



ISO 9001:2015 Quality Self-Assessment

including

Rx-360 Supplier Assessment Questionnaire Module 1, Company Information

Relevant for

Life Science business

The purpose of this document is informing our customer about the quality management system of our Life Science business of Merck KGaA, Darmstadt, Germany.

The table of content of this document is aligned to „Contents of ISO 9001:2015 Quality Management Systems“. The company profile is aligned to „RX 360 Supplier Assessment Questionnaire, Module 1“.

We trust that our quality measures meet our customer's and industry expectations and exceed general standards.

As a trusted partner of our customers, we deliver quality - always.



An International Pharmaceutical
Supply Chain Consortium

Merck KGaA, Darmstadt, Germany is an
active member of the Rx 360 Consortium.

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Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 / +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive Burlington,
MA 01803, USA
Phone +1 (781) 533-6000

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I Company Profile

Our purpose is to solve the toughest problems in life science by collaborating with the global scientific community and through that, we aim to accelerate access to better health for people everywhere.

Please find attached our company profile according to RX 360 Supplier Assessment Questionnaire Module 1, Version 2

SECTION 1. General Company Information--Rx 360	
1.1	<p>Company Name:</p> <p>Merck KGaA, Darmstadt, Germany has a Life Science business</p>
1.2	<p>Company Address:</p> <p>The legal entities that make up the Life Science business are listed below:</p> <ol style="list-style-type: none"> 1. Merck KGaA, Darmstadt, Germany Corporation with General Partners Frankfurter Str.250, 64293 Darmstadt, Germany 2. EMD Millipore Corporation A subsidiary of Merck KGaA, Darmstadt, Germany 400 Summit Drive, Burlington, MA 01803, USA 3. Sigma-Aldrich Corporation A subsidiary of Merck KGaA, Darmstadt, Germany 3050 Spruce Street St. Louis, MO 63103 U.S.A. <p>GPS Coordinates:</p> <ol style="list-style-type: none"> 1. Merck KGaA, Darmstadt, Germany: Coordinates (main entrance): Latitude 49.89510 Longitude 8.65384 2. EMD Millipore Corporation: Latitude: 44.9048126 Longitude:-73.2972118 3. Sigma-Aldrich Corporation, St. Lois USA: Latitude: 38.627156 Longitude: -90.223748
1.3	<p>Phone:</p> <ol style="list-style-type: none"> 1. Merck KGaA, Darmstadt, Germany Phone +49 6151 72-0 2. EMD Millipore Corporation Phone +1 (781) 533-6000 3. Sigma-Aldrich Corporation Phone +1 (800) 521-8956 +1 (314) 771-5765
1.4	<p>Respondent or General Quality Department Email:</p> <p>please refer to 1.5</p>
1.5	<p>Fax:</p> <p>please contact us via the local offices listed on Home>About Us>Worldwide offices</p>
1.6	<p>Website:</p> <p>https://www.merckgroup.com/en/company/who-we-are/life-science.html</p>

