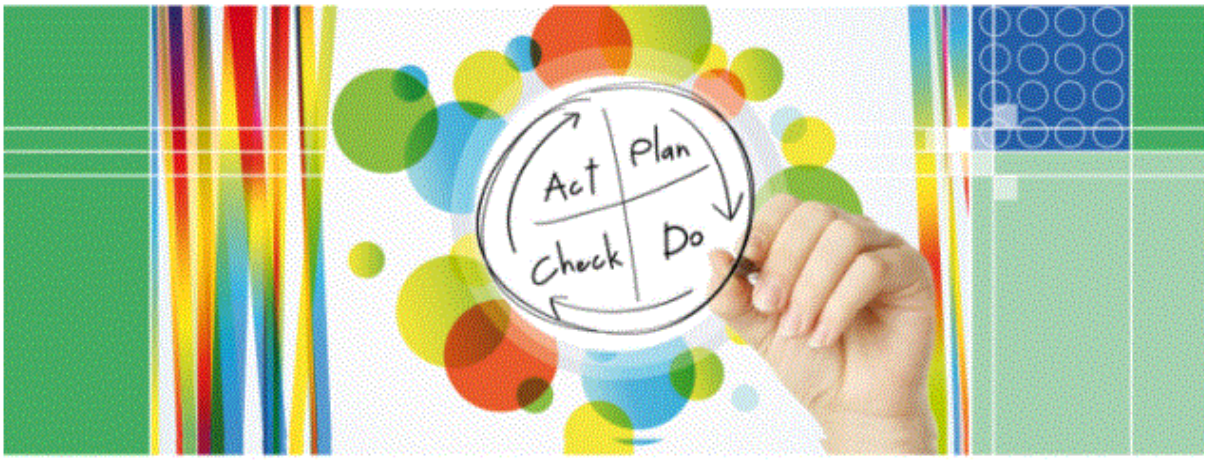
Quality and Environmental Manual



QUALITY & ENVIRONMENTAL MANUAL
Northern European and French Global Commercial Operations

US Headquarters campus in Hercules California

Contents:

1. Bio-Rad – Company information

1.1 Company overview
1.2 Company's Core Values and Global Quality Policy
1.3 Context of the Organization
1.4 Stakeholders
1.5 Roles and Responsibilities

2. Business Operating System

2.1 How the system operates
2.2 Management responsibilities

3. European Business Operational Processes

3.1 Market Access
3.2 Sales and Customer Service
3.3 Distribution
3.4 Customer Feedback Management

4. European Business Support Processes

4.1 Human Resources
4.2 Projects and Change Management
4.3 Infrastructure, Work Environment and Equipment Monitoring
4.4 Documentation Management*
4.5 Regulatory Monitoring*

5. Performance Evaluation and Improvement

5.1 Performance Evaluation
5.2 Improvement

6. Country

6.1 Local Environmental Policy (if applicable)
6.2 Country specific activities and processes
6.3 Key procedures: Links to Standards

7. Glossary

Quality and Environmental Manual

This Quality and Environmental Manual integrates the main requirements of the standards ISO, 9001:2015, 13485:2016, 14001:2015 (14001 where applicable) and 98/79/CE Directive on In Vitro Diagnostic Medical Devices. The chapters of the standards and/or directive, as well as some FDA requirements, are referenced as follows:

✏**Leadership, Management responsibility (ISO 9001:2015 and ISO 13485:2016 chap. 5)**
✏**Vigilance procedure (98/79/CE Directive article 11)**
✏ **Leadership (ISO 14001:2015 chap. 5)**

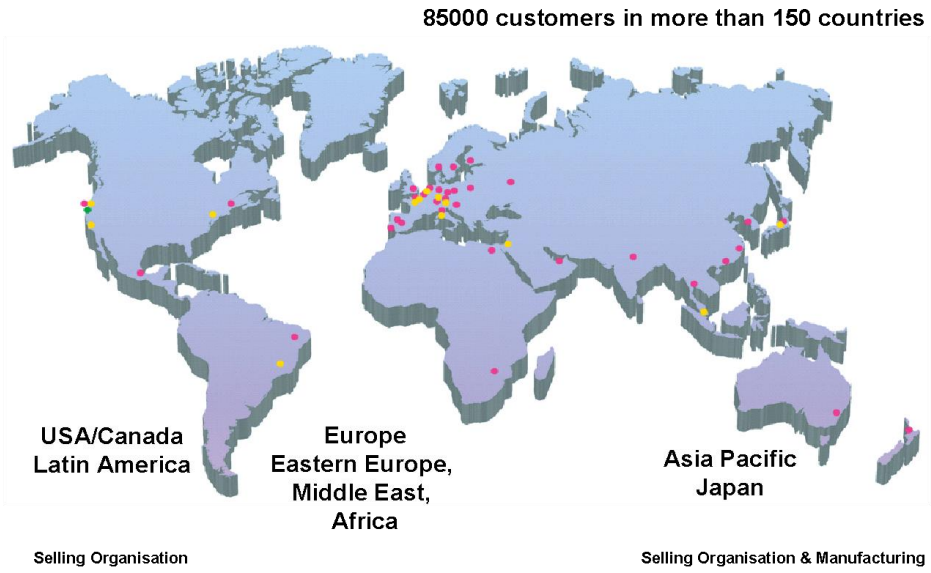
More detailed arrangements for complying with standards and other relevant regulations are described in SOPs; their links between the chapters of the standard are detailed in the chapter 6.2.

This Quality and Environmental Manual is used as a training support and communication tool to maintain European Global Commercial Operations (GCO) and Distribution employees awareness of the Bio-Rad's operating system and quality requirements, as defined in standards and regulations. It is controlled within the electronic documentation management system (Ennov).

**Documentation Management and Regulatory Monitoring are not considered as processes, on their own; nevertheless, these activities are essential for a strong and efficient Quality Management System.*

1. Bio-Rad – Company information

1.1 Company Overview



- Involved in Life Sciences since its creation in 1952
- Located in Hercules, close to San Francisco (California)
- Worldwide sales network in America, in Europe, in Asia
- 8 000 products sold in more than 150 countries
- Production sites in the US (California, Washington), in Europe (France, Germany, Switzerland, UK, Belgium), in Asia (Singapore)
- Over 8250 employees working worldwide for our customers:
  Research Laboratories,
  Food Industries,
  Pharmaceutical and cosmetics Industries,
  Veterinary Laboratories,
  Public and private Medical Laboratories,
  Blood banks
  NGOs
- Sales exceeding $ 2 billion in 2016
- Traded on the New York Stock Exchange

1.2 Company's Core Values and Global Quality Policy

✏ Policy, Quality Policy (ISO 9001: 2015 chapter 5.2 / ISO 13485:2016 chap. 5.3)
✏ Policy (ISO 14001:2015 chap. 5.2)

Our mission

To provide useful and high-quality products and services that advance scientific discovery and improve healthcare.

Principles and Core Values

Innovation, Involvement, Independence and Integrity

Global Quality Policy

Bio-Rad Laboratories is a company with a global network of operations that support the complete lifecycle of innovative products and solutions for the life science research and clinical diagnostic markets.

Bio-Rad is committed to:

- Developing, manufacturing and supplying high-quality products and services that advance scientific discovery and improve global healthcare.
- Fostering long-lasting customer relationships based on understanding and meeting their requirements, responding to their feedback and providing exceptional support.
- Conducting business ethically while complying with applicable industry statutory and regulatory requirements.
- Implementing risk-based process approaches that sustain effective global business operations with internal and external partners.
- Dedicating adequate resources including competent employees, infrastructure and work environments needed to meet our organization's objectives.
- Monitoring, continually improving and maintaining effectiveness of the Quality Management System.

This Quality Policy is integral to our success as a strategic market leader and partner to our customers. We achieve this policy through application of Bio-Rad's Guiding Principles and Core Values: Innovation, Involvement, Independence and Integrity.

(Extracted from. 01.01.GLB.POL.00010 in Bio-Rad Global Document Center)

Environmental policy

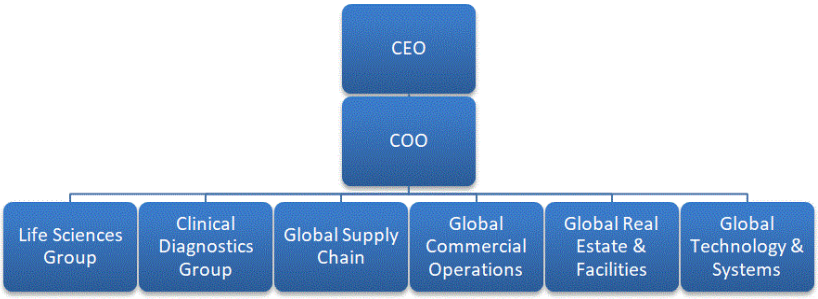
Bio-Rad is sensitive to the impact of its business activities on the environment. Many actions have been implemented to reduce this impact and some countries are already certified according to the ISO 14001 standard (see local environmental policy in chapter 6.1 of this Manual, where applicable).

1.3 Context of the Organization

✏ **Context of the organization, QMS (ISO 9001:2015 /ISO 13485:2016 chap. 4)**

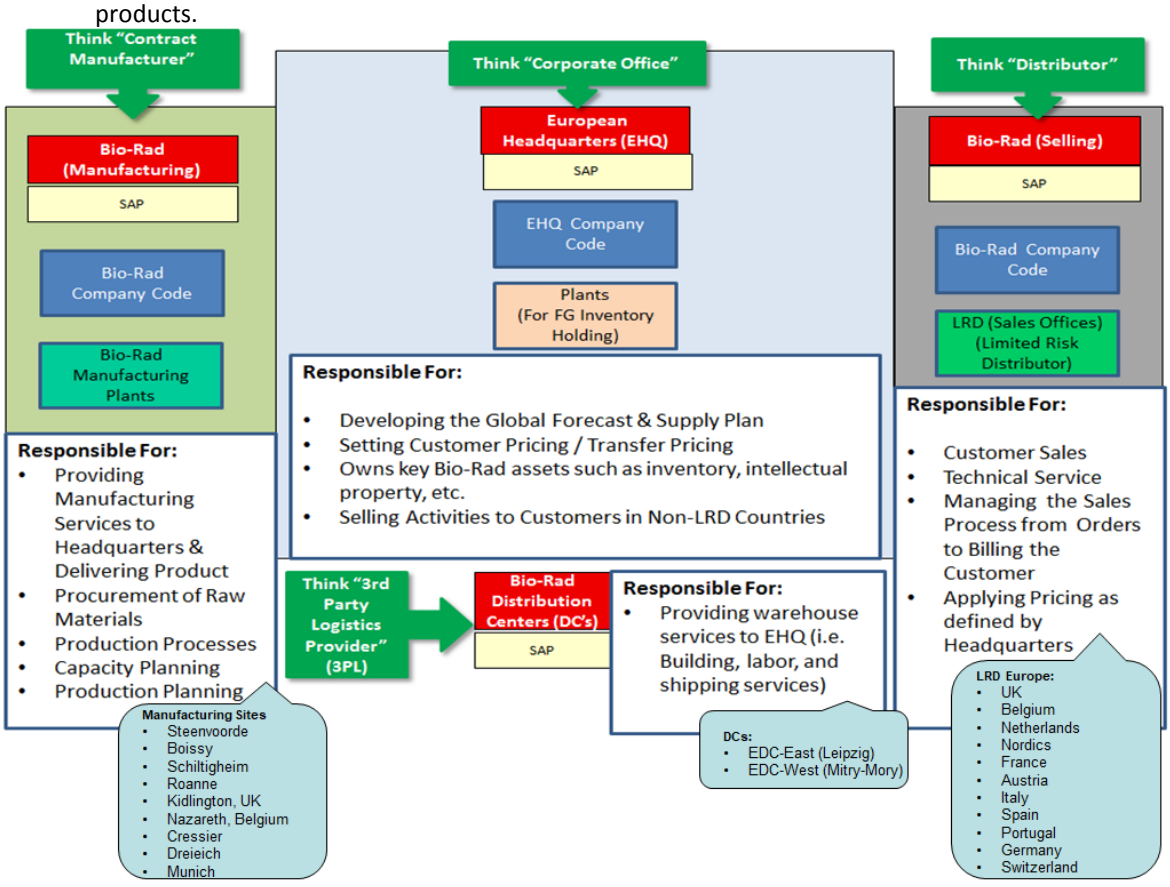
✏ **Context of the organization (ISO 14001:2015 chap. 4)**

Bio-Rad has developed a global organization, covering operating functions on a global basis, namely the Clinical Diagnostics Group (CDG), the Life Science Group (LSG), the Global Commercial Operations (GCO), the Global Supply Chain (GSC), the Global Real Estate and Facilities, and the Global Technology and Systems.



