**Document approval**

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# Purpose

The purpose of this **Quality Manual** is to describe the Quality Organization and Quality Management System (QMS) including management responsibilities associated with it.

It is the responsibility of e.g., Quality Management Director to ensure compliance with the requirements of this **Quality Manual** at the function/entity level.

# Company Profile

Company CDE is produces or plans to produce the following types of products or services:

[Products/services categories list].

e.g., CEO establishes, implements and maintains a quality policy that includes Company CDE’s Quality commitments. Our Quality commitments are reflected in **MD-01 CDE Quality Commitment** **Appendix** to this **Quality Manual**.

Current Company CDE’s organizational structure is reflected in **MD-01 CDE Organigram** **Appendix** to this **Quality Manual.**

# Quality Organization

Company CDE has a developed, implemented, properly functioning and constantly improving Quality Management System in place.

Company CDE’s Quality Management System provides a systematic, risk-based approach to achieving the desired level of product quality consistently and effectively.

The Company CDE’s Quality Organization is an independent function responsible for the development, implementation, and maintenance of the QMS. It consists of a formal organization with defined lines of accountability, as well as advisory and decision-making bodies, and is responsible for Quality Assurance (QA), Quality Management (QM) and Quality Control (QC) throughout the organization. In cases when all parts of Quality are impacted the term Quality Organization may be used, and until Quality Management is formally separated QA and QM are effectively used interchangeably.

The Quality Organization is led by e.g., Quality Management Director and consists of two (2) main functions, the QA function and the QC function:

The QA function is responsible for ensuring that products, devices and materials comply with the requirements for their intended use throughout their life cycle, and for verifying that GxP-related activities comply with the approved procedures.

The QC function is responsible for testing products, devices and materials using approved methods to determine compliance with analytical and physical specifications.

Responsibilities of the Quality Organization include:

* participating in all GxP decision making processes and liaise with relevant business units regarding any quality or compliance risk,
* final authority for all GxP related decisions,
* final authority for interpretation of and compliance with GxP requirements,
* release or disposal of products, devices, materials and components,
* approval of all documents and records related to GxP,
* overseeing the status of GxP compliance and product quality/safety in relation to applicable corporate and regulatory requirements,
* appointment of key quality personnel,
* monitoring changes in regulations, enforcement trends and inspection results for their impact on Quality System,
* development of Quality Plans, Quality Objectives, and monitoring their implementation and effectiveness in the organization,
* ensuring the effectiveness and appropriateness of the QMS,
* implementing of QC in the company,
* analysis of key quality indicators and their compliance status,
* overseeing quality improvement projects and other initiatives,
* conducting monitoring and periodic audits and inspections,
* establishing and provide adequate and appropriate resources and infrastructure necessary to implement and maintain the Quality Management System and to continuously improve its effectiveness,
* ensuring a timely and effective communication and escalation process to raise quality issues to the appropriate levels of management, and
* monitoring the results of inspections and audits, analysis of Deviations, Complaints, Recalls, withdrawals and falsifications.

Quality Organization has the right to:

* enter all areas of Company CDE's facilities and gain access to all records necessary to fulfill Quality Organization’s responsibilities,
* suspend product distribution, if necessary, until quality or compliance issues are resolved, implement mandatory market action up to and including product Recall,

Quality representatives may delegate their tasks, but the primary responsibility remains with the e.g., Quality Management Director. Quality Organization responsibilities may not be delegated to any person performing tasks that could create any conflict of interest.

# Governance

Our top management continuously demonstrates leadership and commitment with respect to the Quality Management Systems. e.g., CEO is the highest-ranking executive in Company CDE, whose primary responsibilities include establishing the vision, making major corporate decisions, managing the overall operations and resources of the company, acting as the main point of communication between the board of directors (the board) and corporate operations, and being the public face of the company.

Quality oversight and governance is achieved through several committees across Company CDE.

