QM001

Rev: 8.0

Quality Manual

Issue Date: 10-October-2023

	Name	Job Role	Signature	Date
Prepared By:	E Scott	Quality Assurance Assistant	Emma Scott	10-October-2023
Reviewed By:	C Kerrigan	Quality Manager	Chloe Kerrigan	02-November-2023
Approved By:	T McCollin	Technical Director	T. McCollin	02-November-2023

Revision History

Issue Date	Revision	Updated by	Detail
07-Jul-2016	1.0	Alison Cookson	Final Amends and Issued
28-Nov-2016	1.1	Ken McWilliam	Added Acquisition Systems Ltd Logo
06 Feb 2018	2.0	Nick Richardson	Removal of appendices, removal of quality policy text, addition of reference to QP001 Quality Policy and TP001 Training Policy, Addition of Company structure.
26-Nov-2018	3.0	Nick Richardson	Updated to reflect changes related to ISO 9001:2015
03-Dec-2019	4.0	Nick Richardson	Company Structure updated, Lisburn Office added, inclusion of Observation Reporting Process
03-Mar-2021	4.1	Ken McWilliam	Company Structure updated following implementation of Employee Ownership Trust.
04-Nov-2021	5.0	Chloe Kerrigan	4.3 – Sandhurst office has been added Quality and Compliance Engineer has changed to Quality and Compliance Department. 6.2 – 'Quality' objectives amended to 'Company' objectives and comment made about review of objectives within the Monthly Management Meeting. Removal of reference to archived document NC001 – Nonconforming Product Procedure, following its merge with procedure CA001 – Corrective Action and Improvement procedure. Section 7 – Edited to include reference to procedure QP13091 – Quality procedures for Service and Support and references to BS EN ISO/IEC 17025:2017.
07-Jan-2022	6.0	Chloe Kerrigan	Addition of: 5.2.1 Establishing the Quality Policy. 5.2.2 Communicating the Quality Policy. 9.3 Management Review. 9.3.2 Management Review Inputs. 9.3.3 Management Review Outputs. Amendments to: 1.1 Company Structure 6.3 Change Control

ACQUISITION SYSTEMS LTD, ALSO TRADING AS PHARMAGRAPH
39 Ivanhoe Road, Hogwood Industrial Estate, Finchampstead, Berkshire, RG40 4QQ
Tel: +44 1252 860700 | email: admin@a-s.co.uk or admin@pharmagraph.co.uk

02-Nov-2022	7.0	Chloe Kerrigan & Emma Scott	Amendments to: 8.4.2 – Amended reference documents. 9.3 - Quality Meeting minutes detailing Regulations and Standards review. Updated to include ISO17025:2017. Updated Management Review section. Addition of: 9.2 – Internal Findings Log – IFL001.
10-October-2023	8.0	Chloe Kerrigan & Emma Scott	Amendments to: Full review of document with amendments to all sections. Addition of: 8.3.4 – Design and Development Controls 8.3.5 – Design and Development Outputs 8.3.6 – Design and Development Changes