The European Headquarter (EHQ), based in Basel, covers European activities and ensures the deployment of Bio-Rad Global strategy and Quality Policy in the region.
It provides centralized, aligned, strategic decision-making for the region. Specifically, the EHQ:

- Develops the forecast and supply plan
- Contracts with EMEA manufacturing entities to meet the demand plan,
- Manages our DCs and logistics operations to hold and move inventory,
- Contracts with Bio-Rad selling subsidiaries and third party distributors to sell EMEA manufactured products.



To optimize customer service, Bio-Rad's Global Commercial Operations are organized into selling regions, managing sales and sales support, marketing and after-sales activities, for all manufacturing group of products, in a given geographical area.

The Global Supply Chain has a strong presence within Europe with:
-Manufacturing sites in France (Steenvoorde, Roanne, Schiltigheim, Boissy l'Aillerie), Germany (Munich, Dreieich), Belgium (Nazareth) and Switzerland (Cressier).
-European Distribution Centers: 2 main Centers of Excellence, EDC West in Mitry-Mory, France, and EDC East in Leipzig, Germany.

This manual supports the selling and distribution activities of the European Commercial Operations and the Global Supply Chain, covered by external certifications.

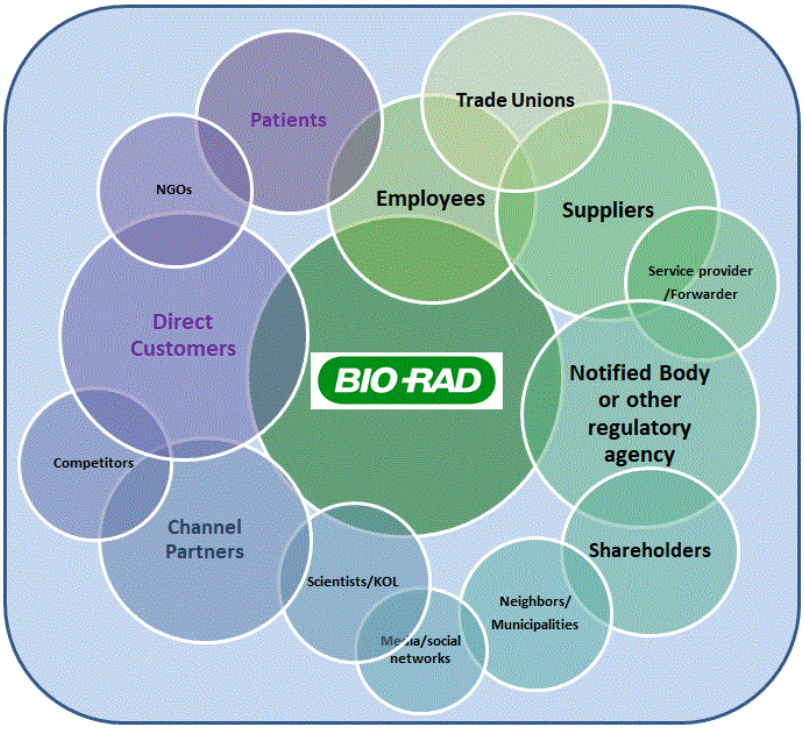
1.4 Stakeholders

✏ **Understanding needs and expectations of interested parties, General requirements (ISO 9001:2015 chap.4.2 /ISO 13485:2016 chap. 4.1)**

✏ **Understanding needs and expectations of interested parties (ISO 14001:2015 chapter 4.2)**

Bio-Rad is carrying out its activities taking into consideration its environment and the multiple stakeholders interacting with its organization. Each stakeholder expresses some expectations, requirements, and communicates with the organization in a defined purpose. Impacts, whether being positive or risky, are strictly measured. Bio-Rad's quality management system investigates these interactions and maps them with the objective of identifying risks and opportunities.

Below is the established mapping. In depth analysis is carried in each region, according to the structure and dedicated activities.



1.5 Roles and Responsibilities

✏ **Leadership and Planning; Planning, Management Responsibility, authority and communication (ISO 9001: 2015 chapter 5 and 6 / ISO 13485:2016 chapter 5.4 & 5.5)**

Top Management shall demonstrate leadership and commitment with respect to the Quality Management System. It should provide evidences of its commitment to the development and implementation of the QMS and maintaining its effectiveness.

✏ **Leadership and Planning (ISO 14001:2015 chapter 5 and 6)**

1.5.1 General responsibilities

Global Management Team

The Global Management Team is responsible for:

- Validating and communicating policy throughout the organization and
- Defining and reviewing the Global Strategic Plan on a regular basis in line with a global company strategy.

European strategy is aligned with the Global Strategic Plan. This Strategic Plan is focused on achieving Financial Objectives; the improvement of Sales and Marketing effectiveness; Customer Care focus; the improvement of Operations and Support Effectiveness and the development of Governance and Controls.

The Senior Management Team is responsible for ensuring that the necessary resources are assigned to allow this strategy to achieve its objectives.

Regional Function and Commercial Managers

Regional Function and Commercial (Sales) managers review the effectiveness of the processes that they are responsible for and actively participate in the regional Quality Management Review process. They jointly define the regional quality plan by setting priorities and assigning appropriate resources, which enables business objectives to be met according to Global Commercial strategy and Quality and Environmental objectives. They are responsible for establishing and documenting Best Practices and for ensuring that staff has required skills and expertise for their job.

Senior managers in each country ensure that the principles described above are applied at country level.

RAQA Team

Regional RAQA organizes Quality Management Reviews and assures its efficiency by preparing any necessary input; arranging cross functional participation and supporting the management team in their continuous improvement activities.
They define and roll out the internal audit program and manage the documentation system and CAPA processes. They ensure that field safety notices and regulatory communications are managed according to the manufacturing instructions.
They are responsible for recognizing and escalating significant regulatory and quality risks and issues to an appropriate level of management.
Local RAQA Managers will act as Management Representatives for their respective countries/regions.

All Staff

Employees must confirm that they have read, understood and accepted Bio-Rad Management Guidelines and Business Ethics and Conduct policy.
These Bio-Rad policies and guidelines must be applied as part of the daily work to ensure compliance across the world. They are part of the strategy reinforcing governance and controls.
Employees are expected to follow Best Practices as defined in company procedures and attend training as required. They are expected to report discrepancies between defined and actual working practices and for suggesting improvements.
Although voluntary, employees will be encouraged and supported to be involved with the internal audit program and participate in other continuous improvement activities.

1.5.2 Local responsibilities

Refer to section 6 for specific local functional responsibilities

2. Business Operating System

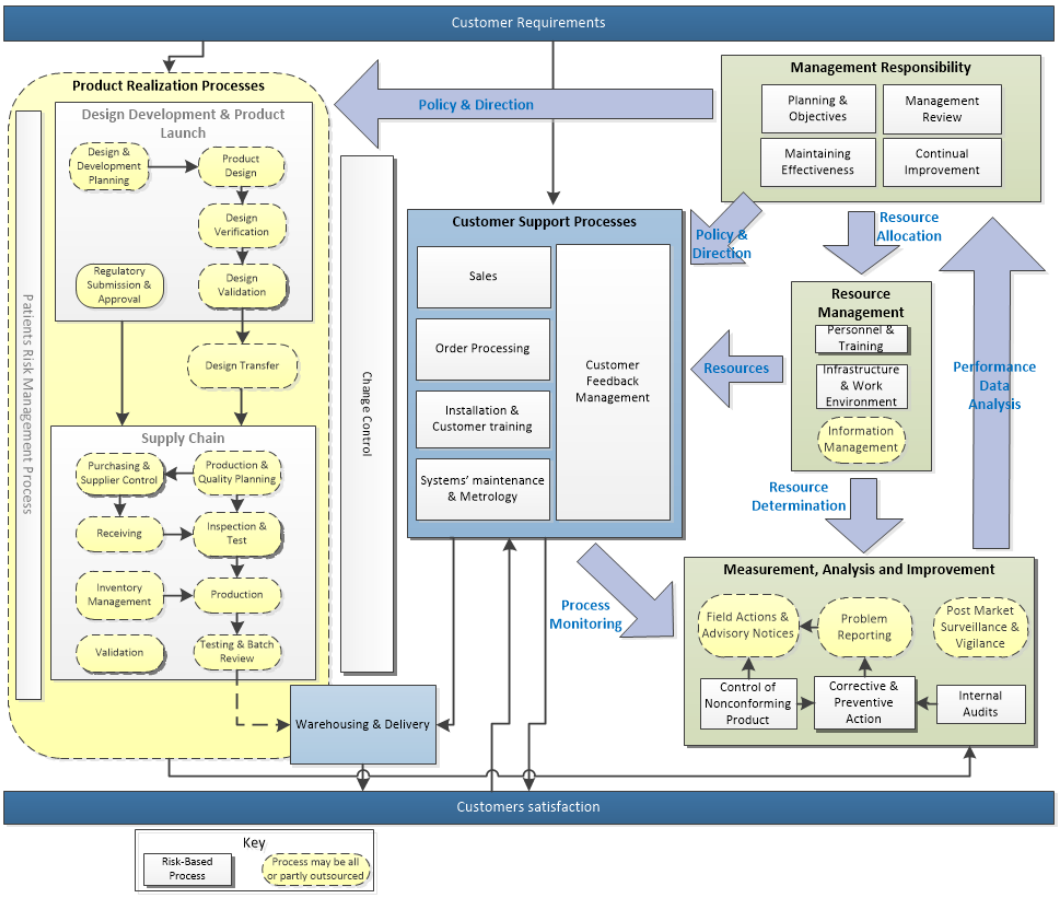
2.1 How the System Operates

The Business Operating System described in this manual operates as follows:

✏ **Quality Management System and its processes; General requirements (ISO 9001:2015 chap 4.4 / ISO 13485:2016 chap 4.1)**

✏ **Environmental Management System (ISO 14001:2015 chap. 4.4)**

Management Processes have been defined and mapped. These are used to monitor the Operational Processes critical to the company's business.



