CARCINOTECH
Reinventing Cancer Research

QUALITY MANAGEMENT SYSTEM MANUAL

Roslin Innovation Centre
The University of Edinburgh
Easter Bush Campus
Roslin EH25 9RG

Certificate No: 15516

Contents

Q01 Document Control

Document

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Authorisation

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Q02 Document Amendments

All copies of this Quality Management Systems Manual (QMSM) must be kept under strict control to prevent the system from becoming unreliable. The following controls will ensure that the system remains current and valid.

1. All copies of the manual will be clearly numbered and the Holder recorded.

2. Each page in the manual will carry its own number.

3. The Quality Representative will be responsible for all revisions and additions being recorded.

4. Changes can be suggested by any Employee but must receive signed approval before being entered into the QMSM.

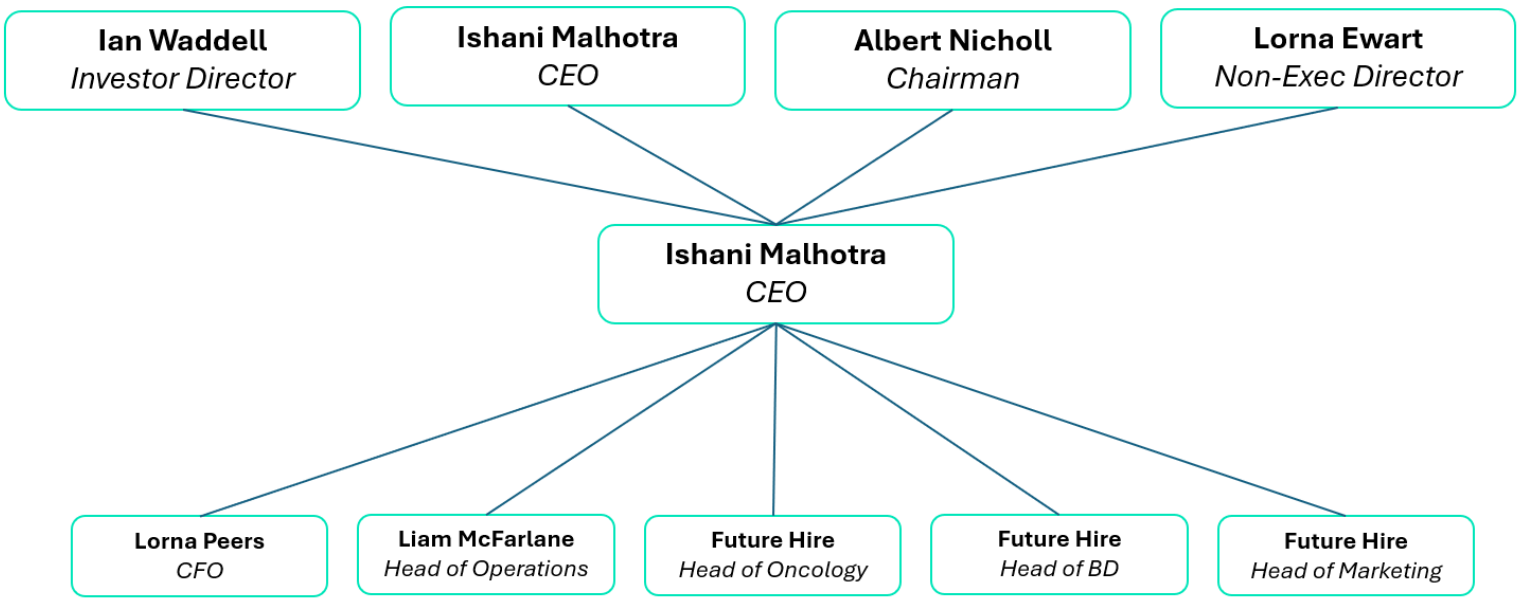
5. All changes must be recorded on the Amendments Table below and appropriate pages in each QMSM changed. Significant changes will be shaded to make them easy to identify. (Where existing text is reworded or reorganised in the document, these changes will not be shaded.)