Contents

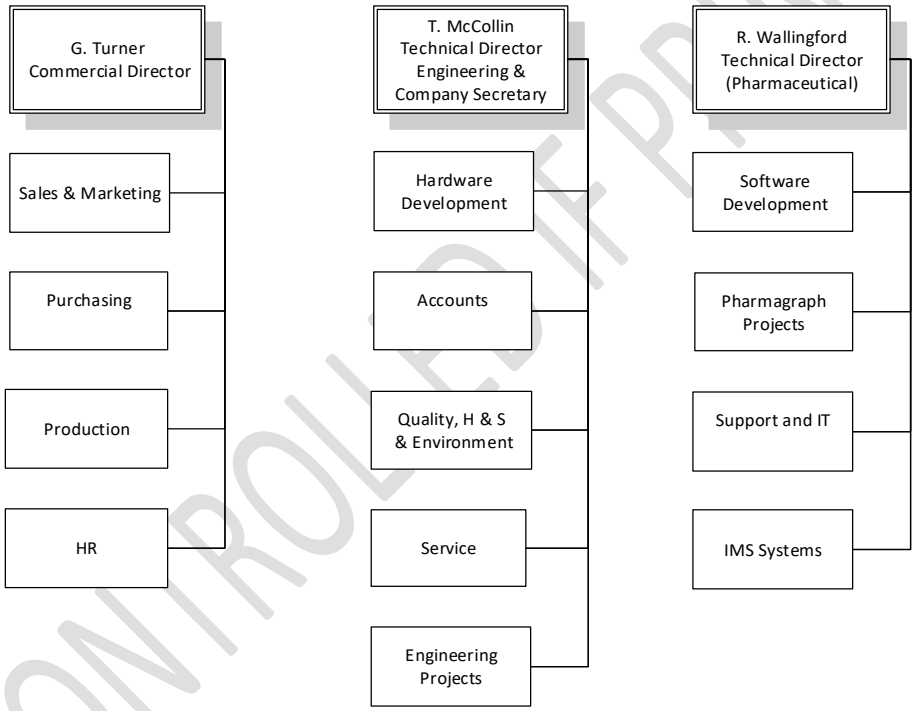
1 Introduction

Acquisition Systems Ltd (ASL) was established in 1989 to provide high performance data acquisition systems to a broad customer base including the utilities, automotive and aerospace industries. ASL began deploying systems into the pharmaceutical industry in 1992. Pharmagraph was formed in 2001 as a wholly owned division of ASL, to provide monitoring systems to the Pharmaceutical and Life Science industries.

In March 2021 ASL became 'employee owned'. All operations continue unchanged following this change of ownership.

Pharmagraph systems are deployed to monitor, record and report on critical process parameters such as temperature, humidity, differential pressure, airborne particulate levels, and microbiological activity.

1.1 Company Structure



2 Purpose and scope

The purpose of this Quality Manual is to establish and state the general policies governing Acquisition Systems Ltd, also trading as Pharmagraph, hereinafter known as the 'Company' Quality Management System (QMS). These policies define management's intended arrangements for managing operations and activities in accordance with representing the company's plans or protocol for achieving quality assurance and customer satisfaction.

This manual is intended for the sole use of the Company and is provided to customers for information purposes only.

The contents of this manual may not be reproduced or reprinted in whole or in part without the express written permission of the Company.

All departmental or functional policies and procedures written must conform to these policies. All changes to policies and procedures are reviewed to ensure that there are no conflicts with the policies stated in this Quality Manual (QM).

Throughout the manual the word 'Product' refers to both 'Product' and 'Systems' formerly and interchangeably known as 'Projects'.

The policies stated apply to all operational activities of the Company. The Quality System applies to the following:

- Design, development, and construction of engineered products including customer projects.

- Definition, implementation, and maintenance of the procedures required by this manual and to ensure all processes conform to these requirements.
- Adherence to the procedures in support of the policies contained within.
- The continuous improvement of activities and processes utilised by the Company.
- This Quality Manual includes the scope of the Company quality system.

3 Relation to ISO 9001

For ease of reference, the sections of this manual are numbered to coincide with the equivalent section numbers of the ISO 9001:2015 standard.

Each section of this manual references the appropriate supporting procedures and their interactions.

4 Context of the organisation

4.1 Understanding the organisation

Our aim is to make it easier for customers to achieve and maintain compliance. This will be achieved by:

- Monitoring changes to regulations.
- Providing technical excellence.
- Retaining customer loyalty.
- Demonstrating a high level of commitment by the management.

ASL / Pharmagraph has reviewed and analysed key aspects of the Company and its stakeholders to determine the strategic direction. This requires a good understanding internal and external issues that are of concern to the Company and its interested parties and is identified within RO001 – Risks and Opportunities.

4.2 Understanding the needs and expectations of interested parties

“Interested parties” are those stakeholders who receive our products and services, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified on the 4.2 Interested Parties tab on RO001 – Risks and Opportunities.

This information is then used by senior management to determine the company’s strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.3 Determining the scope of the QMS

The company has defined the scope of the management systems as follows:

‘Design, supply, implementation and maintenance of environmental and particle monitoring systems’

The quality system applies to processes and employees at our locations listed below:

39 Ivanhoe Road* Hogwood Estate Finchampstead RG40 4QQ United Kingdom **Head Office / Production / Projects**	The Heath Business & Technical Park Runcorn WA7 4QX United Kingdom **Projects / Service / Support**
Suite 706** Lisburn Enterprise Organisation Enterprise Crescent Ballinderry Road Lisburn BT28 2BP United Kingdom **Projects / Service / Support**	Scion House Stirling University Innovation Park Stirling FK7 4NF United Kingdom **Projects / Service / Support**
3 Lakeside Business Park Swan Lane Sandhurst Berkshire GU47 9DN	

Service / Support / Calibration	

*Head Office, ** Managed by the Stirling Office.

Note: Service/Calibration Lab is located on the Sandhurst site.

4.4 Quality Management System and its processes

Throughout this manual and associated procedures and documents, the Company has established, documented and implemented a QMS conforming to the requirements of ISO 9001:2015. The system is designed to result in continually improving the effectiveness of the Company in the operation of the QMS and in the ability to satisfy the customers' requirements.