Each of these processes has an owner who is responsible for ensuring that adequate resources are assigned and for evaluating its efficiency using appropriate Key Performance Indicators.

For each process, the following has been defined and is specified under each process:

	its main objective
	its **owner** and the main stakeholders
	its KPI (**Business** and **Customer**)

To assist with understanding and awareness of the Quality Management System some of the processes are described in the relevant sections of this manual, similarly process descriptions provide an overview.

For the processes not described in this manual or for more detailed sub-processes, please refer to the appropriate SOP controlled within the electronic documentation management.

Not all processes are required to operate in every country. Country level processes, together with information about sites and outsourced activities are described in section 6.

2.2 Management Responsibilities

2.2.1 Customer focus

✏ **Customer focus (ISO 9001:2015 chap 5.1.2 / ISO 13485:2016 chap.5.2)**
Top Management shall demonstrate leadership and commitment with respect to customer focus.
It shall ensure that customer requirements are determined and are met.

Management shall ensure that a process exists to provide feedback to the Divisions about local markets requirements and regulations, in order to assure the development of products that meet market needs.
Management shall verify that products and services provided to the customers meet their needs and expectations. This is achieved through the process Customer Satisfaction (including complaint management) and through the organization of regular Customer Surveys.(NPS - Net Promoter Score, for example)

2.2.2 Responsibility and Authority

✏ **Organizational roles, responsibilities and authorities; Responsibility, authority and communication (ISO 9001:2015 chapter 5.3 / ISO 13485:2016 chap.5.5)**
Top Management shall ensure that the responsibilities and authorities for the relevant roles are assigned, communicated and understood within the organization.
It shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.
✏ **Organizational roles, responsibilities and authorities (ISO 14001:2015 chapter 5.3)**

2.2.3 Internal Communication

✏ **Communicating the quality policy, Quality objectives and planning to achieve them; Communication / Quality Policy, Quality objectives, communication (ISO 9001:2015: chap 5.2.2, 6.2, 7.4 / ISO 13485:2016 chap. 5.3, 5.4.1, 5.5)**
Management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.
✏ **Planning actions to achieve environmental objectives, Communication (ISO 14001:2015 chapter 6.2.2, 7.4)**

Another key management responsibility is the facilitation of communication.
Efforts are taken to ensure adequate communication within functions, between different functions (e.g. Divisions, Sales, Service, Supply Chain, RAQA), and within the Global Commercial Operations (GCO).

The main purpose of communication is to explain the company's strategy, to harmonize working practices, to manage common issues, to inform about changes, to share experiences and to communicate business results.

The formats are multiple: general information meetings such as Town Hall, department meetings, Global Commercial Operations' newsletters, videos or other bulletins.

2.2.4 Health and safety

It is the responsibility of the line manager to ensure that their employees have completed any relevant training organized by the company, according to country regulations.

✏ **Organizational roles, responsibilities and authorities; Resources, roles, responsibility and authority (ISO 14001:2015 chapter 5.3)**

✏ **Compliance obligations; Legal and other requirements (ISO 14001:2015 chap. 6.1.3)**

2.2.5 Resources and budget process

✏ **Resources/Resource Management (ISO 9001:2015 chap.7.1 /ISO 13485:2016 chap.6)**

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

✏ **Resources (ISO 14001:2015 chapter 7.1)**

The resources needed to meet the company's objectives and to achieve compliant products and services are analyzed and decided upon at budget sessions.
These resources may be readjusted or reassigned during the year depending on business developments, needs or the environment.

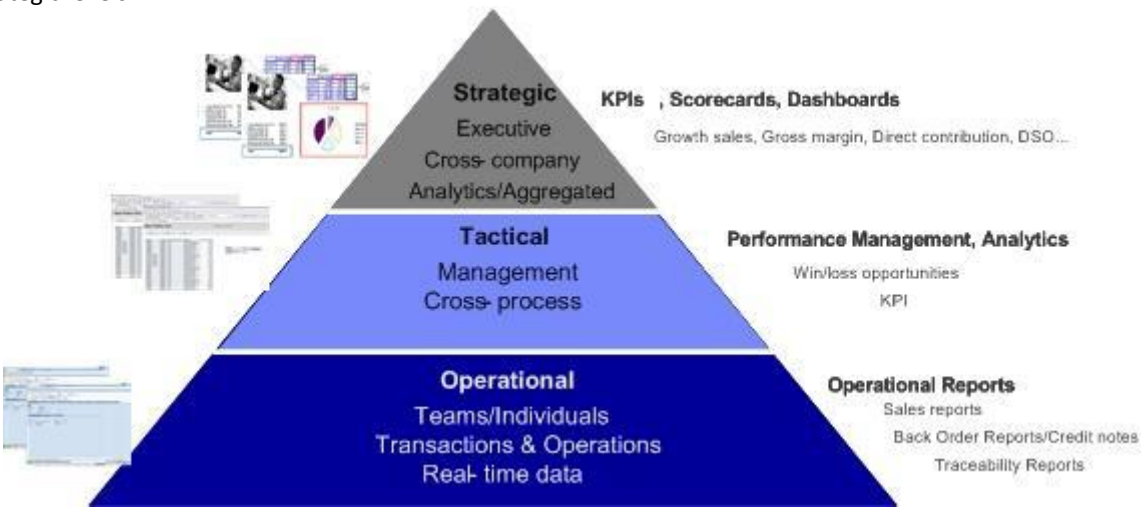
It is each manager's responsibility (Operational and Sales) to determine what resources are required to reach their objectives. This determination should consider both the company's sales growth objectives and the capacity of relevant functional group to support this.

Resources for important projects are managed through dedicated teams.

During the year, managers are responsible for tracking their expenditure according to the data provided by Finance.

2.2.6 Resources and business analytics

Finance provides management with suitable information and analyses for controlling and contributing to improvements in an overall profitability. These business analytics KPIs are available at operational, tactical and strategic levels.



These KPIs, combined with those implemented in different parts of the business, allow monitoring for the implementation of the Global strategy.

2.2.7 Resources and Human Resources Management

✏ **People, Competence / Human Resources (ISO 9001:2015 chapter 7.1.2 and 7.2 / ISO 13485:2016 chap.6.2)**

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

✏ **Competence, Awareness (ISO 14001:2015 chapter 7.2 and 7.3)**

It also is the responsibility of each manager to ensure that they have the right competencies in their team to reach their objectives in terms of performance and compliance.

The performance and competencies of each employee are evaluated on a regular basis by their manager.

Each manager works with the Human Resources Department to align their team organization and competencies with the company's needs and market conditions. Adequate trainings or other actions shall be provided to each employee, formalized and registered in specific records.

Making employees aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives is a clue.

Refer to section 4.1 for the complete process description.

3. European Business Operational Processes

3.1 Market Access

3.1.1 New Product Launch and product modification

✏ **Operation/Product realization (ISO 9001:2015 chap. 8 and ISO 13485:2016 chap. 7)**
The organization shall plan, implement and control the processes needed to meet the requirements for the provision of products and services.
The organization shall plan and develop the processes needed for product realization.

European Product Management prepares a European Product Launch plan according to the information provided by the Divisions in their launch book (which transposes global strategy to European markets).
This plan supports local Sales Support drawing their promotional plans for putting new products on the market.
It provides feedback on data and demands from local markets to Strategic Marketing.

In case of product changes or discontinuations, a communication is made by the concerned Division to relevant internal services (sales, supply chain, etc.) and to appointed customers, with adequate anticipation.

3.1.2 Registration

Product registration for CDG and where relevant LSG products within Europe is managed by the European manufacturing divisions or unit (Infectious Disease Division, ImmunoHematology Division, Food Science Division, unit of Clinical System Division based in Munich) for the products manufactured in Europe.
For the products manufactured outside Europe, but sold in Europe, French manufacturing Regulatory Affairs act as European Authorized Representative.

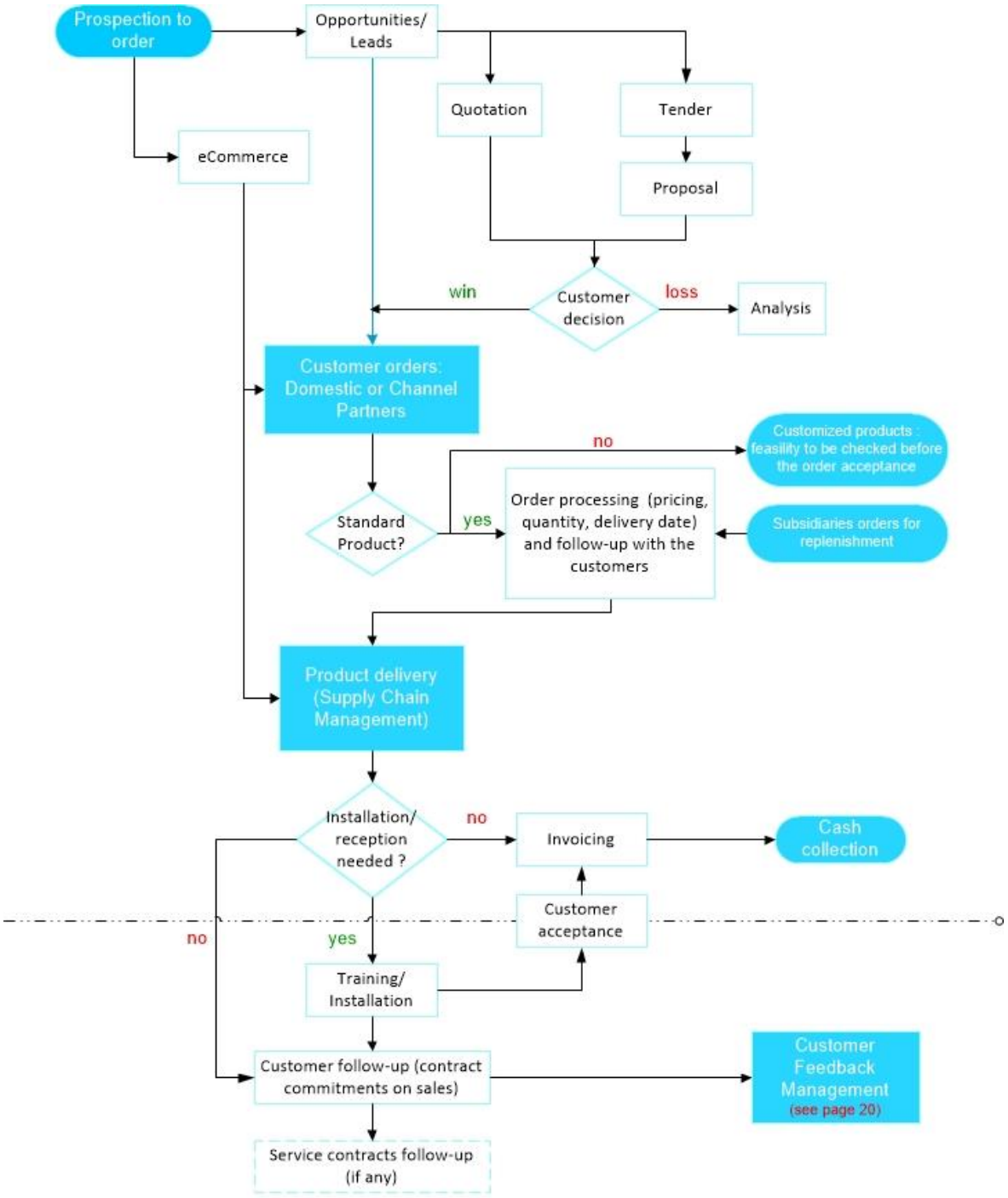
3.1.3 Selection and Follow-up of Distributors

European GCO mainly interacts directly with its customers through its own network of country based subsidiaries.