Amendments Table

Doc. No.	Page No.	Issue	Date	Description of change	Authorisation
Quality Manual	15 , 20	2	20/07/22	Changed all “Q-Pulse” to “Benchling” in Quality Manual	IM
R03	1	2	20/07/22	Changed all “Q-Pulse” to “Benchling” in Quality Manual	IM
M06	2	2	21/07/22	Changed all “Q-Pulse” to “Benchling” in Quality Manual	IM
M07	3	2	21/07/22	Changed all “Q-Pulse” to “Benchling” in Quality Manual	IM
M09	3	2	21/07/22	Changed all “Q-Pulse” to “Benchling” in Quality Manual	IM
R03	1, 2	2	27/07/22	Version 2 of document was made, updated quality objectives	IM
All documents	NA	2	15/08/22	Updated all headers and footers with new branding	IM
R05, R06	NA	NA	22/08/22	New integrated approach for R05 and R06	IM
M01	1	2	22/08/22	Edited the Scope of QMS to the latest company overview	IM
Quality Manual	5	2	22/08/22	Updated Organisation Chart	IM
R09, R10, R11	all	1	22/08/22	Addition of design control processes and outputs	IM

Q03	All	2	25/07/2023	Updated organisation chart	LM
M10	2	2	10/03/2023	Updated R19 to show "Recorded in Benchling"	IM
Quality Manual	21	3	22/06/2023	R08 added	LM
Quality Manual	21	3	22/06/2023	R21 Added	LM
Quality Manual	16	3	22/06/2023	8.6 update to include reference to R08 – Certificate of Analysis	LM
Quality Manual	16	3	22/06/2023	8.5 Addition of R21 - Overview of System Showing Traceability of Products	LM
Quality Manual + R04	13,20	4	17/11/2023	R04 name changed from Calibration Register to Equipment Calibration Log	LM
Q03	All	4	06/02/2024	Updated organisation chart	LM
Q05	21,22	4	09/08/2024	Updated dates and versions of Document Register	IM

Q03 Company Organisation Chart



Operational, Finance, Scientific and Commercial Team

Scientific & Operations Team	Commercial Team
Scientific Manager	Business Development Manager
Senior Scientist	Marketing Manager
BioScientist	Marketing Associate
Imaging Scientist x2	
Senior Lab Technician	
Junior Scientist	
Operations & Admin Associate	

Q04 Quality Management System

4. Context of the organisation

4.1 Understanding the Organisation and its Context

We have determined the relevant external and internal issues that affect our ability to achieve the intended outcomes of our management system. We have considered the full business environment, the key drivers and trends having impact on the objectives of the organisation and the relationship and values of external stakeholders. Details of the context of our organisation are given on our web site www.carcinotech.co.uk

4.2 Understanding the Needs and Expectations of Interested Parties

We have identified the interested parties and their requirements with the emphasis being on quality. We have included a process to determine any legal requirements relating to activities, products and services that are relevant to the scope of our management system.

Interested parties are identified within our Risk and Opportunities register, along with their expectations from us and our obligations to them.

4.3 Determining the Scope of the Quality Management System

We have determined the boundaries and applicability of our management system and have taken into account the issues identified in Clause 4.1 and 4.2 (above) as well as those that relate to our product and service when establishing the scope.

See document – M01 Scope of QMS

4.4 Quality Management System and its processes (QMS)

We have established and implemented and will look to maintain and continually improve our quality management system, including the processes and their interactions needed to meet the requirements of the international standard.