1.7	<p>Facility Establishment Identifier:</p> <ol style="list-style-type: none"> 1. Merck KGaA, Darmstadt, Germany: 3002806906 (pharma), 9610140 (medical device) 2. EMD Millipore, Burlington, USA : 3009432145 (medical device) 3. Sigma-Aldrich Corporation 3300 S Second St, Saint Louis, Missouri (MO), USA: 1937990 (medical device)
1.8	<p>DUNS Number:</p> <ol style="list-style-type: none"> 1. Merck KGaA, Darmstadt, Germany: 342249299 2. EMD Millipore Corporation, Burlington, USA: 00-105-0152 3. Sigma-Aldrich Corporation 3050 Spruce Street St. Louis, MO 63103, USA: 079928354
1.9	<p>If there is an individual contact for the following areas, please provide name and preferred contact information (at a minimum, name and telephone number or email):</p> <p>Quality: please refer to the description of the leadership team on the internet Home>About Us>Leadership Team</p> <p>Technical Services: please refer to the description of the leadership team on the internet Home>About Us>Leadership Team</p> <p>Commercial/Business/Sales: please refer to the description of the leadership team on the internet Home>About Us>Leadership Team</p> <p>Preferred Primary Contact: please contact us via the local offices listed on the internet Home>About Us>Worldwide offices</p> <p>merckmillipore.com or sigmaaldrich.com</p>
1.10	<p>Please list other subsidiaries operating under the company:</p> <p>subsidiaries are listed in our ISO 9001:2015 certificate, please request certificate from your local sales office</p>
1.11	<p>Is your company and affiliates willing to have Rx-360 conduct audits on behalf of your customers according to the RX 360 audit program?</p> <p>yes, please refer to the internet: rx-360.org>audit-programs</p>
1.12	<p>If Rx-360 has performed audits at your sites, please state site and date of the audit:</p> <p>Audit reports are available for the sites listed below: Merck Darmstadt, Germany Merck SLU, Barcelona, Spain Merck Altdorf, Switzerland SAFC Irvine, UK SAFC St. Louis, USA, SAFC Sinking spring, USA SAFC Lenexa, USA Sigma Aldrich, Inc. Buchs, Switzerland Sigma Aldrich, Inc. St. Louis, USA Millipore Sigma Sheboygan Falls, Millipore Sigma, Milwaukee, USA</p> <p>Audit dates can be retrieved from https://rx-360.org/licensable-audit-reports/, enter "Merck" or "SAFC" and "Sigma" in the filter field</p>
1.13	<p>Please list the general product groups manufactured by the company:</p> <p>Our 300,000 products range from lab water systems to gene editing tools, antibodies, cell lines and end-to-end systems and raw materials to manufacture drugs.</p>

	On addition we offer chemicals for research, diagnostic use for analytics and chromatography purposes, customized solutions and services and much more. Please refer to the website as indicated in 1.6 of this questionnaire.
Additional comments:	

SECTION 2. General Company Operating Information-- Rx 360	
2.1	<p>What year was the company established?</p> <p>In 2015, Merck KGaA, Darmstadt, Germany acquired Sigma-Aldrich Corporation. Sigma-Aldrich Corporation combined with Merck Millipore create the Life Science business of Merck KGaA, Darmstadt, Germany.</p>
2.2	<p>Is the legal ownership structure of the company public or private? If other, please elaborate.</p> <p>Life Science is a business of Merck KGaA, Darmstadt, Germany. Merck KGaA is German business entity with General partners, partly public and partly private.</p>
2.3	<p>If public, what is the company's stock symbol and on which exchanges is it listed?</p> <p>Ticker symbol: MRK;</p> <p>Official trading: Xetra, Frankfurt (Germany); OTC (Germany): Regional stock exchanges</p> <p>Additional info: The Merck KGaA established a Sponsored Level I American Depositary Receipt (ADR) program on 26 July 2017, which trades over-the-counter (OTC) in the United States (Ticker: MKKGY)</p>
2.4	<p>How many manufacturing sites does the company have?</p> <p>60 manufacturing sites worldwide</p>
2.5	<p>Does the company have a corporate Quality Assurance Division?</p> <p>yes</p>
2.6	<p>Does the company have any of the following written policies at the corporate level? If so, please provide policy number and title</p> <p>Written site-specific policies can be reviewed within an audit</p>
2.6a	<p>Environmental?</p> <p>EHS Group Policy (20050155)</p>
2.6b	<p>Quality Assurance?</p> <p>Quality Mission Statement for Life Science (00005042POL)</p>
2.6c	<p>Health and Safety?</p> <p>EHS Group Policy (20050155)</p>
2.6d	<p>Global Citizenship/Corporate Responsibility?</p> <p>Please download corporate responsibility reports from https://www.merckgroup.com/en/company/responsibility.html</p>
Additional comments:	

Our Life Science business brings together the legacy expertise of Merck's life science portfolio and Sigma-Aldrich, which was acquired by Merck KGaA, Darmstadt, Germany in 2015.

Link to publications: <http://www.merckgroup.com/en/company/publications/publications.html>

The purpose of this document is to describe processes, maintenance and improvement of the quality system, which is based on ISO 9001:2015 (Title: "Quality Management Systems –Requirements").

Please refer to our Regulations and Guidelines page on the internet which includes the ISO 9001 and other ISO certificates:

II Responsible Personnel from our Life Science Leadership Team

Please refer to section 1.9 of the RX 360 company profile

III Terms and Definitions

The terms and definitions given in ISO 9000:2015 apply to this document.