In certain cases, it uses Channel Partners / Distributors for specific products and/or markets.

✏ **QMS General Requirements, Particular requirements for implantable medical devices (ISO 13485:2016 chap. 4.1.1 and 7.5.9.2)**

3.2 Sales and customer service



To satisfy customers with the delivery of products and services within the agreed deadline and meeting their specifications.

Sales, Customer Care, Logistics.

Turnover Sales forecasting Qualified Opportunities Win/loss ratio DCs Service Rate
Order entry same day as receipt Order entry backlog

Sales

Sales are promoted and developed in response to customer needs with an appropriate product offering. Opportunities are identified and studied via the Salesforce tool, which permits a constant follow-up and helps formalizing the decisions, gathering all occurring events during the negotiation. Review of the opportunities is held periodically to discuss the advancements.

Quotes Team supports Sales initiatives in regards with these offerings (compliance, price policy, documentation and advices to customers). It facilitates customer relations maintaining a forward-going attitude to ensure their satisfaction.
Tenders Team ensures consistent tender's applications, as per markets' requirements.

Customer feedback data and demands are fed back from local markets to European and Strategic Marketing. Promotional plans and global proposals are drawn up while ensuring the company's profitability. European strategies are transposed to the local level. New products are launched onto the market. Customers are trained in the use of our products and systems, on Bio-Rad's site, customer's site or on e-learning.

Solution Architects, Field Application Specialists (FAS) or Field Service Specialists (FSS), and Segment Experts are supporting Sales and advising customers and helping building a high level offer and personalized solutions to customers.

Customer Service

During the order process, quotes and orders are reviewed to ensure that customer requirements are defined and understood and that Bio-Rad has the capability to meet the order requirements.
When changes occur after the order placement communication is prompted both internally and to the customer to ensure customer satisfaction. Products being returned from customers are managed as required. Processes ensure that when products are ordered by customers only those with regulatory approval can be supplied. E-commerce systems are maintained as required.

Technical service

✏ Monitoring and measuring resources, post-delivery activities/ Control of monitoring and measuring equipment, Control of production and service provision (ISO 9001:2015 chap. 7.1.5 and 8.5.5 and ISO 13485:2016 chap.7.6 and 7.5.1)

Installation, after-sale services, and technical support for systems are managed. Calibration, at specified intervals or prior to use, and verification services are provided in the following fields: temperature, mass and volume, time and frequency, pressure, cold chain and some other assays (France). With such services Bio-Rad guaranties that its equipment is providing valid results, according to identified standards.

Finance

The process of ensuring that payments are made in a timely manner is managed.

✏ Customer communication and determining requirements for product and services (ISO 9001:2015 chap.8.2.1/2 and ISO 13485:2016 chap. 7.2.1 and 7.2.3)

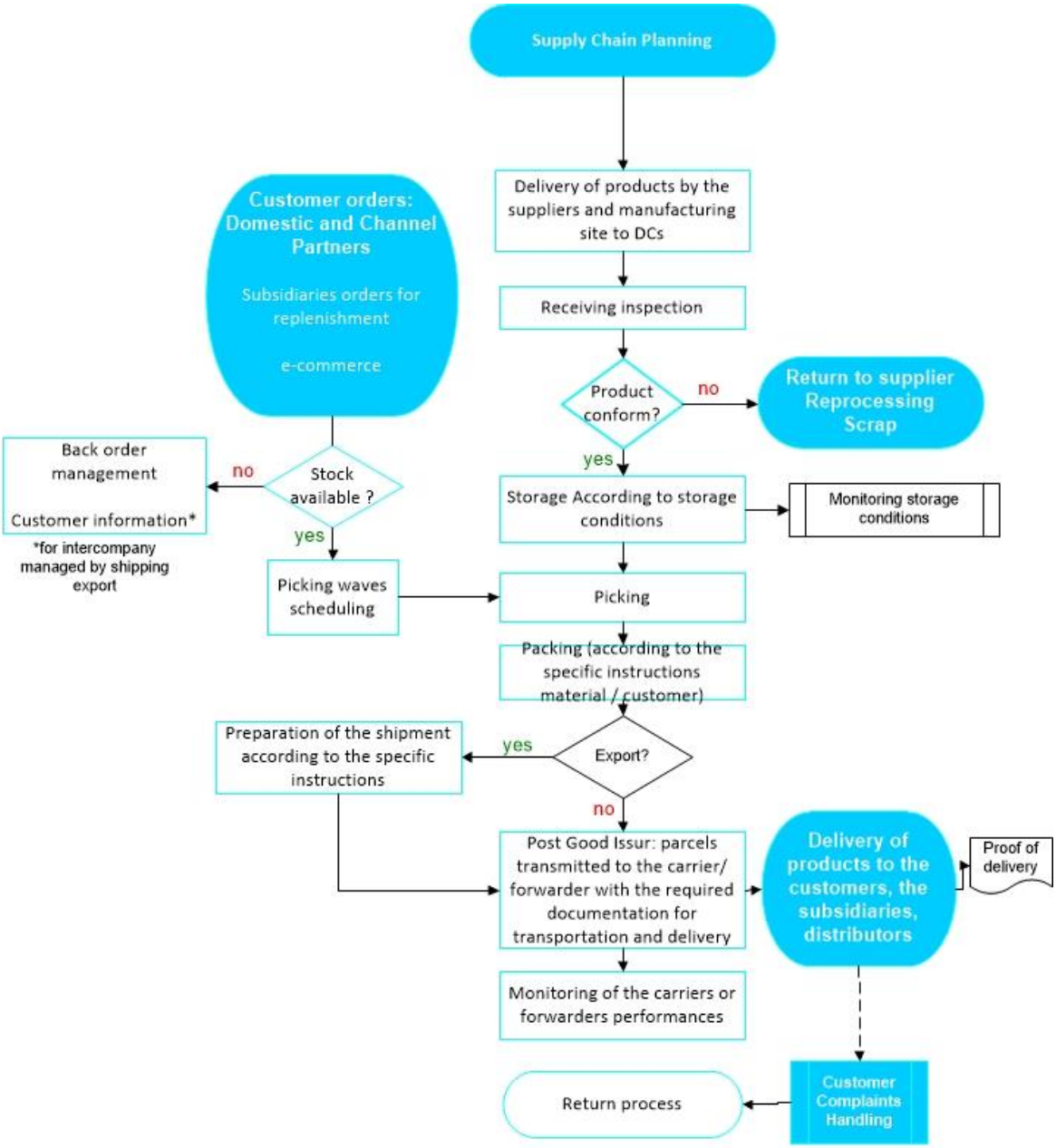
Bio-Rad offers customers product catalogues and additional services such as training, service contracts and metrology verifications. The terms and conditions of sale are described in the price lists.
Pricing strategy is reviewed annually by Marketing and any impact on customers is managed by Sales.
Bio-Rad also supplies customized products based on a price quote (specific procedures apply).
Requirements for delivery, installation and services are determined as part of the order.

Instrument installations are conducted by Bio-Rad employees or trained authorized agents. An intervention report is given to the customer, providing evidence of conformity to the manufacturer specifications. Training of the users is completed before using the system.

In case of changes to product performance and/or packaging, customers are advised and amendments are made to contracts for the public tenders.

Product Safety Data Sheets (SDS) are available for Dangerous goods on www.bio-rad.com

3.3 Distribution



To deliver the right products, at the right time, at the right place, in the right quantities, within the optimized cost and under the specified conditions. Ensuring traceability and performances are preserved through improving the management of both the physical and information flows interacting with our environment

Customers, Sales, Marketing (forecasts, ABC products), Customer Service, Technical Service (spare parts), **Supply chain planning and Warehouses** teams, Manufacturing divisions, **Carriers and forwarders**

Distribution Service rate Inbound: dock to dock Shipment accuracy

Forecasts and Planning

The European Headquarter (EHQ) defines the Global Forecast & Supply Plan, working closely with Sales and Divisions. The routine supply of products from different divisions to DCs is managed.

Distribution

Products are received from all Bio-Rad divisions. These are stored, prepared, shipped and delivered to customers, subsidiaries and distributors, whilst ensuring that the right products are delivered on time and with optimized cost.
Best Distribution Practices ensure that products are handled under specified conditions, that traceability is ensured and that product performance is preserved.
Products being returned from customers are handled as required.

Shipping

Quotes and orders are reviewed to ensure that subsidiaries and distributor requirements are defined and understood and that Bio-Rad has the capability to meet the order requirements.
Export shipments are prepared respecting any applicable regulations. Relationships with forwarders and carriers are optimized.

✏ **Preservation of products (ISO 9001:2015 chap. 8.5.4 / ISO 13485:2016 chap. 7.5.11)**

Documented work instructions are established for preserving the conformity of product during storage (including the control of product with limited shelf-life) and delivery to the intended destination.

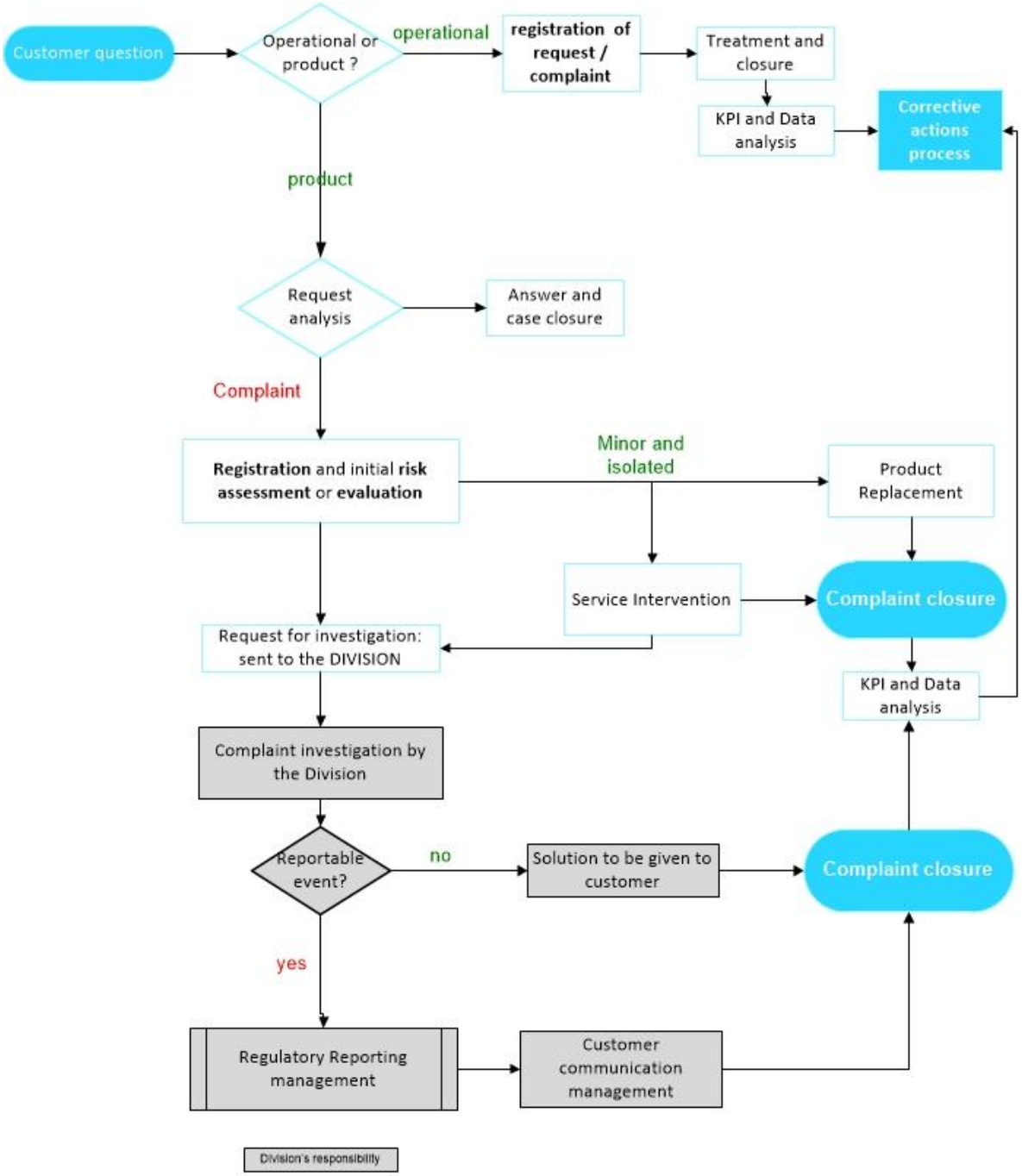
Stability studies and transportation conditions.

