GLOBAL QUALITY

Quality Manual

Version 9.0

February 2023

sanofi

Abbreviations and Acronyms

CHC	Consumer HealthCare
CMC	Chemistry, Manufacturing and Control
GBU	Global Business Unit
GCP	Good Clinical Practices
GDP	Good Distribution Practices
GLP	Good Laboratory Practices
GCLP	Good Clinical and Laboratory Practices
GMP	Good Manufacturing Practices
GQA	Global Quality Audit
GVP	Good Pharmacovigilance Practices
GxP	Combined term for GCP, GDP, GCLP, GLP, GMP, GRP, GVP
M&S	Manufacturing and Supply
ICH	International Council on Harmonization
ICH Q10	An ICH guideline describing the modern quality systems needed to establish and maintain a state of control that can ensure the realization of a quality drug product and facilitate continuous improvement over its life-cycle.
OTC	Over The Counter
QMS	Quality Management System

Foreword

I am pleased to share with you this 9th edition of our Global Quality Manual.

This edition establishes the foundation of our Quality Ambition towards a more dynamic, highly performing, and data-driven operating model in support of our Company transformation.

Our Quality Management System remains based upon our strong commitment to deliver high-quality products and services to address patient needs and operate in compliance with all applicable regulations throughout their life-cycle. The new quality organization reflects our alignment with the operations we support and was established to drive the transformation of our Quality Management System to the operational level. These transformations are meant to strengthen our Quality Culture and to promote a new mindset and ways of working throughout the organization.

Our Quality Management System remains based on standards reflecting our interpretation of all applicable regulations but is further enriched by Global Quality Procedures directly applicable at shopfloor level to ensure a consistent and reliable execution of our activities. This documentation is constantly evolving to ensure continuous improvement and alignment with regulatory developments and to support the needs of our Global Business Units and Global Functions. The electronic tools supporting our Quality Management System are also significantly transforming to better serve our organization in its daily activities. This digital transformation program is meant not only to strengthen our capabilities to continuously improve our systems and processes but also to increase the overall performance of our organization through the introduction of new technologies.

This Quality Manual remains closely connected to the Play to Win pillars of the Company and supplements the Code of Conduct established by the Ethics and Business Integrity group. It provides a concise and useful overview of our Quality System structure and related key processes to all Sanofi personnel, external partners and regulators.

I am convinced that the recent and upcoming evolutions of our Quality Management System will strengthen our capabilities to chase the miracles of science and improve people's lives.

Maite Durrenbach
Chief Quality Officer

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1 Introduction to the Global Quality Manual

1.1 Purpose

The purpose of this Global Quality Manual is to describe the framework and principles of the Sanofi Quality Management System (QMS). It is fully aligned with the ICH Q10 Pharmaceutical Quality System.

The Sanofi QMS is intended to ensure that Sanofi products and services satisfy the expectations of our patients, customers and other public health needs, in full compliance with applicable regulations (GCP, GDP, GLP, GCLP, GMP, GRP & GVP) and other health-related requirements.

In addition, the activities performed by our people are driven by the Sanofi Code of Conduct established by the Ethics and Business Integrity group.

1.2 Scope

This Global Quality Manual applies to all activities related to the research, development, manufacturing, distribution, and discontinuation of Sanofi products and services as well as to medical and commercial activities, regardless of where these activities take place.

1.3 Sanofi at a Glance

Sanofi is a global life sciences Company committed to improving access to healthcare and supporting the people we serve throughout the continuum of care. From prevention to treatment, Sanofi transforms scientific innovation into healthcare solutions, in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes, cardiovascular, and consumer healthcare.

Approximatively 100,000 people at Sanofi are dedicated to making a difference in patients' daily lives, wherever they live, and enabling them to enjoy a healthier life.