## Executive Committee (Leadership Team)

Consists at a minimum of the C-Level representatives, the highest-ranking Quality representative, and may be amended as appropriate. In terms of quality and compliance, the Executive Committee ensures that the following are in place and visible:

long-term planning and strategy for quality and compliance.

the quality plan and strategy for Quality Organization is in place.

compliance with applicable laws, regulations and corporate policies.

quality plan that includes review, approval and monitoring of implementation effectiveness.

## Quality Steering Team

The Quality Steering Team consists of the highest-ranking Quality Leader, his/her direct reports and the quality functional managers and is responsible for communicating regulatory and QMS requirements throughout the organization and providing updates to leaders and the Quality Organization on the effectiveness or changes required to the QMS. In addition, Management is responsible for:

* ensuring compliance with the requirements of this Quality Manual,
* ensuring that Quality Objectives are included in the overall company strategy, communicated and supported by all relevant functions/levels
* establishing a quality commitment that outlines the company's overall intentions and direction regarding quality
* demonstrating strong and visible support for the QMS,
* ensuring that customer requirements and applicable regulatory requirements are identified and met, and

as necessary, participating in the development and implementation of quality plans or corrective actions.

# Management Review

The continued suitability, adequacy and effectiveness of the QMS is ensured through periodic reviews of the Quality Plan(s), key performance indicators, and product quality.

Key persons and stakeholders of Management Review process are defined in
**SOP-04 CDE** **Management Review.**

Multiple functions may be held or represented by a single person.

Management Review meetings shall be conducted by the Quality Organization on at least an annual basis to assess the ongoing suitability and adequacy of the QMS and to identify risks and/or opportunities for continuous improvement.

The purpose of Management Review is:

* to demonstrate product compliance with regulations/standards and certificate of registration, certification and/or registration dossier,
* ensure that the products do not put patients at risk due to lack of safety, quality, or efficacy
* identify and evaluate trends and risks to promote continuous improvement of the QMS,
* ensure that quality systems are effective, appropriate, adequate, and efficient,
* address resources necessary to support the QMS,
* review audit, inspection, and monitoring activities,
* review the quality plan, including the Quality Objectives and quality commitment to ensure alignment and continued applicability to the company's strategy, and
* review follow-up actions from previous Management Review meetings.

Management Review shall be documented and shall include a conclusion on the adequacy of the QMS and a list of appropriate actions. The results of Management Review shall be used as input into the review and revision of quality plans.

# Resource Management

Resources are provided in order to effectively support the needs of the QMS, regulatory requirements, and to meet customer needs. Resource needs are addressed during Management Review and the quality planning cycle.

# Quality Objectives

Company CDE strives to supply clients with high quality, easy to use and reliable products. To achieve these outputs, Quality Objectives are established related to design, execution, manufacturing, distribution, monitoring and continuous improvement of quality in all functions.

# Quality Strategy and Planning

The Leadership Team develops:

* quality plans that outline the company's quality strategy as well as the Quality Objectives and quality commitment. Quality Plans are reviewed and updated periodically.
* Quality Objectives and priorities to ensure the implementation of the quality strategy. Changing business priorities and needs are reflected in periodic reviews of the quality plans.

The planning cycle is aligned with the budget cycle to ensure that the necessary resources are allocated to implement the plan(s). Targets are set based on various inputs, e.g., risk assessments, product evaluations, quality system assessments, audit and inspection findings, industry trends, changing regulatory environments and employee/cultural surveys.

The continued suitability, adequacy and effectiveness of the QMS is ensured through periodic reviews of the Quality Plan, key performance indicators and Annual Product Quality Review at various levels of the organization.

The purpose of QC and QM review process is:

* to demonstrate product compliance with regulations/standards and certificate of registration, certification and/or registration dossier.
* ensure that the products do not put patients and customers at risk due to lack of safety, quality or efficacy.
* identify and evaluate trends and risks to promote continuous improvement.
* ensure that QS is effective, appropriate, adequate and efficient.
* The quality monitoring and Management Review shall be documented and shall include:
* a conclusion on the adequacy of the quality system,
* the potential impact of the deficiencies on the product, and
* a list of appropriate actions.