The Company QMS comprises three levels, level one being the Quality Manual, level two being the Company Procedures and level three the Work Instructions and Documents (e.g. Test Sheets, Service Reports etc).

This Quality Manual, along with the associated procedures, identifies the processes necessary for the QMS at the Company. Maintenance of this QMS is the responsibility of the Quality Department in conjunction with all Department Managers and Senior Management.

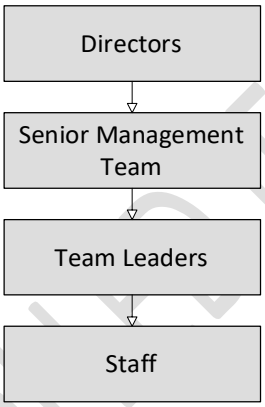


Diagram 1. Company Hierarchy and Reporting Structure

The Quality Department maintains high level documentation such as procedures required for ISO 9001 in coordination with the department managers, defines and improves the procedures defining these processes. Procedures include the methods necessary to ensure the effective operation, maintenance, and control of these processes. These are managed in accordance with the guidelines contained in ISO 9001.

The company determines the processes needed for the QMS and their application throughout the company, and will (ISO 9001 Clause 4.4.1):

- Determine the inputs required and the outputs expected from these processes.
- Determine the sequence and interaction of these processes.
- Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes.
- Determine the resources needed for these processes and ensure their availability.
- Assign the responsibilities and authorities for these processes.
- Address the risks and opportunities as outlined in Section 6.1.
- Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.
- Improve the processes and the QMS.

To the extent necessary, the company will (ISO 9001 Clause 4.4.2):

- Maintain documented information to support the operation of its processes.
- Retain documented information to have confidence that the processes are being carried out as planned.

Management ensures the availability of documentation and resources to support the processes through regular interaction with personnel and through scheduled internal audits. Directors and senior personnel monitor, measure

and analyse processes and implement any actions necessary to achieve intended results and the continued improvement of these processes. These results are reviewed at the monthly management meetings.

Department managers and senior personnel are responsible for identifying any additional documentation needed to ensure the effective planning, operation, and control of processes.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Senior Management is actively involved in implementing the QMS and promoting continuous improvement. It has provided the vision and strategic direction for the growth of the company and QMS, and established company and quality objectives and the quality policy.

The Management team consisting of the Directors, Department Managers and Senior Personnel are accountable for ensuring that products and services meet customer as well as statutory and regulatory requirements.

Senior management shall demonstrate leadership and commitment with respect to the QMS by:

- Taking accountability for the effectiveness of the QMS.
- Ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organisation.
- Ensuring the integration of the QMS requirements into the organisation's business processes.
- Promoting the use of the process approach and risk-based thinking.
- Ensuring that the resources needed for the QMS are available.
- Communicating the importance of effective quality management and of conforming to the QMS requirements.
- Ensuring that the QMS achieves its intended results.
- Engaging, directing and supporting persons to contribute to the effectiveness of the QMS.
- Promoting continuous improvement.
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus

The Management Team strives to identify current and future customer needs, to meet customer requirements and exceed their expectations and ensures focus on improving customer satisfaction is maintained by setting and reviewing objectives related to customer satisfaction during quality management reviews.

Customer satisfaction will be monitored via customer satisfaction surveys and general communications with customers, with a focus on enhancing customer satisfaction.

5.2 Policy

5.2.1 Establishing the Quality Policy

The Company has established a Quality Policy (QP000) that is appropriate to the organisation and meets the requirements set out in the ISO Standard. It provides a framework for setting quality objectives, includes a statement to satisfy applicable requirements and includes a commitment to continual improvement of the QMS.

5.2.2 Communicating the Quality Policy

The Quality Policy, (QP000), is communicated throughout the company along with being displayed in prominent places throughout the building and freely available to all interested parties. The Quality Policy is available to view on the company website.

Managers and Senior personnel are responsible for ensuring that all employees are aware of the policy. To ensure this policy remains appropriate, it is reviewed annually. All new starters are provided with a copy of the policy as part of their Induction process.

5.3 Organisational roles, responsibilities, and authorities

An organisation chart (OC001) has been established to show the interrelation of personnel in the organisation. Job descriptions define the responsibilities and authorities of each of the positions on the organisation chart.

These documents are available throughout the organisation to help employees understand their responsibilities and authorities and notifications of changes are sent via companywide emails.

The Quality Department meet Bi-Annually with the Directors to discuss QMS in full. Monthly slides are also produced detailing any changes and reporting on the QMS.

The Quality Department are responsible for maintaining the ISO 9001 standard with the Directors. This is done by holding the Bi-Annual Quality and Directors meetings and the Monthly Management Meetings.