Stability studies are typically conducted according to standard ISO 23640.

Product expiration date is determined based on the results of stability studies performed during product development. Storage conditions are typically indicated on the product container labelling and any storage constraints identified are incorporated into business systems (e.g. ERP) as required.
Consequently product performance is assured if the product is stored according to recommended conditions.

Transportation stability studies are conducted on finished products to assess performance following shipment under conditions comparable to those encountered during transport to the different destinations.
Products are generally shipped from Bio-Rad's distribution centers to customer delivery points at ambient temperature using regular proven transportation services.
No special shipping conditions are required in the vast majority of cases, but where stability studies have identified that performance could be impacted, then special transportation conditions (dry ice, etc.) are used to enable transportation at ambient temperature.

3.4 Customer Feedback Management



Customer satisfaction through effective solutions to problems

Customer care (Customer Service, Customer Technical Support, Technical Service), Quality Assurance, Divisions, Distribution, Sales

Customer complaints service & product, Case closed same day, % Escalated cases, Average speed of anwser

Time to Repair Spare parts inventory

Check in Ennov if the document is the last version

Customer Care

Customer questions on products, applications and available services are handled and solutions are provided to ensure efficient resolution to customers' concerns.

Complaint Handling

Customer complaints are forwarded together with supporting information to the relevant departments for recording and handling. Complaints are received from customers and handled according to defined procedures. All relevant information is recorded.
Complaint metrics are established according to the complaint handling activities.

Technical Service

Repairs are handled at customers' sites or in a workshop, according to the instrument type and service agreements. Details of the intervention are documented in a report for both the customer and Bio-Rad. The service report indicates all operations done; the time spent; any changed spare parts or application update, and the name of the field service employee. The field service employee prepares the report testifying that the system conforms to Bio-Rad's specifications and presents it to a responsible person in the lab for signature before leaving.

Customer property is ensured to be adequately identified by ways of the Asset Tag and recorded within the relevant case record for the job completed.

Quality Assurance

Ensures that appropriate corrective actions have been implemented and are effective.

✏ **Property belonging to customers (ISO 9001:2015 chapter 8.5.3 / ISO 13485 chap. 7.5.10)**
Customer property can include intellectual property or confidential health information.
✏ **MEDDEV 2.12-1 rev 8 chapter 6.1-** Patient confidentiality should be maintained
✏ **FDA Quality System Regulation 21 CFR 820:2014 chapter 820.180.a**
Confidentiality. Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation.

Bio-Rad commits to ensure that its employees respect the confidentiality of customers and patients (including remote data monitoring operations). This is enforced through appropriate clauses in employment contracts. It is a legal requirement in some countries as well as a trade association membership commitment.

Post Market Surveillance and Vigilance

To comply with traceability requirements from EC Directive 98/79/CE, records are maintained for each delivery. This allows the identification of impacted customers in case quality issues are raised on a specific batch or serial number of a Bio-Rad product.

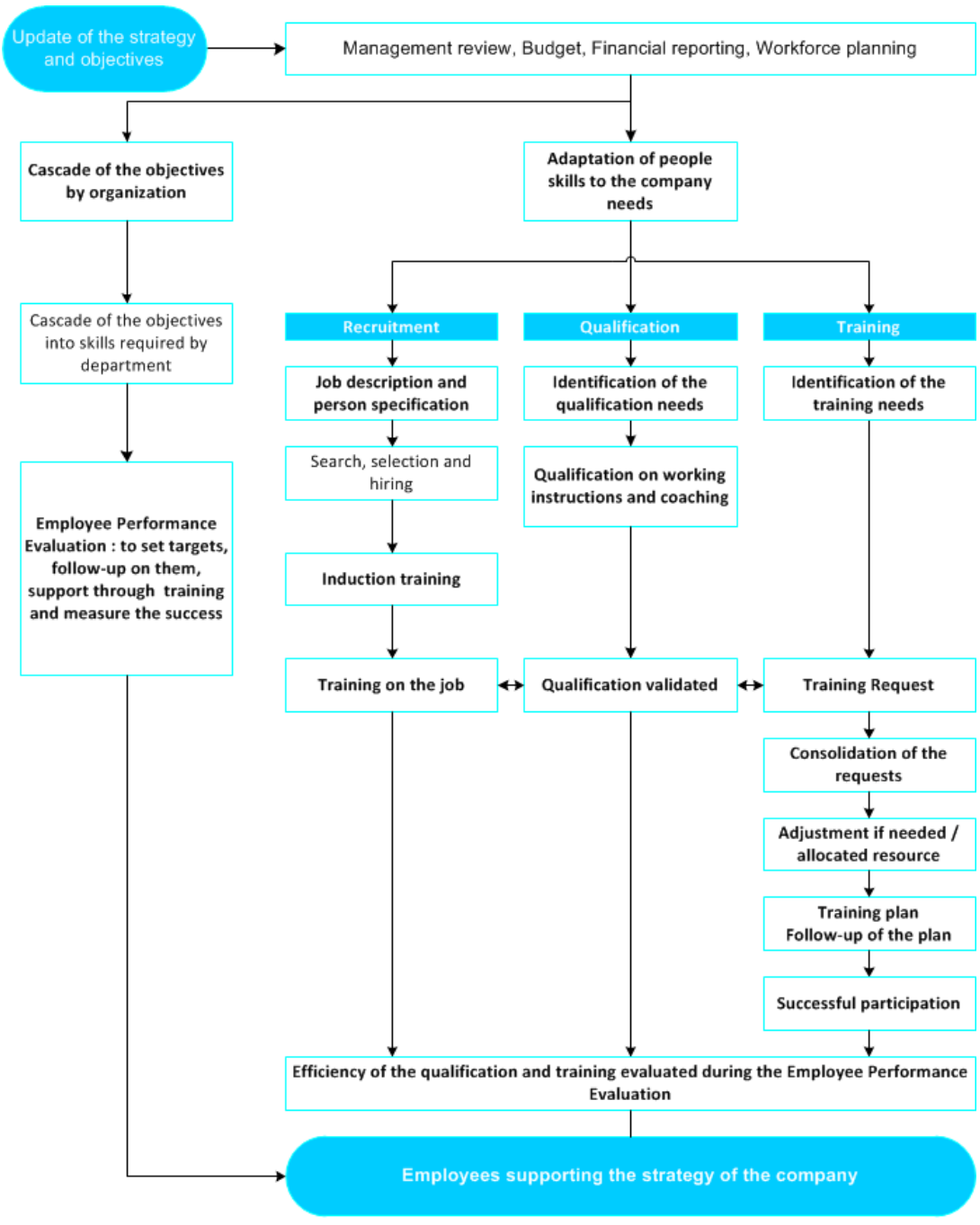
Divisions are responsible for complaints analysis, risk assessment, generation of Field Safety Notice communications and Regulatory Affairs are responsible for the regulatory reporting to the competent authorities. A follow-up of customers' acknowledgments is done.

The person at the customer's site - indicated to Bio-Rad to be the responsible for handling post market issues (vigilance contact) - is informed about the problem and about any action which should be taken, according to the investigation results.

Moreover, Post Market Surveillance allows Bio-Rad to improve products and service quality.

4. European Business Support Processes

4.1 Human Resources Management



Have employees competent, informed and motivated on clearly identified and defined smart goals.

Human Resources and managers.

Turnover, trainings days

The development and personal growth of our employees is considered a key factor in Bio-Rad's success and is therefore also embedded in our Global strategy.
The objectives for the overall company are cascaded down through the Top management into all parts of the organization. Individual employees see these overall objectives individualized in their personal objectives and with this how they can support the strategy of the company.

Employee competency requirements are set and if necessary adjusted depending on the overall objectives of the company. Training plans support an individual's development and acquisition of competencies in line with meeting these company objectives.

✏ **Competence, awareness / Human resources (ISO 9001:2015 chapters 7.2 and 7.3 / ISO 13485:2016 chap.6.2 and 6.2.2)**