Monitoring of key indicators should include as a minimum the results of:

* inspections and audits,
* analysis of Deviations, Complaints, Quality Defects, Recalls, withdrawals and falsifications,
* follow-up actions from previous Management Review.

Management Review shall be conducted by the quality system owners on an annual basis to assess the ongoing suitability and adequacy of the quality system and to identify risks and/or opportunities for continuous improvement.

The results of the Management Review shall be used as input into the review and revision of Quality Plan.

# Leadership Responsibilities

Senior Leadership is responsible for implementing an effective and appropriate quality system to improve the quality and availability of reliable products.

Quality leaders, together with their respective business partners (e.g., functional leaders), have the following responsibilities:

* ensure compliance with the requirements of this Quality Manual,
* ensure that Quality Objectives are defined in line with the overall company strategy, communicated and supported by all relevant functions/levels,
* establish a quality commitment that outlines the company's overall intentions and direction regarding quality,
* participate in the development, implementation, monitoring and maintenance of an effective QMS to ensure the achievement of Quality Objectives,
* demonstrate strong and visible support for the QMS, ensure its implementation in the organization and support continuous improvement,
* ensure that customer requirements and applicable regulatory requirements are identified and met,
* participate in the development of quality plans and ensure their implementation, maintenance and review,
* define the individual and collective roles, responsibilities, authorities and relationships of all organizational units related to the quality system,
* Ensure that these interactions are communicated and understood at all levels of the organization,
* establish and provide adequate and appropriate resources and infrastructure necessary to implement and maintain the QMS and to continuously improve its effectiveness,
* ensure a timely and effective communication and escalation process to raise quality issues to the appropriate levels of management,
* ensure that product and process knowledge is managed from development through the product's commercial life cycle to product discontinuation by applying a systematic approach to the collection, analysis, storage and dissemination of information related to products, production processes and components,
* carrying out process and Annual Product Quality Review assessments of process and quality effectiveness, and of the QMS, and
* participate in the appointment of key management personnel.

# Quality Management System

The purpose of a QMS is to comply with applicable regulatory requirements and customer expectations and to ensure that products and/or clinical trial materials are of the required quality for their intended use.

The QMS is a structured and documented approach that outlines Company CDE's expectations of GxP requirements and other relevant standards/recommendations to ensure the quality of GxP processes, products and services. It provides a systematic, risk-based approach to achieving the desired level of quality consistently and effectively.

Company CDE has a single QMS for all aspects of our GxP business that covers GxP processes across the entire product lifecycle, from the early stages of product creation and development, through manufacturing and market delivery, product launch or Recall, simplifying manufacturing and speed up delivering drug to the patients.

A QMS promotes innovation and continuous improvement and strengthens the link between development and production throughout the product life cycle.

Company CDE uses a QMS approach based on a system aiming to meet regulatory requirements related to specific GxP processes, including elements such as organization, management, standards, procedures, training, IT tools and respective metrics.

All quality subsections with the associated systems have a designated owner who is responsible for developing and maintaining an appropriate, purposeful, effective quality system. The owner ensures the effective and efficient implementation of regulatory requirements in applicable areas at Company CDE. Changes in regulations, enforcement trends and inspection results are monitored for their impact on quality systems, gaps are evaluated, and the owner determines the need for new or revised documentation.

Each owner is responsible, at a minimum, for:

* defining the quality strategy for the respective system and its implementation in cooperation with all affected functions,
* defining, developing and maintaining procedures for the implementation of the quality system strategy,
* defining, develop and maintain an appropriate level of harmonization within the systems., and
* monitoring performance and evidence of continuous improvement.

# Documentation of the QMS

The QMS and its requirements are outlined in the formal QMS documentation. The documentation system consists of four (4) levels of documentation, as described in [***Figure 1***](#_bookmark17) below.



***Figure 1: Company CDE documentation system***

## Tier One - Master Documents

The first tier documents like Master Documents define Company CDE's key principles based on the regulatory requirements for quality system. The quality system Owner is responsible for overseeing the content of the Quality Module.