1.4 Our Business Strategy

The Sanofi business strategy, Play to Win, is built upon four key priorities:

- Focus on Growth: Portfolio prioritization to strengthen profile
- Lead with Innovation: Bring transformative therapies to patients
- Accelerate Efficiency: Decisive actions to expand margins
- Reinvent How We Work: Empowerment and accountability

1.5 Our Products and Services

Sanofi manufactures a diverse profile class of products and services, categorized as:

- Drug substances (Active Pharmaceutical Ingredients)
- Cosmetics
- Investigational medicinal products
- Medical devices, including digital solutions, and combination products
- Medicinal products (including OTC products)
- Nutraceuticals
- Vaccines

1.6 Our Behaviors

Sanofi Play to Win strategy is supported by four behaviors:

#1 Stretch to go beyond the level we have operated at up until now

#2 Take action instead of waiting to be told what to do

#3 Act in the **interest of our patients and customers**

#4 Think Sanofi first: put the interest of the **organisation** ahead of ourselves or our team

1.7 Sanofi Organization and Activities

The Sanofi Company is organized as follows:

- Four Global Business Units (GBUs) integrating global franchises, country-level commercial and medical organizations for each of our major businesses:
    - Specialty Care - Dupixent and specialty production (Rare Diseases, Multiple Sclerosis, Oncology & Immunology)
    - General Medicine (Insulins, Clexane, and new product launch)
    - Vaccines
    - Consumer Healthcare
- Various Global Functions
    - Corporate Affairs
    - Finance
    - Digital
    - Global Business Services
    - Global Manufacturing & Supply
    - Global Research & Development
    - Human Resources
    - Internal Audit & Risk Management
    - Legal, Compliance & Business Integrity

2 Sanofi Quality Policy

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QUALITY POLICY

We chase the miracles of science to improve people's lives

Sanofi's transformation is anchored by our "Play to win" strategy, based on 4 key priorities: Focus on growth, lead with innovation, accelerate efficiency and reinvent how we work.

Quality supports this transformation, ensuring we operate in compliance with regulations and deliver high quality products throughout their full life cycle, to address patients' needs.

This objective is achieved by implementing a single Quality Management System across all activities in Sanofi that is simple and robust and deeply integrated. The QMS leverages data and digital to enhance our risk-based approach and improve our prevention and prediction capabilities. We are converting our operating model to become more dynamic, performance oriented and data driven.

Because our company is committed to a Quality-driven culture, it is the responsibility of each and every employee to act in a compliant and ethical way, as we work together to transform the practice of medicine.

September 2022

Paul Hudson
Chief Executive Officer

POLITIQUE QUALITE

Nous poursuivons les miracles de la science pour améliorer la vie des gens

La transformation de Sanofi est ancrée dans notre stratégie 'Play to Win', et est basée sur quatre priorités : Se focaliser sur la croissance, être à la pointe de l'innovation, accroître l'efficacité opérationnelle et réinventer notre façon de travailler.

Notre engagement Qualité est de soutenir cette transformation, en s'assurant que nous opérons conformément aux réglementations et que nous délivrons des produits de haute qualité tout au long de leur cycle de vie, afin de répondre aux besoins des patients.

Cet objectif est atteint par la mise en œuvre d'un système unique de gestion de la qualité pour toutes les activités de Sanofi. Il se veut simple et robuste, profondément intégré. Il exploite les données et les technologies numériques pour renforcer notre approche basée sur l'analyse du risque et améliorer nos capacités de prévention et de prédiction. Nous convertissons notre modèle opérationnel pour le rendre plus dynamique, plus performant et axé sur les données.