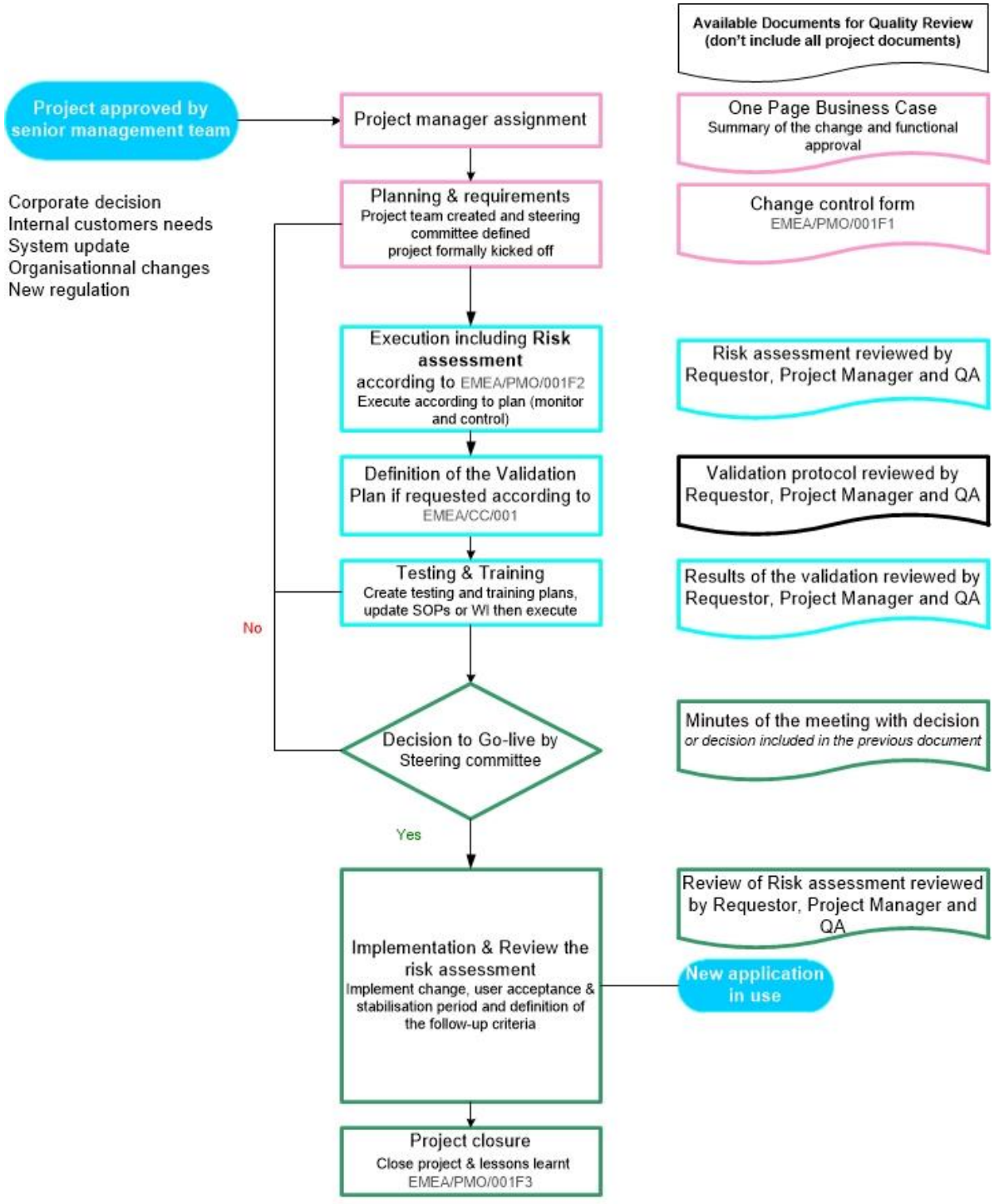
Bio-Rad ensures that its employees have the appropriate education, training, skills and experience to fulfill their responsibilities, particularly in regard to meeting quality requirements.

✏ **Competence and awareness (ISO 14001:2015 chapter 7.2 and 7.3)**

Employees who perform duties that impact product or service quality have this embedded in their job description which indicates the level of skill and experience required. Those requirements and goals are addressed in the individual's performance evaluation. Both employee and manager evaluate regularly progress made in regards to these objectives.

Appropriate procedures have been established to identify training needs and ensure that employees are trained adequately for their responsibilities.

4.2 Projects and Change Management



Implementing and documenting changes within Bio-Rad, which are deemed to pose a potential impact on the Quality Management System

Project Management Office, Steering Committee, Project manager, QA and stakeholders

Project completion (%)
Project requests : planing execution (time, cost, resource…)

When a project is approved by Senior Management a Project Manager is assigned, with dedicated teams to follow it and ensure that it is aligned with our business goals and Strategy.

Project management activities include managing changes in the organization, which are deemed to pose a potential impact on the Quality Management System, its processes or intended outcomes (e.g. integration of new businesses, facilities changes (warehouses or offices).

All project requests are reviewed by the Project Management Office (PMO) and a designated steering committee. According to the risk assessment and validation protocol outcomes, the decision is made by the steering committee to implement or reject the project plan.

When a project is approved, a project team is built which includes a project manager and team members. The project team holds regular reviews with the business sponsor and the steering committee (if necessary). In addition there are regular formal reviews of strategic projects and initiatives, which take a more in depth view of the status, plans, risks and issues.

Business is in charge of deciding how IT service requests are prioritized on the basis of a defined framework (Statutory or Regulatory, Customer satisfaction, Process efficiency) and IT and business resource availability.

✏ Planning of changes; (ISO 9001:2015 chapter 6.3 and 8.5.6 / ISO 13485:2016 chap. 5.4.2 and 7.5.1)

✏ Planning actions (ISO 14001:2015 chapter 6.1.4)

All projects are managed to ensure effective Change control in regards to standards, regional or local regulations, and to the impact on the Quality Management System.

4.3 Infrastructure, Work Environment and Equipment Monitoring

4.3.1 Infrastructure

✏ **Infrastructure (ISO 9001:2015 chap. 7.1.3 / ISO 13485:2016 chap. 6.3)**
✏ **Organizational roles, responsibilities and authorities; Resources, roles, responsibility and authority (ISO 14001:2015 chapter 5.3)**
✏ **Resources (ISO 14001:2015 chapter 7.1)**

The manager responsible for facilities ensures that site infrastructure is maintained and improved. Maintenance activities are managed internally or through external subcontractors whose performances are evaluated at the local level.

Corporate and/or European SOPs are in place to ensure data safety in IT systems (confidentiality, safety, access management, backup and necessary upgrades) and an IT hotline exists to assist users in the daily routine use of their validated IT systems (infrastructure and applications).

According to the local organization, purchasing of disposables necessary for the day to day activities is managed by different departments. Critical suppliers are evaluated locally according to the European procedure.

4.3.2 Work environment and environmental/sustainable development approach

✏ **Environment for the operation of processes; Work environment (ISO 9001:2015 chapter 7.1.4 ISO 13485:2016 chap. 6.4) and Cleanliness of product control (ISO 13485:2016 chap.7.5.2)**
✏ **Resources (ISO 14001:2015 chapter 7.1)**

In relation to the above listed ISO chapters, selling activities have no specific critical requirements of work environment, cleanliness of product and contamination control.
In most of the regions, Environment Health Safety (EHS) management programs have been implemented.

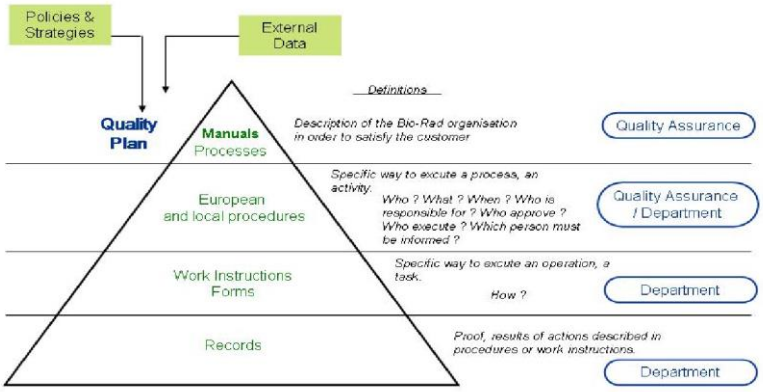
Bio-Rad is sensitive to the impact of its business activities on the environment. Many actions have been implemented to reduce this impact and some countries are already certified according to ISO 14001 standard.

4.3.3 Equipment monitoring

✏ **Control of monitoring and measuring devices (ISO 9001:2015 chapter 7.1.5 / ISO 13485:2016 chap.7.6)** Documented procedures are established to ensure that monitoring and measurement are carried out in a manner that is consistent with the monitoring and measurement requirements.
✏ **Monitoring and measurement (ISO 14001:2015 chapter 9.1)**

4.4 Documentation Management

The Quality Management and Environmental System is supported by the documentation management. The documentary structure includes: manuals, policies, goals and objectives, procedures, work instructions, forms and records.



✏ **Documented information; Controlled documents (ISO 9001:2015 chapter 7.5 / ISO 13485:2016 chap. 4.2)**

✏ **Documented information (ISO 14001:2015 chapter 7.5)**

Applicable documents are available to all Bio-Rad employees through a validated Electronic Document Management system in accordance with the rules of access, security and confidentiality.
Printed, downloaded documents are considered as uncontrolled copies.

Changes in the documents are reviewed and approved by the same function or organization that performed the original review and approval, unless specifically designated otherwise.

Documents in the Global Documentation Center are not covered in the scope. However their use is discretionary by the European GCO and Distribution RAQA.

✏ **Control of documented information; Control of records (ISO 9001:2015 chapter 7.5.3 / ISO 13485:2016 chap. 4.2.4 and 4.2.5)**

Records are defined and established to provide evidence of conformity to requirements and effective operation of the Quality Management System.
Procedures define the requirements for identification, storage, protection, retrieval, retention time and disposition of records.

✏ **Control of documented information; Control of records (ISO 14001:2015 chapter 7.5.3)**

Management of the Quality Operating Manual by country: in the chapter 6-Country, are specifying the following points:

- Country specific activities and processes covered by the certifications (Production and manufacturing/quality control will be specified here if relevant)
- The non-applicable sections of the QMS
- Outsourced activities: transportation; …
- Key procedures and their links to the standard: Global/European/Local ones
- The maintenance of the Country Quality (and Environment) Manual
  - It is made of the *Country Quality and Environment Manual Template* and *Chapter 6*
  - It is strongly recommended to have it translated in the country language, being one of the main tool to ensure awareness on the QMS
  - Each new version of the template will generate a new version of the Country Quality (and Environmental) Manual Template; but a new country version could be generated if modifications on the local organization would require it. As an example, a Country Quality (and Environmental) Manual Template could be on version 2, Nordics on v.3, Germany on v.4….All are managed under Ennov. The local management will approve the country specific part.

4.5 Regulatory Monitoring

The Quality Management System described in this Manual has been designed to ensure compliance with:

✏ **Bio-Rad Company Policies (published in the Global Documentation Center)**

- Bio-Rad Management guidelines
- Anti-Corruption and Healthcare Compliance Policy
- Code of Business Ethics and Conduct
- Conflict Minerals Policy
- "Sunshine Act" Compliance (Sales Agents)
- Export Management and Compliance Program (EMCP)
- Privacy Policy on HR info from Europe
- Supplier Code of Conduct
- Any other relevant policy…

✏ **Compliance obligations; Legal and other requirements (ISO 14001:2015 chap. 6.1.3)**

✏ **International and national legal, regulatory and quality system requirements, as applicable to our business, among them:**

- ISO 9001:2015
- ISO 13485:2016 Medical Devices-Quality Management Systems-Requirements for regulatory purposes
- ISO 14971:2012 Medical Devices – Application of risk management to medical devices
- EU Directive 98/79/EC on In Vitro Diagnostics Medical Devices
- FDA CFR Title 21 Part 820 - Quality System Regulation (if relevant for manufacturing units)
- FDA CFR Title 21 Part 820 - Medical Device Reporting (if relevant for manufacturing units)

✏ **Compliance obligations; Legal and other requirements (ISO 14001:2015 chap. 6.1.3)**

- ISO 14001:2015

The Company must ensure that all IVD medical devices (mostly CDG products) and the services provided to customers are conforming to the requirements of the IVD Directive 98/79/EC. This requires:

- Achieve and maintain a Quality Management System certification according to standards ISO 13485 in all Manufacturing Sites.
- Draw up the Products Technical File including: performances, risk analysis, stability studies (including shipping conditions), product labeling (labels and instructions for use), chemical and biological risks.
- Follow the conformity assessment procedures defined by the IVD Directive 98/79/EC.
- Apply to the devices covered by Annex II, List A, the examination and approval of the technical documentation by a Notified Body and subsequent release of each lot of product.
- Draw up the CE Declaration of Conformity before placing the device on the market.
- Make available the Instructions For Use and the Safety Data Sheets in the language required by the Country where the device is marketed.