Referenced documents
QP000 - Quality Policy
OC001 – Organisation Chart

6 Planning

6.1 Actions to address risks and opportunities

The document Risks and Opportunities – RO001, can be found in the following location on the server: *Q:\ISO 9001\Company Risks and Opportunities*.

Risks and Opportunities are monitored regularly through bi-annual Quality/Director meetings where the Risks and Opportunities are discussed, and the severity and probability levels are decided upon. The Risks are marked as either M – Mitigate/Reduce Risk or A – Accept Risk by informed decision.

For the Risks identified as Mitigate/Reduce risk, actions are then suggested that aim to reduce the overall risk rating. The actions are reviewed at the next Quality/Directors Meeting in order to review changes and chase progress.

6.2 Company objectives and planning to achieve them

The Company establishes Company Objectives on a regular basis. These objectives are measurable and consistent with the Quality Policy. The Company Objectives – CO001, are discussed within the bi-annual Quality/Directors meeting to review the objectives and check whether the objectives are achievable and realistic for the set timeframe. Any updates are given, and progress is discussed.

As part of strategic planning, the Company establishes objectives for improvement of company services, processes, and customer satisfaction. These objectives are supported by measures that track performance against those objectives. Managers in turn set departmental objectives with specific performance measures and targets that support the company objectives.

6.3 Planning changes

If changes to the QMS are considered, (either to meet objectives or because of changing business conditions), they are reviewed to ensure that the integrity of the quality system is maintained.

Once processes are determined and documented within the QMS, then associated Risks and Opportunities are identified.

Risks and Opportunities – RO001.

Located: *Q:\ISO 9001\Company Risks and Opportunities*

Risks and Opportunities may identify changes needed to the QMS.

These changes could relate to any aspect of any process such as its inputs, resources, suppliers, personnel, activities, controls, measurements, and outputs.

This is documented in the flowchart below.

When changes to the QMS occur, whether because of a Risk or an Opportunity, then Upper Management and Quality should ensure that all employees are made aware of any changes that affects their processes and procedures.

Referenced documents
CO001 - Company Objectives
QP000 – Quality Policy
RO001 – Risks and Opportunities

7 Support

7.1 Resources

7.1.1 General

During planning and budgeting reviews and as necessary, the management team determines and ensures that the appropriate resources are available to implement and maintain the QMS and continually improves its effectiveness and enhance customer satisfaction by meeting customer requirements.

7.1.2 People

Personnel performing work affecting products and services quality are competent based on appropriate education, training, skills, and experience.

7.1.3 Infrastructure

The Company provides the infrastructure necessary to achieve conformity to process requirements. During the annual budgeting and strategic planning, processes, buildings, workspace, and associated equipment are evaluated for required improvements. When new personnel are added, the department Manager coordinates to ensure that appropriate workplace materials, equipment and training are provided. This is arranged by the department Manager completing a 'New Starter and Leaver Form'.

7.1.4 Environment for the operation of processes

The management team monitors the work environment to ensure that personnel have a safe and desirable place to work, and that the environment is appropriate for achieving conformity to the QMS requirements.

The company ensures that social, psychological, and physical factors are considered.

The HR department ensure that social events are planned throughout the year for all staff.

7.1.5 Monitoring and measuring resources

The Company determines the monitoring and measurement to be undertaken and the devices needed to provide evidence of conformity of product to determined requirements. The Company establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner consistent with the monitoring and measurements requirement and in accordance with BS EN ISO/IEC 17025:2017, where applicable.

Where necessary, to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded.
- Adjusted or re-adjusted as necessary.
- Identified to enable the calibration status determined.
- Safeguarded from adjustments that would invalidate the measurement result.
- Protected from damage and deterioration resulting from handling, maintenance, and storage.

In addition, the Company assesses and records the validity of the previous measuring results when the equipment is found not to conform to the requirements. The company takes appropriate action on the equipment and any product affected. The Service and Support department have a budget for equipment so that we can ensure we have the latest equipment / resource required.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed.

Records of the results of calibration and verification are maintained.

7.1.6 Organisational Knowledge

The proprietary information regarding ASL/Pharmagraph products is maintained within the following systems:

- Source code control database for software and hardware.
- Service Database.
- Sales Database.
- Projects Database.
- Drawings and design documentation.

The company ensures organisational knowledge is maintained by internal resources and external resources with training and continuous improvement.

- Internal: Nonconforming Outputs.
- External: Standards, External Training Courses.

7.2 Competence

The minimum competencies required for each position within the Company are defined in each positions Job Description. Directors, Managers, HR and Senior Personnel are responsible for ensuring job descriptions are current.