The relationship between the different phases of the PDCA (Plan, Do, Check, Act) cycle and the chapters of this document is shown in the following table:

Step	Chapter
Plan	4 Purpose and context of the organization 5 Leadership 6 Planning 7 Support
Do	8 Operation
Check	9 Performance Evaluation
Act	10 Improvement

IV. Purpose and Context of the organization

IV.1. Understanding the organization and its context

	Yes	No
1. Is the quality management system based on the "Plan – Do – Check – Act" (PDCA) cycle?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is there an understanding of the context of the organization via defining, monitoring and reviewing the key factors, which influence the organizations' purpose and objectives?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. The context of organization is not determined once, but is monitored, reviewed and updated as necessary on a regular basis, for example during management reviews with regard to?		
a. Strategic direction of the organization	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Purpose of the organization	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Intended result of the QMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Scope of the QMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. Definition of Risks and Opportunities	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. Definition of Quality Policies/ Objective	<input checked="" type="checkbox"/>	<input type="checkbox"/>

IV.2. Needs and expectations of interested parties

	Yes	No
1. Is there a definition and listing of interested parties to recognize and understand?		
a. Who these parties are	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. What their needs and expectations are	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Which of them are relevant and pose a significant risk to the organization	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Which actions are needed to mitigate these risks?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is the information about interested parties monitored in different ways for example in?		
a. Annual reports	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Strategic consideration	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Customer and employee surveys	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Supplier feedback	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. Customer and internal audits	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. Management reviews	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Is it intended to keep a good relationship with the neighbourhood?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Is the process for determination of the context of the organization and the interested parties captured in the Quality manual?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

IV.3. Scope of the QMS

	Yes	No
1. Does the QMS include the following?		
a. Quality Policy and Quality Objectives	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Quality Manual	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Documented Procedures and Records	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Documents/ Records necessary to ensure the effective planning, operation and control of processes	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Does the Quality Manual include the following?		
a. Establish the scope of the QMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. A description of the interaction between the processes of the QMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Definition of Risk management and derived actions of the QMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. A description of tools to maintain organizational knowledge	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Is the Quality Manual available to customers upon request during a customer audit?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Are global QMS requirements shared and aligned with local and regional QMS requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

IV.4. Management of Business processes

	Yes	No
1. Does the organization define and differentiate between the following processes?		
a. Added value	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Management processes	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Support processes	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. locally managed processes	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. globally managed processes	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Does the process description cover the following topics?		

a.	The business process descriptions are kept up to date	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b.	The required resources for these processes are determined and are available	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c.	The processes are evaluated and any necessary changes are implemented to ensure that these processes achieve their intended results and that the QMS is improved	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d.	The risks and opportunities associated with these processes are determined and addressed in an appropriate way	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e.	The responsibilities and authorities within these processes are determined and addressed in an appropriate way	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f.	Key Performance Indicators (KPIs) are defined and monitored by the departments for which they are relevant. They are reviewed regularly. By monitoring and reviewing KPIs it is ensured that processes deliver their intended outputs, or, if not, that the processes can be improved as necessary	<input checked="" type="checkbox"/>	<input type="checkbox"/>

V Leadership

V.1. General

	Yes	No
1. Does top management establish and support leadership principles in form of values for unity of purpose and direction of the organization at all levels?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is a quality and regulatory culture maintained based on these values?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Does top management provide evidence of its commitment to the development and implementation of the QMS and continually improve its effectiveness?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Is top management accountable for the quality and regulatory compliance of the products and ensures that effective quality and regulatory systems are in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Has top management appointed members of the management organization, who shall ensure that Quality and continual improvement is considered as a strategic pillar of the organization by:		
a. Establishing a global quality management system based on ISO 9001 and other applicable quality and regulatory requirements,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Formulating a set of documents that include this commitment,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Setting the framework to establish quality objectives in line with the global group objectives,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Principles, charters and the Quality Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. Establishing the purpose and context of related organizations and supporting their strategic direction, and	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. Creating and maintaining a work environment in which our employees become fully involved in achieving the objectives.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Does top management ensure that the QMS achieves its intended results (e.g. by regular reviews, evaluation and communication of results, customer surveys etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Are regular management reviews conducted?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Does top management communicate the importance of effective quality management and of conforming to the QMS requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