All products placed on the market by Bio-Rad must comply with the enforced applicable European directives and regulations. The functional groups are responsible for monitoring the new regulatory requirements in their area of responsibility and their application to the business.
As applicable new regulations and standards come into force, the quality system is reviewed and modified when necessary to assure the continuous ability to fulfill the requirements.

✏ **Global and/or European SOPs are in place to ensure the monitoring of Directives, Regulations, Laws, Guidelines etc., whether new, modified or upgraded, impacting on products and on European Global Commercial Operations (GCO) and Distribution activities.**

✏ **Compliance obligations; Legal and other requirements (ISO 14001:2015 chap.6.1.3)**

5. Performance Evaluation and Improvement

5.1 Performance Evaluation

5.1.1 Measurement, analysis and evaluation

✏ **Monitoring, measurement, analysis and evaluation (ISO 9001:2015 chap. 9.1 / ISO 13485:2016 chap. 8.2)** Customer satisfaction and internal audit are considered as sub-processes of monitoring and measurement.

✏ **Monitoring, measurement, analysis and evaluation (ISO 14001:2015 chap. 9.1)**

Customer satisfaction

Monitoring customer perception includes receiving input from periodic customer satisfaction surveys; meetings with customers; customer data on delivered product quality; lost business analysis; customer evaluations regarding our products and services; and customers complaints.

Process Improvement and Control

Each function identifies, assesses and manages various existing or possible risks in terms of legal or regulatory compliance.

✏ **Analysis and evaluation (ISO 9001:2015 chapter 9.1.3 / ISO 13485:2016 chap.8.4)**

✏ **Monitoring, measurement, analysis and evaluation (ISO 14001:2015 chap. 9.1)**

The following data sources are available for analysis:

- Internal and external audit results;
- Key Performance Indicators (Business and Customer satisfaction indicators); their selection and the target setting are reviewed on a yearly basis;
- Results of the external surveys and Customers' Evaluations;
- Review of experiences after debriefing the roll-out of a project or a specific event;
- Supplier follow-up
- Challenges with management and inside the RAQA Team

5.1.2 Internal Audits

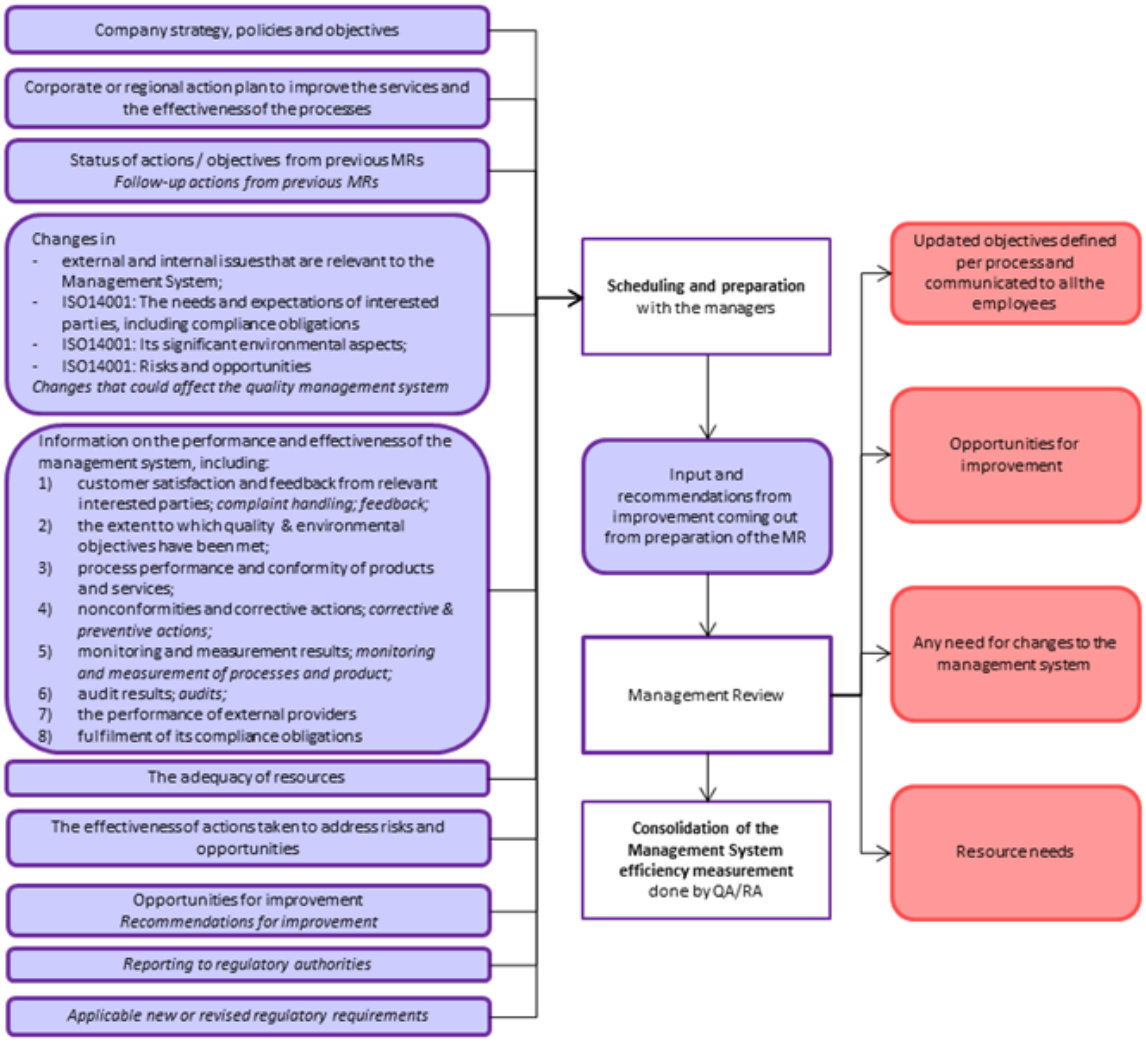
✏ **Internal audit (ISO 9001:2015 chapter 9.2 / ISO 13485:2016 chap.8.2.4, 8.2.5 and 8.4)**

✏ **Internal audit (ISO 14001:2015 chap. 9.2)**

Internal audits

Audits are performed to verify that the Quality Management and Environmental System is being implemented in line with standards, but mainly, to support the business and move forward addressing its priority challenges.

5.1.3 Management Review



ISO 9001:2015 and ISO 14001:2015

ISO 13485:2016

Define the local/regional action plan for improving the customer satisfaction and the efficiency of the Bio-Rad processes in the respect of the regulatory requirements and Global or Regional objectives.

The local/regional managers for defining, validating and communicating the improvement plan and the QA/RA manager for coordinating this plan.

% improvement actions done in time

One key responsibility of management is to participate in the management review process:

✏ **Management Review (ISO 9001:2015 chap. 9.3 / ISO 13485:2016 chap. 5.6)**

Top management shall review the organization's quality management, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. It includes assessing opportunities for improvement and the need for changes of QMS.

✏ **FDA Quality System Regulation 21 CFR 820:2014 chap. 820.20.c**

Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency

✏ **Management Review (ISO 14001:2015 chap. 9.3)**

Management Review is a sub-process of improvement process and covers internal efficiency and customer satisfaction.

It is rolled out by RAQA at country level with the attendance of the local senior management. Points that can't be resolved at the local level are escalated at the regional level.

Management Reviews are held annually. Efficiency of the processes and follow-up of actions are done through the CAPA and KPI tools, and/or during regular meetings with managers.

5.2 Improvement

✏ **Improvement; Nonconformity and corrective action (ISO 9001:2015 chap. 8.3, 8.7 and 10.2 / ISO 13485:2016 chap. 7.3, 8.3)** CAPA is considered as sub-process of improvement.
✏ **FDA Quality System Regulation 21 CFR 820:2014 chapter 820.100.a**
✏ **Improvement; Nonconformity, corrective action and preventive action (ISO 14001:2015 chap. 10)**

CAPA process

Bio-Rad establishes and maintains procedures for implementing corrective and preventive action.
Corrective actions are continuously being implemented and monitored in response to ongoing non-compliances.
Improvement actions and projects are decided upon annually, based on a global analysis of Quality Management System performance (mainly in management reviews, process reviews). Dedicated resources and/or multidisciplinary working groups or committees are tasked with improving processes or products if necessary.
These actions may be corrective or preventive (training, communication, risk analysis, etc.).

Measurement of effectiveness

Monitoring is conducted through the systematic analysis of trends in:

- Company's economic performances in comparison with its peers;
- Periodical customer surveys;
- Number of complaints and their types;
- Costs of non-quality;
- Unmet project deadlines;
- Internal Audit reports
- Occasional analyses of external audit or inspection reports (customers, certification bodies, healthcare authorities, etc.).

6. Country

6.1 Northern European and French sites structure and scope

	Country	Site	Scope for ISO 9001:2015	Scope for ISO 13485:2016	Scope for ISO 14001:2015	Scope for ISO 17025:2017
Parent Site	UK	**Bio-Rad Laboratories Ltd** The Junction, Station Road, Watford, WD17 1ETS	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales, customer technical support, after-sales service, installation and distribution of in vitro diagnostic products	N/A	N/A
Annexes to the certificate	BE	**Bio-Rad Laboratories NV** Winninglaan 3 9140 Temse	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales, customer technical support, after-sales service, installation and distribution of in vitro diagnostic products	N/A	N/A
	NL	**Bio-Rad Laboratories BV** Winninglaan 3 9140 Temse	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales, customer technical support, after-sales service, installation and distribution of in vitro diagnostic products	N/A	N/A
	BE	**DiaMed Benelux NV** Winninglaan 3 9140 Temse	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales, customer technical support, after-sales service, installation and distribution of in vitro diagnostic products	N/A	N/A
	SE	**Bio-Rad Laboratories AB** Solna Strandväg 3 171 54 Solna	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales, customer technical support, after-sales service, installation and distribution of in vitro diagnostic products	Sales and after-sales service of life science research products and medical diagnostic products	N/A
	NO	**Bio-Rad Laboratories** Torgbygget Nydalsveien 33 NO-0421 Olso	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales and after-sales service of in vitro diagnostic products	Sales and after-sales service of life science research products and medical diagnostic products	N/A
	FI	**Bio-Rad Laboratories OY** Valimotie 1A 00380 Helsinki	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales and after-sales service of in vitro diagnostic products	Sales and after-sales service of life science research products and medical diagnostic products	N/A
	DK	**Bio-Rad Laboratories** Symbion Science Park Fruebjergvej 3 2100 Kobenhavn O	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales of in vitro diagnostic products	Sales and after-sales service of life science research products and medical diagnostic products	N/A
	FI	**DiaMed Fennica OY** Valimotie 1A 00380 Helsinki	Sales and after-sales service of life science research products, medical diagnostic products and special databases and chemistry publishing software	Sales, and after-sales service of in vitro diagnostic products	Sales and after-sales service of life science research products and medical diagnostic products	N/A

	FR	**Bio-Rad France** Boulevard Raymond Poincaré 92430 Marnes La Coquette	Sales and technical support of reagents and systems of Bio-Rad. Sale and technical support of trading products	Sales and technical support of all reagents, instruments and systems of in vitro diagnostic medical devices and reagents and kits used as alternative method for the detection of micro-organisms. Sale and technical support of trading products	N/A	N/A
	FR	**Bio-Rad France** Rue des Frères Lumière 77290 Mitry-Mory	Technical support of systems of Bio-Rad. Technical support of trading products	Technical support of all instruments and systems of in vitro diagnostic medical devices and reagents and kits used as alternative method for the detection of micro-organisms. Technical support of trading products	N/A	-Testing/ calibration in industrial equipment and engineering products/ climatic chambers-c old chain equipment -Calibration in temperature, time and frequency, mass and volume