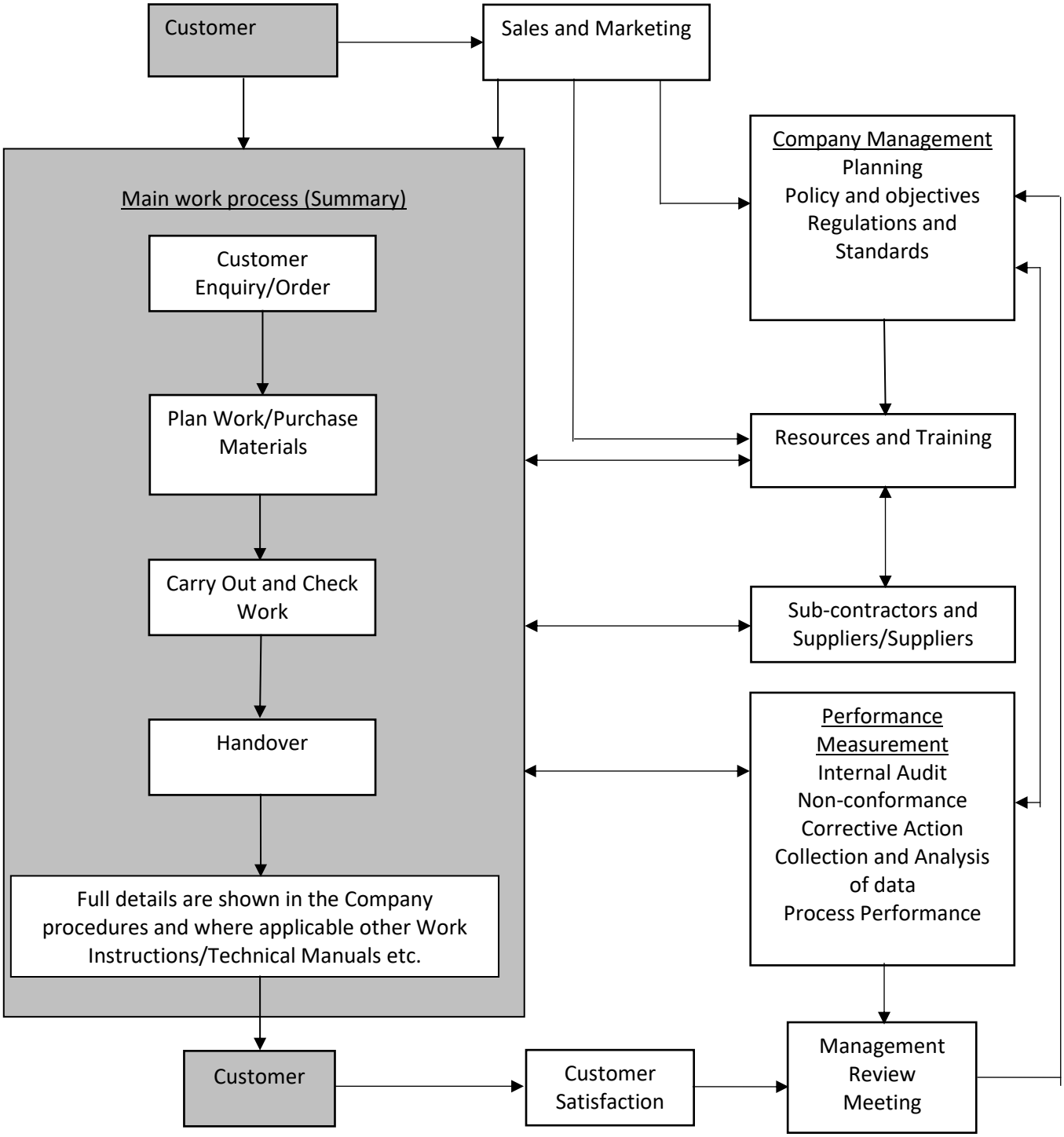
In order to deliver the requirements, we have identified:

- the processes needed for the implementation, operation and maintenance of the management system along with opportunities for its improvement and their application throughout the organisation;
- the inputs required and outputs expected from these processes;
- the sequence and interaction of these processes;
- criteria and methods needed to ensure that both the operation and control of these processes are effective;

- the availability of resources and information necessary to support the operation and monitoring of these processes;
- the risks and opportunities within the management system and how to plan to address them;
- the monitoring, measuring and analysing of these processes, and implement actions necessary to achieve planned results and continual improvement.

Appropriate documented information is maintained to support these processes and is retained as records to demonstrate that all processes are working as planned.

QMS Process Diagram



5. Leadership

5.1 Leadership and Commitment

5.1.1 General

Our Top management have demonstrated leadership and commitment with respect to our QMS by taking accountability of the effectiveness of the QMS; by establishing a quality policy and quality objectives that are compatible with the direction of the organisation; by ensuring that both policy and objectives are communicated, understood and applied within the organisation; ensuring integration of QMS requirements into the organisation's business processes and by promoting awareness of a process approach and risk based thinking.

In addition, our Top Management have provided the necessary resources for the QMS; communicated the importance of effective quality management and of conforming to QMS requirements; ensuring that the QMS achieves intended results; engaging with, directing and supporting persons to contribute to the effectiveness of the QMS; promote improvement and support other members of the management team to demonstrate their leadership as it applies to their area of responsibility.