Where required, training for personnel is carried out to meet the minimum competency requirements. Each department provides task specific training.

General training or education is provided or coordinated via Managers, HR or Senior Personnel. The appropriate department Manager or Directors evaluate the effectiveness of training or education programs.

Each department generates records of task-specific training. The department Manager and HR maintain records of all training, education, skills, and experience.

7.3 Awareness

Managers are responsible for ensuring that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the company and quality objectives.

The Quality Manual, Quality Policy and Company Objectives are uploaded to the online HR tool, where there is a 'read and understood' requirement.

7.4 Communication

The company determines the internal and external communications relevant to the QMS.

Departmental meetings, the Monthly Management meetings, Quality and Directors meetings are all forms of internal communication within the company.

The quarterly company newsletter is used as a way of communicating changes and updates to all staff, across all sites as well as regular email communication to all staff.

7.5 Documented Information

7.5.1 General

The company's QMS includes documented information required by standard ISO 9001, determined as being necessary for the effectiveness of the QMS.

7.5.2 Creating & Updating

The Document Control procedure (DC001) defines the controls needed to:

- Approve documents.
- Review, update & re-issue documents.
- Ensure that document changes and revision status is clear.
- Ensure that relevant current release versions of applicable documents are available at points of use.
- Ensure that documented information remain legible and readily identifiable.
- Ensure that documented information of external origin is identified and distribution appropriately.
- Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained or dispositioned for any purpose.
- Storage, protection, retrieval, retention time and disposition of records.

7.5.3 Control of Documented Information

All documents required by the QMS are made available for use on the company shared drive and are controlled.

Procedures are locked down (saved as PDF) so that changes can only be made by the Quality department, Manager or Director.

All procedures are watermarked to state 'Uncontrolled if Printed'.

Referenced documents

DC001 – QMS Document Control Procedure

8 Operation

8.1 Operational planning and control

The Company has planned and developed the processes needed to provide customers with services that meet their requirements.

The results of this planning are the processes and procedures defined in the QMS documentation.

These processes and procedures include the quality objectives and requirements for customer products, the required verification, validation, monitoring, review, and test activities specific to customer products and the criteria for finished product acceptance verification.

The records provide evidence that these processes and the resulting products meet requirements as defined in the procedures.

Consideration is given for the need to establish processes, documents and obtain resources specific to a new product, as they are developed or during contract review.

8.2 Requirements for products and services

8.2.1 Customer communication

In keeping with the Company's commitment to customer satisfaction, the Company views effective customer communication as an essential element of customer satisfaction. Appropriate handling of communications can reduce customer dissatisfaction in situations and in many cases, turn a dissatisfying scenario into a satisfying experience.

Initially the Sales team are responsible for establishing communication methods to ensure that enquiries, contracts, order handling including amendments and Customer feedback, are handled expeditiously and professionally before handing over to the Project team.

The Projects Team, Service and Support Team will liaise with the customer regarding the Service Contract, should they choose to take up the service contract.

8.2.2 Determination of Requirements Related to the Product

During the quotation process, requirements specified by the customer including implementation and post-implementation activities are defined.

Requirements not stated by the Customer, but that may be necessary for the product's specified or intended use, are identified by a combination of authorities having jurisdiction, external organisations or as established by Sales.

Requirements and change requests determined by external organisations or the authorities having jurisdiction are communicated during design review and as required thereafter.

8.2.3 Review of requirements related to products and services

Before committing to the Customer, the Company reviews their requirements related to the product to ensure that they can be met. These reviews include the review of quotation, design, orders and change orders.

The purpose of these reviews is to determine if the product requirements are adequately defined. Any requirements differing from those previously understood or contracted are resolved. The Company reviews its ability to meet the defined or re-defined requirements in terms of performance and delivery.

Where Customers request an order, an order confirmation is generated and sent to the Customer to ensure agreement on the requirements.

The Project Team or the Department Manager coordinate change orders or contract amendments to ensure that these items are reviewed by the appropriate departments and that work orders and any other documents are updated, and affected personnel are made aware of the changes.

8.2.4 Changes to requirements for products and services

Design and development changes are identified, and records maintained. The changes are reviewed, verified and qualified as appropriate before implementation.

The review of design and development changes includes evaluation of the effect of the changes on constituent parts already provided/delivered.

Records of the results of the review of changes and any necessary actions are maintained.

8.3 Design & development of products and services

8.3.1 General

The design phase is an important phase in the life cycle of a product. The inherent quality effectiveness, safety and customer satisfaction of a product is established during this phase. With the required supporting activities being detailed in QP0504A Specifying and Developing Products.