V.2. Customer Satisfaction

	Yes	No
1. Does top management ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Does top management ensure that this customer focus is promoted throughout the whole organization, e.g. during employee meetings or by publications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Does top management communicate the importance of meeting customer as well as statutory and regulatory requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Are objectives and KPIs established to focus on enhancement of customer satisfaction?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

V.3 Quality Mission Statement

	Yes	No
1. Does the Quality Mission statement set the framework for the quality objectives and form the basis for all employees' daily work?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is the Quality Mission Statement reviewed at least annually as part of management review for adequacy and continued suitability?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Is the Quality Mission Statement made known to all employees through induction, ongoing training, and postings displayed in appropriate locations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VI Planning

	Yes	No
1. Is there a formal risk management program?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are risk and opportunities identified to investigate all relevant aspects which may affect the achievement of quality objectives?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are actions defined to mitigate the risk and pursue the opportunities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Are data resulting from actions evaluated to check for the effectiveness of those actions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Does top management ensure that quality objectives, including those needed to meet requirements for products, are established at relevant functions and levels within the organization?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Are personnel made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Does change management ensure that the integrity of the QMS is maintained, when changes are planned and implemented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VII Support

VII.1-VII.4 Resources, Competence, Awareness, Communication

	Yes	No
1. Are well-trained, engaged and motivated personnel considered as a decisive asset for the success of the company?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are there written job descriptions for all critical positions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Is training provided or are other actions taken to achieve the necessary competence of employees in their positions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Are appropriate records of education, training, skills and experience maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Do employees undergo periodic performance reviews?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Does management ensure that appropriate infrastructure (buildings, workspace, utilities, and process equipment, supporting services) is available to achieve product conformity?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Are all relevant aspects from EHS requirements considered to provide adequate protection level to all employees as needed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Are there facilities for eating, smoking, restrooms, and lockers separate from production?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. Is measuring and monitoring of equipment either verified or calibrated by internal personnel or by qualified sub-contractors as applicable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10. Are calibration records maintained during the life of the equipment and archived per record retention policies?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
11. Does the organization maintain a variety of tools to convert individual knowledge of employees into organizational knowledge and to make this knowledge available within the organization to the extent necessary?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VII.5 Documented Information

	Yes	No
1. Are documents required by the QMS controlled?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is a document hierarchy defined which is aligned to the levels of the organization?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are minimum requirements for documents defined?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Is an electronic document control system utilized?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is the document system centralized (by site)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Are knowledge management systems established to maintain internal knowledge?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Are documented procedures established to define the controls for the following?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
a. Approval of documents for adequacy prior to issue	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Review and update of documents as necessary with re-approval	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Ensuring changes and current revision status of documents are identified	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Ensuring that relevant versions of applicable documents are available at points of use	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. Ensuring that documents remain legible and readily identifiable	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. Ensuring that documents of external origin are identified, and distribution is controlled	<input checked="" type="checkbox"/>	<input type="checkbox"/>
g. Preventing unintended use of obsolete documents with appropriate identification if they are retained for any purpose	<input checked="" type="checkbox"/>	<input type="checkbox"/>

8. Are documents managed through the following stages of quality document lifecycle as applicable?		
a. Evaluation of Need	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Document Creation	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Document Revision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Document Review and Approval	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. Implementation and Training	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. Control and Distribution	<input checked="" type="checkbox"/>	<input type="checkbox"/>
g. Periodic Review	<input checked="" type="checkbox"/>	<input type="checkbox"/>
h. Obsoleting	<input checked="" type="checkbox"/>	<input type="checkbox"/>
i. Retention, Archiving and Destruction	<input checked="" type="checkbox"/>	<input type="checkbox"/>
j. Monitoring	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. Are records established and controlled to provide evidence of conformity to requirements and of effective operation of the QMS?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10. Is there a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention, and disposition of records?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
11. Are procedures in place for making changes to specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
12. Are there written specifications for incoming raw materials and finished products?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13. Are batch records used to document critical production processes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14. Are production related records retained for a defined period of time?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
15. Are product dependent records retained as described in procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
16. Does use of the lot number provide traceability back to the receipt of incoming raw materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VIII Operation