First tier documents are no working documents. Other QMS documentation e.g., Standard Operating Procedures (SOP) describe how principles are applied to operations.

The Quality Manual is a Master Document and describes the QMS, its scope, the fundamental processes, procedures and the responsibilities of management. The Quality Manual may be shared on request, for example, with external stakeholders like Health authorities or inspectors.

The Quality Manual is defined by e.g., Quality Management Director, approved and signed by e.g., CEO, and reviewed during Management Review. The Quality Manual is revisited least every three (3) years to ensure alignment with the Company CDE's strategy.

## Tier Two – Policies

Policies are not working documents and describe the general policies which apply within the company.

## Tier Three – Operating Procedures (SOPs, Working Instructions)

Standard Operating Procedures (SOP) describe overarching general technical standards or Company CDE policies related to the QMS. Working Instructions (WI) describe how to conduct processes, methods, or activities. Their aim is to achieve a certain tier of standardization in an organization. Whenever a standardized process is described, the standards define the key steps of the process and the roles involved in performing the process, as well as their respective responsibilities. SOPs and WIs include templates for forms or other documentation required by legislation, such as protocols, master files or specifications.

## Tier Four – Records, Reports

Quality Tier four documents include filled quality records, reports are evidence, plans, forms, and checklists indicating that procedures and related instructions have been followed to achieve the expected results. These documents shall be managed by the relevant body in which the process is carried out.

## Applicability of QMS documentation

The Company CDE Master Documents and Policies applies to all GxP sectors and organizations.

The quality modules, SOPs and WIs apply to all relevant Departments depending on the processes and/or technologies applied in them.

Company CDE operations using specific technologies that require compliance with certain regulatory requirements will apply the Company CDE, Policies, SOPs and WIs on an individual assessment basis. Such specific regulatory requirements will be included in respective documents of Company CDE.

# Fundamental Quality Systems and Processes

## Quality Risk Management

The quality management and governance system cover the definition of the QMS strategy and its documentation, as well as the quality monitoring and planning processes and Quality Risk Management. The continued suitability, adequacy, and effectiveness of the QMS shall be monitored and evaluated through periodic Management Review.

A Quality Risk Management process is to be established to provide a proactive approach to identifying potential risks to the quality, safety and effectiveness of products and processes. As part of the assessment, the quality risk assessment considers the severity and impact of the event. Results of risk assessments are implemented, as necessary, in Quality Plan or CAPAs.

## Data and Records

A Company CDE Document Management System has been implemented that defines the creation, control, distribution, periodic review, storage, and destruction of GxP documents and records. This includes documents related to the execution (e.g., SOPs, WIs, protocols), recording (e.g., forms, worksheets), and evaluation (e.g., reports) of quality-related actions and decisions.

Records and data must be managed to ensure their accuracy, completeness, consistency, and security. Established standards applicable to printed or electronic records must be followed. Data must be attributable, legible, current, original, accurate, and complete, consistent, permanent, and accessible. Data integrity must be maintained throughout the product lifecycle. Record retention times must be defined and aligned with Regulatory.

## Events

A process is in place to ensure that all events (e.g., Deviations, Complaints, Quality Defects, OOS, OOT, OOE, incidents) that may adversely affect the identity, potency, quality, purity, product safety, or effectiveness of a commercial product or clinical trial material are documented, investigated, addressed, closed, and controlled appropriately in a timely manner.

Nonconforming Products and materials are closely monitored, tracked, and quarantined as necessary.

## Change Management

The Change Management process ensures that changes that may affect product quality, validation status, or regulatory compliance are properly managed. Changes must be evaluated for their impact on quality and reviewed, approved, implemented, and documented by appropriate personnel.

## Audits Management

A program for internal auditing and external service providers/contractors is to be implemented. This ensures ongoing compliance with Company CDE’s regulatory requirements and standards.

The regulatory inspection management process is to be established to coordinate and manage regulatory inspections, including the follow-up and closure of inspection results, and to ensure communication both internally and with the appropriate regulatory agency on any findings. It should also ensure proper communication within the organization on specific compliance issues.