6.2 Specific activities and processes

Activities/Process	Subprocess	BioRad UK	DiaMed GB	BioRad BE	BioRad NL	DiaMed BNL	BioRad Sweden	BioRad Denmark	BioRad Norway	BioRad Finland	DiaMed Finland	Bio-Rad Marnes	Bio-Rad Mitry-Mory
CAPA	CAPA	Yes		Via Belgium			Via Sweden					Yes	Yes
Change control, project management	Change Control	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Control of anomalies and Non-conforming product	Complaint Handling / CAPA	Yes		Via Belgium			Via Sweden					Yes	Yes
Continual improvement	Management Review / CAPA	Yes		Via Belgium			Via Sweden					Yes	Yes
Communication	Change Control/ Resource Management	Yes		Via Belgium			Via Sweden					Yes	Yes
Customer feedback Management	Technical support	Yes		Via Belgium			Via Sweden					Yes	No
	Service Intervention	Yes		Yes	Yes	Yes	Yes	Via Sweden	Yes	Yes	Yes	Yes	Yes
	Customer Service	Yes		Via UK			Via Sweden					Yes	No
Customer satisfaction	Global Survey BR evaluation as supplier	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Design, development and product launch	New product launch/ Training and communication to GCO	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Maintaining effectiveness	Management Review	Yes		Via Belgium			Via Sweden					Yes	Yes
Information management (Resource Management)	Document Control / Record Management	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Infrastructure, Work environment and Equipment management	EHS/ Facilities	Yes		Via Belgium			Via Sweden					Yes	Yes
Installation and customer training	Installation	Yes		Yes	Yes	Yes	Yes	via Sweden	Yes	Yes	Yes	Yes	Yes
Internal Audits	Internal Audits	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Management Review	Management Review	Yes		Via Belgium			Via Sweden					Yes	Yes
Order processing	Customer Orders	Yes	Yes	Via UK			Via Sweden					Yes	No
Personnel and training (Resource Management)	Development, Recruitment, Training	Yes		Via UK/ Belgium			Via UK/ Sweden					Yes	Yes
Planning and objectives	Quality Objectives	Yes		Via Belgium			Via Sweden					Yes	Yes
Post Market Surveillance and vigilance	Complaint Handling	Yes		Via UK/ Belgium			Via UK/ Sweden					Yes	Yes
Problem reporting, Field Actions and Advisory Notices	Field Safety Notification / Product Quality Notification	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Production	Manufacturing	No	No	No	No	No	No	No	No	No	No	No	No
Purchasing & Supplier control	Selection and evaluation of GCO suppliers	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sales	Sales	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Supply Chain	Planning	No	No	No		No	No				No	No	No
Systems' maintenance and metrology	Service /Repair/ Calibration	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Warehousing and delivery	Logistics/ Distribution	No	No	No		No	No					No	No
Certifications	ISO 9001	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	ISO 13485	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	ISO 14001	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No

Check in Ennov if the document is the last version

Exclusions:

Not Applicable ISO 9001: 2015	Not Applicable ISO 13485 : 2016
8.3: Design and development Reason: All design and development processes are handled by the manufacturing divisions which are outside the scope of the GCO and Distribution QMS	**7.1 Planning of product realization**: Reason: All planning of product realization and processes are handled by the manufacturing divisions which are outside the scope of the GCO and Distribution QMS
	7.3: Design and development (all requirements) Reason: All design and development processes are handled by the manufacturing divisions which are outside the scope of the GCO and Distribution QMS
	7.5.1 Control of production and service provision - Reason: maintenance of record / amount of manufactured and approved for distribution not in the scope for GCO and Distribution QMS
	7.5.5: Particular requirements for sterile medical devices Reason: No products sold by Bio-Rad Laboratories are sterile medical devices
	7.5.7 - Particular requirements for validation of processes for sterilization and sterile barrier systems Reason: Bio-Rad do not dispose of sterilization and sterile barrier systems
	7.5.9.2 Particular requirements for implantable medical devices Reason: No products sold by Bio-Rad Laboratories are implantable medical devices

- Product registration managed by Manufacturing divisions or its European Authorized Representative

6.3 Key procedures: Links to Standards

Standard Chapter	*ISO 9001: 2015*	*ISO 13485: 2016*	*ISO 14001: 2015*	Related document European , Global and Local
Quality Management system	***4***	***4***	***4, 7***	
General requirements Context of the organization Process and Risk approach	*4*	*4*	*4.3* *4.4*	Country Quality and Environmental Manual Regulatory monitoring (ESO/RA/001)
Documentation requirements Control of documents/records	*7.5*	*4.2* *(1-5)*	*7.5* *7.5.1* *7.5.2* *7.5.3* *7.5.4*	Management Guidelines European Documentation management (ESO/QA/001) European Records Management (ESO/QA/018) Records minimum retention time (ESO/QA/019) Technical Documentation management (EMEA/TSE/001) European template procedure (ESO/QA/002)
Management responsibilities	***5, 6, 7 and 9***	***5***	***5, 6, 7 and 9***	
Management commitment	*5.1*	*5.1*	*5.1*	Global Strategy FCPA Policy Ethic Code Data Protection (local regulatory rules)
Customer Focus	*5.1.2*	*5.2*	*6.1.2* *6.1.3* *9.3*	Global Customer Surveys ESO/Customer Care/001 Global Product Complaint Handling (07.02.GLB.SOP.0012) Global Operational Complaint Handling (07.02.GLB.SOP.0015)
Quality Policy	*5.2*	*5.3*	*5.2*	Global Quality Policy (01.01.GLB.POL.00010)
Planning	*6*	*5.4.2*	*6.2*	Global Strategy
Planning of changes	*6.3 and 8.5.6*			Project Management and Change Control (EMEA/PMO/001)
Responsibility, authority and communication	*5.3 and 7.4*	*5.5 (1-3)*	*5.3 and 7.4*	Country Quality and Environmental Manual Organizational charts
Management review	*9.3*	*5.6*	*9.3*	ESO Management review (ESO/QA/004)
Resource management	***7 and 8***	***6 and 7***	***7 and 8***	
General	*7*	*6*	*7*	Country Quality and Environmental Manual
Human resources	*7.2 and 7.3 and 7.1.2*	*6.2*	*7.2 and 7.3*	EMEA Commercial Operation Training Process (EMEA/HR/001) Training & Development policy (ESO/HR/006) Training Request Process (ESO/HR/007) Induction program and competence monitoring (ESO/HR/008) Technical Training Organization (ESO/TSE/002) FSE Technical Skill evaluation (ESO/TSE/004)
Infrastructures	*7.1*	*6.3*	*7.1*	Storage temperature monitoring (ESO/DIS/001)
Work environment	*7.1*	*6.4.1*	*7.1*	Managed locally by the warehouse and distribution teams
Product realization or Operation	*8*	*7*	*8*	Not applicable Product Launch (ESO/MKT/002)
Planning	*8.1*	*7.1*	*8.1*	ABC Classification (ESO/SCP/002) Inventory Stock Management for Reagents & Systems (ESO/SCP/004) ***Procedures linked to Distribution QMS (not applicable for GCO activities)***

Standard Chapter	ISO 9001: 2015	ISO 13485: 2016	ISO 14001: 2015	Related document European , Global and Local
Customer related processes	8.2	7.2 (1-3)	8.2	Customer operational requests/complaints in logistics (EMEA/CC/002) Customer communication (ESO/QA/012) Customer Care Process (EMEA/CC/003) Pricing approval (ESO/CS/001) Pricing policies (ESO-PP-003, ESO/SAL/004) Reagent rental processes (ESO-RR-001,002,004,005) Roles & responsibilities towards recording selling prices into the ERP (ESO/SAL/001) Customer Technical Support Process : Product Cases (EMEA/CTS/001)
Design and development	8.3	7.3		Not applicable
Purchasing	8.4	7.4		Selection and Evaluation of critical suppliers (ESO/PUR/001)
Production and service realization	8.5	7.5 (2-4)		Product Modification Activities (ISO/QA/002) Shipping conditions (ESO/QA011) Best Service Practices (EMEA/TSE/001) Spare Parts return to ISIT (ESO/TSE/009) Service Intervention Process (ESO/TSE/012) Service Best Practices (EMEA/Service BP) Distribution Best Practices (EMEA/Distribution BP) Temperature Storage Monitoring (ESO/DIS/001) Inventory Management Process (ESO/SCP/001)
Control of monitoring and measuring devices	7.1.5	7.6		Control of monitoring and measuring devices (ESO/MTR/001)
Measure, analysis and improvement	**9**	**8**	**9**	
General	9.1	8.1	9.1	Country Quality and Environmental Manual
Control	9.1 9.2	8.2 (1-4)	9.1 9.2	QMS/EMS Internal audits (ESO/QA/006)
Management of non-conforming product	8.8	8.3	8.2 10.2	CTS process (ESO/CTS/001) Global Regulatory Reporting Procedure (07.03.GBL.SOP.0017) Global Execution of Ship Holds (08.02.GBL.SOP.0021) Global Execution of Field Actions (08.03.GBL.SOP.0023) Ship Hold (ESO/QA/017) Ship Hold with SAP (ESO/QA/023)
Data analysis	9.1.3	8.4	9.1	Global Product Complaint Trending Procedure (07.02.GLB.SOP.00013)
Improvement	10	5.6.1 8.5	10	ESO Management Review (ESO/QA/004) CAPA Management (ESO/QA/007) QA Register (ESO/QA/009)

All local procedures and Work Instructions are available in Ennov or the Global Document Center

Appendices

***Appendix 1**: Organisational structure*

- NEF/QA/001-01 Northern European Organisational Chart

***Appendix 2**: Environmental Policy*

- NOR/EP/55: Nordic Environmental Policy

***Appendix 3**: Quality & Environmental Certificates*

7. Glossary

Acronyms	Meaning	Field
CDG	Clinical Diagnostics Group	Organization
Channel Partners	A type of customer	Organization
CTS	Customer Technical Support	Organization
EDC	European Distribution Center	Organization
EHQ	European Headquarter	Organization
ESO	European Selling Organization	Organization
GCO	Global Commercial Operations	Organization
EHS	Environment Health Safety	Process
EMEA	Europe Middle East and Africa	Organization
Ennov	Software used for Documentation management	Tool
ERP	Enterprise Resource Planning	Tool
FAS	Field Application Specialist	Organization
FCPA	Foreign Corruption Practices Act	US law
FDA	Food and Drug Administration (US)	External organism
FSE	Field Service Engineer	Organization
FSN	Field Safety Notice	Tool
FSS	Field Service Specialist	Organization
IVD	In-Vitro Diagnostics	
KPI	Key Performance Indicator	Tool
LSG	Life Science Group	Organization
LRD	Limited Risk Distributor	Organization
Q&EM	Quality & Environmental System	Organization
SDS	Safety Data Sheet	Document linked to product

Refer to **02.03.GLB.REF.00009 - Global Quality Management System Glossary,** in the Global Documentation Center for additional Quality Management definitions.