VIII.1 Operational planning and control

	Yes	No
1. Does the organization plan and develop processes needed for product realization?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. In planning product realization, is the following determined, as appropriate?		
a. Quality objectives and requirements for the processes,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. the need to establish processes and documents,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. the need to provide appropriate resources and facilities to ensure that product realization meets all requirements	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. required verification, validation ¹⁾ monitoring, measurement, inspection and testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. activities specific to the product and the requirements for product acceptance (e.g. product specification)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. aspects of activities related to product realization which influence (directly or indirectly) environment,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
g. occupational health & safety hazards and risks related to the activities, regulatory requirements which have to be met for specific products and activities,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
h. establishing operational and process controls and performance criteria where necessary,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
i. records needed to provide evidence of conformity of the processes and resulting products and service	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are appropriately documented records maintained in all phases of product realization as needed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VIII.2 Determination of requirements for products and services

	Yes	No
1. Are product and / or service specifications provided via e-commerce platforms or electronic catalogues to enable customers to review before placing an order?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are the following requirements determined?		
a. Customer specified requirements, including delivery and post-delivery,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Requirements not customer specified but necessary for use, where known,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Statutory and regulatory requirements applicable for the product,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Additional requirements considered necessary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Is there a determined and implemented effective arrangement for communication with customers in relation to the following?		
a. Product information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Enquiries, contracts or order handling, including amendments	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Customer feedback, including customer complaints	<input checked="" type="checkbox"/>	<input type="checkbox"/>

4. If product requirements change, are relevant documents amended and relevant personnel notified of changes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is there a review of the requirements related to the product (if applicable)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Does the company provide adequate product information for internet sales where a formal product review is not applicable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VIII-3 Design and development of products and services

	Yes	No
1. Is the design and development of products (product development process) controlled and does this process include the following main aspects?		
a. Commercialization	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Roll outs	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Meeting safety and regulatory standards	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Does the expected level of control for the design and development process depend on the nature of the product?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are controls to each design and development process or project implemented to ensure that the results to be achieved?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Are verification, validation ¹⁾ and review processes defined for design and development reviews if applicable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is verification performed to assure that the design and development outputs meet the input requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Is an organization unit established which provide the following services for customers like		
a. Answering quality and regulatory related product requests,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Establishing change notification commitments and negotiation of quality agreements,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Providing standardized documents, certificates and dossiers depending on product quality	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Is complaint, CAPA and internal change management based on a valid process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Are Customers notified about product specific changes based on product quality levels?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. Is there a definition of notifiable product changes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VIII-4 Control of products and services

	Yes	No
1. Does the organization ensure that outsourced processes remain within the control of the QMS?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is a supplier qualification program in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are controls of external supplier implemented which include records based on defined requirement?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Are there established and implemented inspections or other activities necessary for ensuring that purchased product meets specified purchase requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VIII-5 Production and service provision

	Yes	No
1. Are production and service provisions planned and carried out under controlled conditions, including the following?		
a. The availability of documented information that describes the characteristics of the product / service to be provided,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. The availability of work instructions as necessary,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. The results to be achieved,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. The use of suitable infrastructure,	<input checked="" type="checkbox"/>	<input type="checkbox"/>

e. The availability and use of monitoring and measuring equipment,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. The definition of monitoring and measuring activities to verify that criteria for control of processes and/ or acceptance criteria for products and services have been met,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
g. The definition of training requirements for employees,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
h. If needed (either by customer or regulatory requirements or because the resulting output cannot be verified by subsequent activities) , validation ¹⁾ and periodic revalidation of processes,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
i. The implementation of required actions to prevent human error	<input checked="" type="checkbox"/>	<input type="checkbox"/>
j. The implementation of product release, delivery, and post-delivery activities.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are documents describing specific instructions or procedures, specific use of equipment, monitoring and measuring devices and delivery and post-delivery made available to all users?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence deficiencies become apparent only after the product is in use or the service has been delivered?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Is the status of a product always identifiable during production, filling and distribution?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is the unique identification of the product controlled, where traceability is a requirement?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Are documents confirming the conformance of products to requirements made available to customers as appropriate?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Does the organization identify, verify, protect and safeguard customer property provided for use or incorporation into the product?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Are changes reviewed for an effect on product quality and performance, and further determine whether or not the changes affect customer requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. Are any changes in production or service provision reviewed, verified and validated, as appropriate, and approved before implementation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VIII.6 Release of products and services