5.1.2 Customer Focus

As an organisation, we strive to meet our clients' expectations; our top management has demonstrated their leadership and commitment by ensuring that clients' requirements and applicable regulatory and statutory requirements are met; that risks and opportunities that could affect our products and services have been addressed and that our focus is on consistently providing client satisfaction.

5.2 Policy

Our Top Management has developed a quality policy that is in line with the requirements of the standard. The Policy is available as documented information, is communicated throughout the organisation and is also available to interested parties, as appropriate.

See Document – M02 Quality Policy

5.3 Organisational Roles, Responsibilities and Authorities

Our Top management will ensure that the responsibilities and authorities for relevant roles are assigned and communicated throughout the organisation. The organisation has identified, documented, and communicated the roles, responsibilities and authorities of those involved in the management system and their interrelationships within the organisation.

See Document – R01 Job description

6. Planning

6.1 Actions to Address Risks and Opportunities

We have considered the issues detailed in clause 4.1 and 4.2 of this document and have determined the risks and opportunities that need to be addressed to assure the QMS can achieve its intended outcomes; that we prevent or reduce undesired effects and achieve continual improvement.

We have put a plan in place to address these risks and opportunities and also a plan to integrate and implement these actions in the QMS and evaluate their effectiveness. We have produced a risk assessment register to show what has been achieved.

See document – M03 Risk Assessment Procedure
R02 Risk and Opportunities Register

6.2 Quality Objectives and Planning to achieve them

We have established quality objectives at various levels throughout the organisation in line with the requirements of ISO9001:2015 Clauses 6.2.1 and 6.2.2; a document has been produced detailing these objectives and the procedure around establishing them.

See document – M04 Quality Objectives Procedure Document
R03 Quality Objectives

6.3 Planning of Changes

If we make changes to our QMS they would be carried out in a planned and systematic manner. We will consider the purpose of any change, its potential consequences, the integrity of the QMS, the availability of resources and the allocation or reallocation of responsibilities and authorities.

See document – R14 Document Change Request

7. Support

7.1 Resources

7.1.1 General

We have determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of our QMS. We have considered the capabilities of our existing resources and what we need to obtain from external providers. See Document - M14 Resources

7.1.2 People

Those resources include people who have the necessary skills and competencies to effectively operate our QMS and to meet and exceed our clients' expectations. Also see Clause 7.2.

7.1.3 Infrastructure

We have provided the infrastructure determined necessary for the provision of our processes and conformity of our products and services.

7.1.4 Environment for the Operation of Processes

We have provided the environment determined necessary for the provision of our processes and conformity of our products and services.

7.1.5 Monitoring and Measuring Resources

We have determined that we need to use measuring and monitoring resources for evidence of conformity for our products and services and have created specific documented information detailing how we have approached this requirement.

See document – M05 Measuring and Monitoring Resources
R04 Equipment Calibration Log

7.1.6 Organisational Knowledge

We have determined the knowledge necessary to operate our processes when achieving conformity of our products and services. We have systems in place to address any changes to our needs and possible trends that come up from time to time. The knowledge is in the form of documented information or other media and is available to those who require it.

7.2 Competence

We have determined the competence of people doing work under our control that affects performance to ensure that these people are competent on the basis of appropriate education, training or experience and where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken.

See document – R05 Skills Matrix/Competency Statement
R06 Training Record

7.3 Awareness

We have ensured that people doing work under our control are aware of our policies; our quality objectives relevant to them; their contribution to the effectiveness of the system and the implications of not conforming to the QMS requirements.

See document – R06 Training Record

7.4 Communication

We have determined the need for internal and external communications relevant to the system including on what, when, with whom, how and who would communicate.

7.5 Documented Information

We have written policies and procedures as appropriate to meet the requirements of our QMS and the ISO9001:2015 standard. Details of how we produce and control our documented information are given in M06.

See document – M06 Document Control & Records

8. Operation

8.1 Operational Planning and Control

We have planned, implemented and controlled processes needed to meet requirements for the provision of our products and services, and to implement the actions determined in clause 6.1 of this document by determining the requirements and establishing criteria for those processes and for the acceptance of our products and services. We have also determined the resources needed to achieve conformity of our products and services and by implementing control of the processes in accordance with the detailed criteria.