## Escalation Event Management

The company has established process for the necessary escalation of product related events and includes:

* + - escalation of quality-related issues to the appropriate management levels
		- assessment of the need for market action related to such issues (returns, Recalls, product withdrawals), and
		- informing regulatory authorities of potential product quality and compliance issues, as required by applicable law.

Reporting to health authorities should be done in a timely manner. The system ensures that all regulatory obligations and corrective and preventive actions (CAPAs) are implemented and adhered to.

## Material Management

Procedures are in place to control the components used in the manufacture or development of products to receive, process, store, control, and release materials throughout the life cycle of a product. These controls ensure that the product is approved and released by the responsible person and documented.

## Supplier Management

A system has been introduced to control suppliers on materials and services (outsourced activities) related to GxP activities. These processes should include selection, evaluation, monitoring and control of third parties and third-party materials related to GxP processes and Quality Risk Management.

## Computerized Systems Management

A system is in place that outlines the requirements for validation of computerized systems and lifecycle management of computerized systems regulated by GxP to ensure patient safety, product quality, and the integrity of regulated data. Continuous Improvement of Process Efficiency, Product Quality and Quality Management System

Monitoring information at each stage of the lifecycle is used to continuously improve process efficiency, product quality and QMS performance. The results of regular Management Review meetings and monitoring of internal and external factors affecting the QMS are used to determine CAPA that improve the system and related processes, allocate or reallocate resources, and/or revise the quality plan and Quality Objectives. These reviews and results shall be documented and communicated to Leadership Team.