8.3.2 – Design and Development Planning

Procedure QP0504A Specifying and Developing Products **addresses *product*** development work to meet Acquisition Systems' / Pharmagraph's requirements:

> *The objective is to allow the creation of a high quality, reliable, maintainable product that demonstrably satisfies both the Customer's and regulatory requirements.*

8.3.3 – Design and Development Inputs

Conceptually, the Marketing department represents the customer, and the Engineering department represents the supplier.

The following aspects of the project are covered:

- Marketing Requirement Specification.
- Target Specification.
- Hardware/Software structure and design.
- Design Review.
- Implementation.
- Testing and review.
- Final testing within a project.
- Maintenance and change control.

8.3.4 – Design and Development Controls

Controls are applied to the design and development process to ensure that:

- The results to be achieved are defined.
- Reviews are conducted to evaluate the ability of the results of design and development to meet requirements.
- Verification activities are conducted to ensure that the design and development outputs meet the input requirements.
- Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use.
- Any necessary actions are taken on problems determined during the reviews, or verification and validation activities.
- Documented information of these activities is retained.

8.3.5 – Design and Development Outputs

The company ensures that design and development outputs:

- Meet the input requirements.
- Are adequate for the subsequent processes for the provision of products and services.
- Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria.
- Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organisation shall retain documented information on design and development outputs.

8.3.6 – Design and Development Changes

The company will identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organisation shall retain documented information on:

- Design and development changes.
- The results of reviews.
- The authorisation of the changes.
- The actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products, and services

8.4.1 General

The Company ensures that requested goods and services conform to the specified purchase requirements. The type and extent of controls applied to the suppliers and their product or services are dependent upon the effect of the purchased product or services on subsequent product realisation or final product.

The Company evaluates and recommends suppliers or contractors based on their ability to supply in accordance with company requirements. Criteria for selection, evaluation and re-evaluation are defined in the SC06111_Approved Suppliers procedure.

Each supplier is given a Tier Level, decided upon by the Quality Department with an input from the person who has requested the new supplier. Tier levels are reviewed routinely, at six monthly Quality meetings held by the Quality Department and attended by the Board of Directors and are amended by the Quality Department using a risk-based approach. The Tier Levels are defined as follows:

- High Surveillance – Requires highest level of surveillance. Includes subcontractors and suppliers that are key to continuity of the business or are currently single source.
- Low Surveillance – Suppliers are necessary to the running of the business but are not single source and other companies are available.
- No Surveillance – No Surveillance suppliers do not impact product or service. These suppliers do not require any method of surveillance.

Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

8.4.2 Type and extent of control

Information describes the product and/or services to be contracted including where appropriate:

- Requirements for approval of product, processes, and equipment.
- Requirements for qualification of personnel.
- Quality control requirements.

The Company ensures the adequacy of the specified request requirements before communication with the contractor.

8.4.3 Information for external providers

The Company establishes and implements the review or other activities necessary for ensuring that the contracted products or services meet specific contract requirements. If the Company must perform verification, the verification arrangements and method of product/service/approval/release are provided to the external provider.

8.5 Production and service provision

8.5.1 Control of production and service provision

Where specified, the Company plans and completes production service activities under controlled conditions. Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product.
- The availability of work instructions as necessary.
- The use of suitable equipment.
- The availability and use of monitoring and measuring devices.
- The implementation of monitoring and measurement.

- The use of suitable infrastructure and environment for the operation of processes.
- The appointment of competent persons, including any required qualification.
- The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.
- The implementation of actions to prevent human error.
- The implementation of release, delivery and post-delivery activities.

The Company validates processes used for production service provision where the resulting output cannot be verified by subsequent monitoring or measurement.

Validation demonstrates the ability of these processes to achieve the planned results.

The Company arrangements for these processes, including as applicable, documentation of the following:

- Defined criteria for review and approval of the processes.
- Approval of equipment and qualification of personnel.
- Use of specific methods and procedures.
- Requirements for records.
- Revalidation.

8.5.2 Identification & traceability

Where appropriate the Company analyses a product by suitable means throughout the component life cycle. The Company analyses the product status regarding monitoring and measurement requirements. All products are given a unique reference number.

8.5.3 Property belonging to customers or external providers

The Company exercises care with Customer Property (including intellectual property) while it is under the company control or being used.

On receipt the company identifies, verifies, protects, and safeguards client property provided for use or incorporation into a product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, it is reported to the customer and records maintained. Customer property is detailed further in QP13091_Quality Procedures for Service and Support.

8.5.4 Preservation

The Company handles materials, components and information in a manner that preserves their conformity during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection.

8.5.5 Post-delivery activities

As applicable, the Company conducts the following activities which are considered “post-delivery activities”:

- System support.
- Service and Calibration activities.