We keep documented information to the extent necessary to have confidence that the processes have been carried out as planned and that demonstrate the conformity of our products and services.

We shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects as necessary. We shall ensure that outsourced processes are also controlled.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

We communicate with clients where necessary in relation to information related to our products and services, enquiries, contracts or order handling including changes, customer property, obtaining their feedback, including complaints and specific contingency actions where appropriate.

8.2.2 Determination of Requirements Related to Products and Services

When determining the requirements for our products and services offered to potential clients, we have ensured that applicable regulatory and statutory requirements have been defined, that we have the ability to meet those requirements and that we can substantiate any claim made for our products and services.

8.2.3 Review of Requirements Related to Products and Services

We review our Clients' requirements, including those for delivery and post-delivery activities and any statutory and regulatory requirement applicable to the product and service being provided. We also review those requirements not stated by the client, when known, plus any contract or order requirements that are different from the original request.

We conduct this review prior to our commitment to supply our products and services.

Where requirements change, we ensure that all relevant documentation is amended and that personnel are made aware prior to delivery.

8.2.4 Changes to requirements for products and services

We will ensure that when changes are made to our products and services relevant persons are made aware and relevant documentation is amended to reflect those changes made.

See Document - M15 Customer requirements

8.3 Design and Development of Products and Services

Design and development is an integral part of our products and services. We provide resources for evidence of conformity for our products and services and have created specific documented information detailing how we have approached this requirement.

See document – M07 Design and Development Procedure

8.4 Control of Externally Provided Processes, Products and Services

We have produced a procedure (M08) which details how our organisation would deal with the control of externally provided products and services.

See document – M08 Control of Externally provided products and services

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

We have implemented controlled conditions for the production and service provision, including delivery and post-delivery activities in line with the requirements of Clause 8.5.1 of the ISO9001: 2015 quality management system standard.

8.5.2 Identification and Traceability

We have introduced a system to uniquely identify our products and services for the purposes of identification and traceability, and maintain appropriate documentation. We identify the status of our processed outputs with respect to the monitoring and measurement requirements of our products and services. This is automatically recorded in Benchling as work is conducted.

8.5.3 Property belonging to Customers or External Providers

We exercise due care and attention when dealing with property belonging to external providers (including clients). We report any defect, damage or loss to the external provider as soon as it has been identified by our personnel.

8.5.4 Preservation

We ensure the preservation of our products and services to the extent necessary to maintain their conformity throughout the production process.

8.5.5 Post-delivery Activities

We ensure that where applicable we meet the requirements for post-delivery activities associated with our products and services to the extent that we have considered the associated risks, the nature of use and lifetime of the products and services, customer feedback and statutory and regulatory requirements.

8.5.6 Control of Changes

We review and control changes necessary to ensure continued conformity of our products and services. We keep documented records of any such changes using form R14.

See document – M09 Production and Service Provision
R14 Document Change Request
R21 - Overview of System Showing Traceability of Products

8.6 Release of Products and Services

We have implemented arrangements at appropriate stages of production or service provision to verify that product and service requirements have been met; evidence of such acceptance criteria is recorded on appropriate Acceptance Documentation (Certificate of Analysis)

Products and services will not be released to our clients until the verification arrangements have been met. Appropriate records of who authorised the release are recorded on the appropriate Acceptance Documentation (Certificate of Analysis)

See document – R08 Acceptance Documentation (Certificate of Analysis)

8.7 Control of Nonconforming Outputs

We have produced a procedure (M10) which details how our organisation would deal with the control of nonconforming process outputs, products and services.

See document – M10 Control of Non-conformance

9. Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

We have determined what needs to be monitored and measured; the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results; when the monitoring and measuring shall be performed and when the results from monitoring and measurement shall be analysed and evaluated.

We retain documented information on the results of such monitoring and measurement to enable us to evaluate the effectiveness of our QMS.

See document – M11 Monitoring and Measurement Results

9.1.2 Customer Satisfaction

We have determined the methods for obtaining information regarding our clients' perception of our organisation in terms of meeting or exceeding their requirements in the provision of our products and services. The information gathered is reviewed as part of the Management Review process.

9.1.3 Analysis and Evaluation

We analyse and evaluate data gathered as part of our monitoring and measuring activities and the results are used as part of our Management Review process.