	Yes	No
1. Are release processes defined to verify that requirements have been met as appropriate for		
a. Raw materials,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Intermediate products,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Final products	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are there processes that ensure only tested and released material is used for production, filling and distribution?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are products not released unless evidence of conformity to established criteria is verified?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Is the appropriate monitoring and measuring determined and is the monitoring and measuring equipment necessary to provide evidence of conformity determined?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is the release of customer documents and services based on the principles described on chapter documented information?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

VIII.7 Control of non-conforming outputs

	Yes	No
1. Does the organization ensure that process outputs, products, or services that do not conform to requirements are identified and controlled to prevent unintended use, delivery or impact on environment, health or safety?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. If a nonconformity is observed are the following actions taken and documented?		
a. Investigation, root cause analysis	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Corrective and preventive actions	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. Effectiveness check	<input checked="" type="checkbox"/>	<input type="checkbox"/>

IX Performance Evaluation

IX.1 Monitoring, measurement, analysis and evaluation

	Yes	No
1. Has each responsible manager to determine for their area of responsibility?		
a. what needs to be monitored and measured (KPIs),	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results (e.g. process controls, audits, analysis of complaint data, statistical analyses, balanced scorecards)	<input checked="" type="checkbox"/>	<input type="checkbox"/>

c. when and how often the monitoring and measuring will be performed and when the results from monitoring and measurement will be analysed and evaluated	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are quality complaints formally documented and investigated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Is the information relating to customer perception as to whether the organization has met customer requirements monitored?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Is customer satisfaction data obtained from many sources, such as:		
a. customer surveys, complaints, and suggestions for improvements,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. customer audits,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. customer contacts with our customer-facing departments	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. customer feedback obtained during sales and marketing visits and trade shows	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is the stability and effectiveness of the QMS ensured by:		
a. regular analyses of KPIs	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. regular reviews of quality objectives, the context of the organization, the needs and expectations of relevant interested parties, audit results, corrective actions and of the Quality Mission Statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>

IX.2 Internal audit

	Yes	No
1. Are internal audits planned on an annual basis based on complexity and criticality?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Does the internal audit program take into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits, customer feedback, previous management reviews and nonconformities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are records of the audits and their results maintained and corrective and preventive actions resulting from audits implemented in a timely manner?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

IX.3 Management review

	Yes	No
1. Are management reviews planned on at an annual basis and are the results reviewed by the upper management?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are records of the management review maintained and does the inputs include the following aspects?		
a. status of actions from previous management reviews	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. changes relevant to the QMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. data on the performance and effectiveness of the QMS, including trends	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. resources required for maintaining the quality management system	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. review of how well the QMS is addressing risks and opportunities	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. any opportunities for improvement	<input checked="" type="checkbox"/>	<input type="checkbox"/>

X Improvement

X.1 General

	Yes	No
1. Are improvement initiatives part of objectives?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are there different starting points for improvements like		
a. investigations of nonconformities which lead to corrective actions	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. opportunities for improvement observed at any level, either "spontaneously" or within the daily work or based on the review of KPIs, processes, documents etc	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. opportunities for improvement observed during management reviews	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. consideration of risks at any level can also show the need for risk mitigation	<input checked="" type="checkbox"/>	<input type="checkbox"/>

X.2 Non-conformity and corrective action

	Yes	No
1. Are corrective and preventive actions defined based on the root cause investigation of non-conformities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is it ensured that product or a service which does not conform to product requirements be identified and controlled to prevent its unintended use or delivery?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Is there a documented procedure established to define the controls and related responsibilities and authorities for dealing with nonconforming product and service?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

4.	Is a non-conforming product subject to reverification to demonstrate conformity to the requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.	Are suitable actions defined to eliminate the cause of non-conformities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.	Are these actions monitored in appropriate system and is the result of the effectiveness check documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

X.3 Continual improvement

	Yes	No
1.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

XI Survey contact information

For more information please contact your local sales representative.

Approved by:

Title: Head of Life Science Quality Management Systems & Audits

Audits Date: July 2020

This document has been produced electronically and is valid without signature.

[Note 1]: Definition of validation according to ISO 9000:2015, 3.8.13]