5	All documents and drawings will be supplied with two hard copies and one electronic version.	N/A	C	Documentation is not received and is not accurate.	System documentation would not be accurate.	1	3	10	30						x		
DD-6	Textual documents such as manuals shall be provided in Word format (.doc)	N/A	C	Documentation is not received in word format.	Documentation not received in word format.	1	3	10	30						x		
DD-7	The vendor shall provide training of AICL KP System Administration on the LIMS Application Software.	N/A	C	No training provided.	Users could not build or maintain the system.	10	1	10	100	x					x		
DD-8	The vendor shall provide training to AICL KP User Level on the LIMS Application Software	N/A	C	No training provided.	Users could not build or maintain the system.	1	3	10	30						x		
DD-9	A soft copy and configuration shall be provided as back up. In the event that soft copy of configuration cannot be provided, hard copy shall be provided instead.	Y	C	Software Error. Backup of the base release of the system not maintained.	Disaster Recovery Procedure not possible.	1	3	10	30	x					x		
SAP-1	The LIMS system shall be able to connect to the SAP QM Subsystem	Y	B	Network/Software/Configuration Error. Can't connect to SAP.	No lot creation or disposition through SAP.	1	3	1	3	x		x		x		Business requirement.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
SAP-21	The SAP system shall be able to pass data from SAP to LIMS for use in the LIMS. SAP is required to provide the master inspection characteristic and confirmation number.	Y	B	Software/Configuration Error. No data passed between LIMS and SAP.	No lot creation in LIMS.	1	3	1	3			x		x		Business requirement.	
SAP-31	The SAP system shall be able to pass data from SAP to LIMS in order to allow LIMS to return them back to SAP at lot disposition. SAP is required to provide the master inspection characteristic and confirmation number when the lot is created in LIMS.	Y	B	Software/Configuration Error. No data passed between LIMS and SAP.	No lot creation or disposition through SAP.	1	3	1	3			x		x		Business requirement.	
SAP-4	The LIMS system shall be able to provide SAP with the following lot dispositions:	Y	C	Software/Configuration Error. No usage decision passed between LIMS and SAP.	No lot disposition through SAP.	1	3	1	3			x		x		Business requirement.	
	*Approved								-								
	*Rejected								-								
	* Partial Approval								-								
SAP-5	For partial approval, the SAP system shall have a inspection lot characteristic to record any partial disposition comment, and is required to provide the master inspection characteristic and confirmation number of this result to LIMS during the lot creation process	Y	C	Software/Configuration/ User input Error.	Can't add a comment to the lot required for Partial approval.	1	3	1	3			x		x		Business requirement.	
SAP-6	For partial approval, the LIMS system shall prompt the user for a free text disposition lot comment, which will be returned to SAP as an additional inspection lot characteristic	Y	C	Software/Configuration/ User input Error.	Can't add a comment to the lot required for Partial approval.	1	3	1	3			x		x		Business requirement.	
SAP-7	If the SAP system provides the LIMS system the name of the single batch that was used to create the batch in SAP, if this same lot exists in the LIMS system, the LIMS system will link the two lots together.	Y	C	Software/Configuration/ User input Error.	LIMS can't connect one or more batches.				-			x		x		Business requirement.	
SAP-8	The SAP system shall have an inspection lot characteristic to record disposition date time, and the SAP system is required to provide the master inspection	Y	C	Software/Configuration/ User input Error.	SAP can't record the date of disposition.	1	1	1	1			x		x		Business requirement.	

Req. No.	Requirement	Conf	RT	Potential Failure	Effect of Failure	S	O	D	Risk	VA	UT	UAT	IQ	OQ	PQ	Comment\ Justifications	Mitigating Action(s)
	characteristic and confirmation number of this result to LIMS during the lot creation process																
SAP-9	The LIMS system shall post the disposition date time as part of the disposition process described in requirement SAP-4	Y	C	Software/Configuration error.	SAP can't record the date of disposition.	1	1	1	1			x		x		Business requirement.	
SAP-10	The LIMS system shall be able to disconnect to the SAP QM subsystem	N	B	Software/Configuration error.	Can't perform tasks manually in LIMS.	1	3	1	3			x		x		Business requirement.	
SAP-11	A process shall be put in place to manage update required to the LIMS due to changes in the Item Code as required through the implementation of SAP.	N	C	Processes not put in place.	Can't update the systems.	10	3	5	150					x			Must be done prior to SAP-LIMS interfacing in the Live environment.