9.2 Internal Audit

We conduct internal audits at planned intervals to provide information on whether our QMS conforms to our requirements, to the requirements of ISO9001:2015 Quality Management System standard and is effectively implemented and maintained; it also takes into consideration the importance of the processes concerned. We have implemented a procedure (M12) that covers in detail the process surrounding the internal audit process.

See document – M12 Internal Audit
R16 Internal Audit Programme
R17 Internal Audit Report

9.3 Management Review

Our Top management reviews the organisation's QMS at planned intervals, at least once every 12 months, to ensure its continuing suitability, adequacy and effectiveness. Each

review will take into consideration the status of actions from any previous meetings and any

changes in internal or external issues relevant to our QMS and performance information, including trends and indicators as detailed in ISO9001: 2015 Clause 9.3.1 and 9.3.2.

Information relating to each of these meetings is recorded using document R18 Management Review Agenda and Minutes

See document – M13 Management Review
R18 Management Review Agenda and Minutes

10 Improvements

10.1 General

We have determined and shall select such opportunities as necessary for improving our clients' requirements and satisfaction. This will include improving our products and services; correcting, preventing or reducing undesired effects improving the performance and effectiveness of our QMS.

10.2 Nonconformity and Corrective Action

When non-conformity occurs, we shall react to the nonconformity and take action to control and correct it and then deal with the consequences. We will evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere in the organisation. We will implement the actions required and review the effectiveness of any corrective action taken, update risks and opportunities determined during planning (if necessary) and make changes to the QMS, where necessary.

We record all nonconformities, actions taken and the results of any corrective action using the appropriate documentation.

See documents – M10 Non-conformance and Corrective Action
R19 Non-conformance Register
R20 Non-conformance & CA Report Form

10.3 Continual Improvement

We shall continually improve the suitability, adequacy and effectiveness of our QMS. We consider the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that could be addressed as part of our continual improvement.

Q05 Document Register

Reference	Title	Issue No.	Date	Authority
M01	Scope of QMS	4	AUG 2024	IM
M02	Quality Policy	4	AUG 2024	IM
M03	Risk Assessment Procedure	4	AUG 2024	IM
M04	Planning to Achieve Quality Objectives	4	AUG 2024	IM
M05	Monitoring & Measuring Resources	4	AUG 2024	IM
M06	Document Control & Records	4	AUG 2024	IM
M07	Design & Development	4	AUG 2024	IM
M08	Control of Externally Provided P & S	4	AUG 2024	IM
M09	Production & Service Provision	4	AUG 2024	IM
M10	Non-conformance & Corrective Action	4	AUG 2024	IM
M11	Monitoring & Measurement Results	4	AUG 2024	IM
M12	Internal Audit	4	AUG 2024	IM
M13	Management Review	4	AUG 2024	IM
M14	Resources	4	AUG 2024	IM
M15	Customer Requirement	4	AUG 2024	IM
R01	Job Description	4	AUG 2024	IM
R02	Risk Assessment Register	4	AUG 2024	IM
R03	Quality Objectives	4	AUG 2024	IM
R04	Equipment Calibration Log	4	AUG 2024	IM
R05	Skills Matrix/Competency Record	4	AUG 2024	IM
R06	Training Record	4	AUG 2024	IM

Reference	Title	Issue No.	Date	Authority
R07	Conformity Documentation in Benchling	4	AUG 2024	IM
R08	Certificate of Analysis	4	AUG 2024	LM
R09	Confirmation of D & D Requirements	4	AUG 2024	IM
R10	D & D Process Outputs	4	AUG 2024	IM
R11	D & D Changes	4	AUG 2024	IM
R12	External Vendor list and Evaluation	4	AUG 2024	IM
R13	Traceability Record in Benchling	4	AUG 2024	IM
R14	Document Change Request in Benchling	4	AUG 2024	IM
R15	Acceptance Documentation in Benchling	4	AUG 2024	IM
R16	Internal Audit Programme	4	AUG 2024	IM
R17	Internal Audit Report	4	AUG 2024	IM
R18	Management Review Agenda & Minutes	4	AUG 2024	IM
R19	Non-conformance Register	4	AUG 2024	IM
R20	Non-conformance & Corrective Action Report Form	4	AUG 2024	IM
R21	Screenshot of Benchling Overview from a 3D Printed Plate – Showing Traceability of Product	4	AUG 2024	LM