# Terms and Abbreviations and Definitions

|  |  |
| --- | --- |
| **Term/abbreviation** | **Definition** |
| ALCOA | Acronym which stands for Attributable, Legible, Contemporaneous, Original, Accurate principles of data integrity. |
| CAPA | Corrective and Preventive Action. |
| Complaint | Expression of dissatisfaction with a product or service, which is filed by a consumer, customer, client. |
| Correction | Any actions immediately taken to minimize product, process and/or patient impact upon nonconformity discovery or other undesirable situation. Correction relates to containment whereas Corrective Action relates to the Root Cause. |
| Corrective Action | Action to eliminate the cause of a detected nonconformity or other undesirable situation (complaints, product rejections, quality defects, recalls, deviations, audits and regulatory inspections findings, trends from process performance and product quality monitoring).Corrective Action is taken to prevent recurrence. |
| Customer | Person or organization that could or does receive a product or a service that is intended for or required by this person or organization.EXAMPLE Consumer, client, end-user, retailer, receiver of product or service from an internal process, beneficiary and purchaser. |
| CoA | Certificate of Analysis; Indicate all parameters, associated Specifications, and methods used to test for Product release. |
| Deviation | Non-fulfilment approved instruction, procedure or established standard. Any unexpected event or occurrence where an established process was not followed.Deviation can result in Nonconformances (Nonconforming Material, Nonconforming Product, Nonconforming Service). |
| Event | Deviations, OOS, Complaints, Nonconformances, CAPAs, or exceptions may adversely affect the identity, potency, quality, purity, Product safety, or effectiveness of a Product or Material. |
| GMP | Good Manufacturing Practices means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use. |
| GxP | Good x Practices (whereas x is a placeholder including, manufacturing, distribution, clinical, laboratory, or any other regulated environment applicable). |
| Leadership Team | The Leadership Team refers to the top management at Company CDE and includes all Chief Executives. It provides strategic and operational leadership to the company. It sets goals, develops strategy, and ensures the strategy is executed effectively. |
| e.g., Manufacturing Head | Head of Manufacturing/Producion (per 2003/94/EC, AMWHV §12(1); Ensures appropriate production of goods, training of employees, validation of equipment and processes and approval of production documentation. |
| MAH | Marketing Authorization Holder |
| Nonconformance | Non-fulfilment of a requirement related to material/product characteristics (specifications) or results of material/product/condition/value/process/system monitoring, measurement, inspection, review, test, audit.Nonconformities may arise as a result of previously occurring Deviations and may also lead to other Deviations and Nonconformances. |
| Nonconforming Material | Material that does not fulfill its specified requirements (damaged, non functional and/or does not meet the required specifications for its intended use).Material is declared nonconforming in cases of confirmed OOS, serious handling Deviations and Nonconformities. |
| Nonconforming Product | Product that does not fulfill its specified requirements.The Product is declared nonconforming in cases of confirmed Quality Defects, OOS, serious manufacturing process Deviations and product related Nonconformities. |
| OOE | Out-of-expectation; Atypical or abnormal result that meets specification but is not in line with historic testing. |
| OOT | Out-of-trend refers to a result over time that fails prediction intervals or statistical process controls (e.g., stability testing compared to other batches). |
| OOS | Out-of-Specification; Single point test result that fails the preset Specification acceptance criteria. |
| Preventive Action | Action to eliminate the cause of a potential non-conformity or other undesirable potential situation (complaints, product rejections, quality defects, recalls, deviations, audits and regulatory inspections findings, trends from process performance and product quality monitoring). Preventive Action is taken to prevent occurrence. |
| QA | Quality Assurance (assures adherence to outlined processes and compliance guidelines) |
| QC | Quality Control (responsible for analytical testing against a predefined specification) |
| e.g., QC Head | Head of Quality Control (per 2003/94/EC) responsible for acceptance or rejection of raw materials, bulk, intermediates and final product; creation of test protocols and procedures, acceptance of specifications, and all validations). |
| QMS | Quality Management System (outlines the individual systems in order to tackle the strategy outlined in this Quality Manual).It is a dynamic system providing a framework for planning, executing, monitoring and improving the performance of Quality Management activities. |
| Quality Management | Includes all Quality Processes from systems, production processes to labor and employee quality |
| QP | Qualified Person (Article 48 of Directive 2001/83/EC) The qualified person referred to in Article 48 shall in the case of medicinal products intended to be placed on the market in the Union, ensure that the safety features referred to in point (o) of Article 54 have been affixed on the packaging |
| Quality Defect | Product related Nonconformity. Faulty manufacture, product deterioration, detection of falsification, non-compliance with the marketing authorization or product specification file, or any other serious quality problems which may result in the Recall of the Product or an abnormal restriction in the supply.A Confirmed Quality Defect indicates that a Nonconforming Product was released or became nonconforming after release due to Deviations, factors/circumstances that occurred. |
| Quality Objectives | The quality objectives are the main method used by companies to focus the goal(s) from the Quality Commitment into plans for improvement. |
| Recall | The action of withdrawing specific batch/batches of Nonconforming Product (with confirmed Quality Defects) from the distribution chain for reasons related to Product quality, safety or efficacy, which could have adverse effects and compromise health of patients. |
| Root Cause | The underlying reason for or cause of one or more Deviations or event. When the Root Cause is removed or corrected, the Deviation will be eliminated. |
| SME | Subject Matter Expert. The person who possesses a deep understanding of a particular requested subject. Departments delegates, who assess for the potential impact in their domain of expertise, document the outcome and initiate appropriate actions. |

# Applicable documents

SOP-01 (CDE) Documentation Management

SOP-02 CDE Good Documentation Practice

SOP-03 CDE Quality Plan

SOP-04 CDE Management Review

SOP-05 CDE Change Management

SOP-06 CDE Deviation and Nonconformance Management

SOP-07 CDE CAPA Management

SOP-08 CDE Audits Management

SOP-09 CDE Quality Risk Management

SOP-10 CDE Training Management

SOP-11 CDE Annual Product Quality Review

SOP-12 CDE Complaints and Recalls Management

SOP-13 CDE Supplier Management

SOP-14 CDE Material Management

SOP-15 CDE Computerized Systems Management

SOP-16 CDE Archiving

# Appendices

Appendix Quality Commitment

Appendix Organigram

# Document revision history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Valid from** | **Description of the revision** | **Reason for the revision** |
| 1 | See header | Document created | QMS implementation |