Post-delivery activities are conducted in compliance with the management system. In determining the extent of post-delivery activities that are required, ASL / Pharmagraph considers:

a) Statutory and regulatory requirements.

b) The potential undesired consequences associated with its of products and services.

c) The nature, use and intended lifetime of its of products and services.

d) Customer requirements.

e) Customer feedback.

8.5.6 Control of changes

The company reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Product and software change management is defined in the documents, QP0504A – Specifying and Developing Products and CM0405A – Software Release and Configuration Management.

Documents are changed in accordance with procedure, DC001 – QMS Document Control Procedure.

8.6 Release of products and services

The Company monitors and measures the characteristics of products to verify that the requirements have been met. This is carried out at the appropriate stages of the product realisation process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorising release.

8.7 Control of nonconforming product

Release of products must not proceed until the activities defined in the quality plan have been satisfactorily completed. The company takes appropriate action based on the nature of the nonconformity and its affect on the nonconformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. Any exceptions need to be approved by management and, where applicable, by the Customer (ISO 9001 Clause 8.7.1).

Products that do not conform to requirements are identified and controlled to prevent their unintended use or delivery by means of:

- Correction.
- Acting to eliminate the detected nonconformity.
- Segregation, containment, return or suspension of provision of products and services.
- Informing the customer.
- Authorising its use, by way of release or acceptance under concession, by a relevant authority and, where applicable, by the Customer.
- By acting to preclude its original intended use or application.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained (ISO 9001 Clause 8.7.2).

When a non-conformance is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

When a non-conformance is detected after delivery or use has started, the Company takes appropriate action to the effects, or potential effects, of the nonconformity.

The company retains documented information that:

- Describes the nonconformity.
- Describes the actions taken.
- Describes any concessions obtained.
- Identifies the authority deciding the action in respect of the nonconformity.

Referenced documents
QP0690B – Quality Procedures for Project Implementation
SO001 - Sales Procedure
ASL001 – ASL Approved Suppliers List
SC06111 – Approved Suppliers Procedure
CA001 – Corrective Actions and Improvements
NC002 - Nonconforming Outputs Form
DC001 – QMS Document Control Procedure
QP0504A – Specifying and Developing Product
CM0405A –Software Release and Configuration Management
QP13091 – Quality procedures for Service and Support

9 Performance evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

The Company plans and implements the monitoring, measurement and improvement processes needed to:

- Demonstrate conformity of the services.
- Ensure conformity to the QMS.
- Continually improve the effectiveness of the QMS.

Evidence of monitoring, measurement, analysis and evaluation can be seen in the Monthly Management Meeting slides and Quality and Directors Meeting slides.

9.1.2 Customer Satisfaction

As one of the measurements of the performance of the QMS, the company monitors information relating to the customer perception as to whether we have met the Customer requirements.

The Service and Support team and the Projects team routinely send out Customer Satisfaction questionnaires to customers and the feedback is logged by Quality personnel and discussed during the Monthly Management Meetings.

Where required, if customer dissatisfaction is raised, subsequent meetings would be arranged with the customer to investigate (providing that the customer has identified themselves).

9.1.3 Analysis and evaluation

The organisation shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate:

- Conformity of products and services.
- The degree of customer satisfaction.
- The performance and effectiveness of the QMS.
- If planning has been implemented effectively.
- The effectiveness of actions taken to address risks and opportunities.
- The performance of external providers.
- The need for improvements to the QMS.

9.2 Internal Audit

9.2.1 General

The Company conducts internal audits at planned intervals to determine whether the QMS system conforms to:

- The planned arrangements for product realisation, to the requirements of the ISO 9001:2015 standard and to the QMS requirements established by the Company.
- Effective implementation and maintenance.

9.2.2 Audit Schedule

An audit schedule is planned to take into consideration the status and importance of the processes and areas to be audited as well as the results of previous audits. IAS001 – Internal Audit Schedule.

The audit criteria, scope, frequency, and methods are defined in the Internal Audit procedure – IA001.

Selection of auditors and conduct of audits ensures the objectivity and impartiality of the audit process.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined by the Quality Department and documented in the quality procedures.

The Manager responsible for the area being audited is to ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow up activities include the verification of the actions taken and the reporting of verification.

Referenced documents
IA001 - Internal Audit Procedure
IAS001 – Internal Audit Schedule
IFL001 – Internal Findings Log

9.3 Management Review

9.3.1 General

The Quality Department and the Board of Directors shall review the organisations QMS, during bi-annual review meetings. The Quality and Directors meeting minutes are documented, and actions are discussed and implemented. The status of an issue is amended to closed upon completion and will then be removed ahead of the next scheduled meeting.

In addition to the Quality and Directors bi-annual review meeting, there is also a Monthly Management Meeting which aims to provide updates from each Department and acts as a monthly overview to capture changes and increase awareness of any issues or updates.

9.3.2 Management Review Inputs

The Management Review includes a detailed review of the stated policies and objectives related to the fulfilment of ISO9001:2015 and ISO17025:2017, on the following:

- The status of actions from previous management reviews (ISO9001:2015 & ISO17025:2017).
- Suitability of policies and procedures (ISO17025:2017).
- Changes in external and internal issues that are relevant to the QMS (ISO17025:17025).
- Changes in internal and external issues that are relevant to the laboratory (ISO17025:2017).
- Information on the performance and effectiveness of the QMS, including trends in:
    - Customer satisfaction and personnel feedback from relevant interested parties (ISO9001:2015 & ISO17025:2017).
    - Complaints (ISO17025:2017).
    - The extent to which quality objectives have been met (ISO9001:2015 & ISO17025:2017).
    - Process performance and conformity of products and services (ISO9001:2015).
    - Nonconformities and corrective actions (ISO9001:2015 & ISO17025:2017).
    - Monitoring and measurement results (ISO9001:2015).
    - Internal and External audit results (ISO9001:2015 & ISO17025:2017).
    - The performance of external providers (ISO9001:2015).
    - Assessments by external bodies (ISO9001:2015 & ISO17025:2017).
- Changes in the volume and type of the work or in the range of laboratory activities (ISO17025:2017).
- The adequacy of resources (ISO9001:2015 & ISO17025:2017).
- The effectiveness of actions taken to address risks and opportunities (ISO9001:2015 & ISO17025:2017).
- Opportunities for improvement (ISO9001:2015).
- Effectiveness of any Implemented Improvements (ISO17025:2017).
- Outcomes of the assurance of the validity of results (ISO17025:2017).
- Other relevant factors, such as monitoring activities and training (ISO17025:2017).

There is an opportunity for any attendee to suggest a change or raise a concern.

9.3.3 Management Review Outputs

Updates are added to the actions during the Management Review, right up until the point they are closed out and the status is amended. The outputs of the management review shall include decisions and actions related to:

- Opportunities for improvement.
- Any need for change (and any need for changes to the QMS) (ISO9001:2015 & ISO17025:2017).
- Resource needs (ISO9001:2015 & ISO17025:2017).
- The effectiveness of the management system and its processes (ISO17025:2017).
- Improvement of the laboratory activities related to the fulfilment of the requirements of this document (ISO17025:2017).

The minutes of the meeting are kept indefinitely and can be found in the following location:

Q:\Management Meetings\Management Review - Quality and Directors – Management Review

Q:\Management Meetings\Monthly Minutes – Monthly Management Meeting

The attendees may discuss the content of the meeting with their teams, should it be relevant to them.

Referenced documents
MM001 – Management Review Minutes

10 Improvement

10.1 General

The Company uses the QMS to improve its processes, products, and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties.

These shall include:

- Improving products and services to meet requirements as well as to address future needs and expectations.
- Correcting, preventing or reducing undesired effects.
- Improving the performance and effectiveness of the QMS.

10.2 Non-conformity and Corrective Action

When a nonconformity occurs, including any arising from complaints, the company will (ISO 9001 Clause 10.2.1):

- React to the nonconformity and, as applicable.
- Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere.
- Implement any action needed.
- Review the effectiveness of any corrective action taken.
- Update risks and opportunities determined during planning, if necessary.
- Make changes to the QMS, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The CA001 – Corrective Actions and Improvements procedure defines the process for raising and reporting complaints and nonconformancies on the the NC002 – Nonconforming Outputs Form and the NCR001- NCR Register.

The company retains documented information as evidence of (ISO 9001 Clause 10.2.2):

- The nature of the nonconformities and any subsequent actions taken.
- The results of any corrective action.

The nonconformity is documented on the NC002 – Nonconforming Outputs Form, where the Root Cause , Containment Action and Corrective Actions are completed by the Process Owner. An independent review of the Corrective Actions is completed and signed off by the Quality Department.

The nonconformity is also logged on the NCR001- NCR Register. Any repeated finding is raised to a higher priority, for example a Minor NCR would become a Major NCR or an OFI would be raised to a Minor NCR.

10.3 Continual Improvement

The Company continually improves the effectiveness of the QMS through use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions, and management review.

Referenced documents
CA001 – Corrective Actions and Improvements
NC002 - Nonconforming Outputs Form
NCR001- NCR Register
DC001 – QMS Document Control Procedure

End of Document