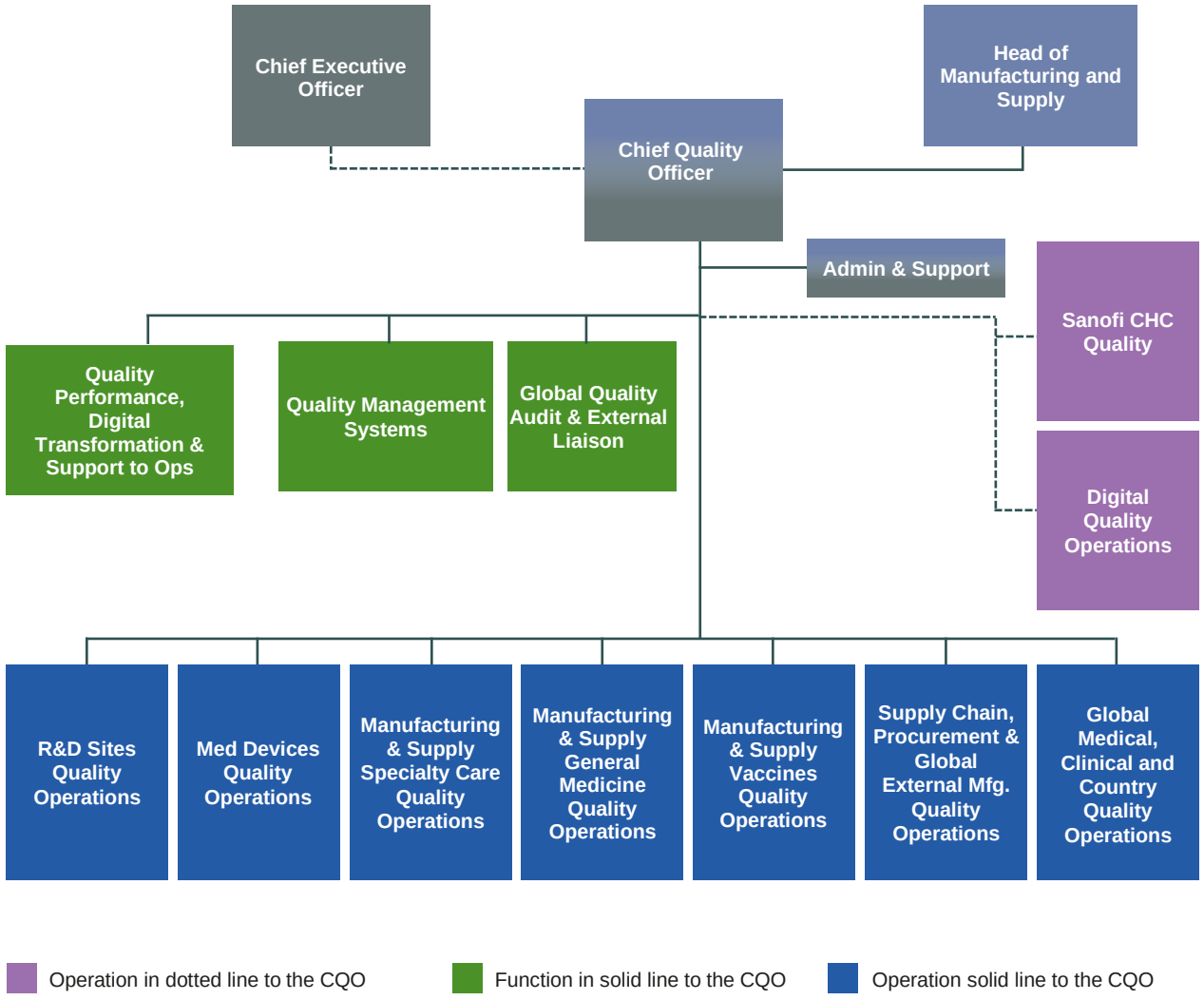
Parce que notre entreprise est engagée pour la culture qualité, il est de la responsabilité de chaque employé d'agir de manière conforme et éthique, alors que nous travaillons ensemble pour transformer la pratique de la médecine.

September 2022

Maïté Durrenbach
Chief Quality Officer

3 Quality Organization and Responsibilities

3.1 Organization Chart



3.2 Sanofi Chief Quality Officer

The Sanofi Chief Quality Officer is directly responsible to the Chief Executive Officer for defining the Sanofi Quality Policy, coordinating its implementation across the relevant Sanofi entities, and ensuring compliance with the related regulatory and Company requirements. The Sanofi Chief Quality Officer is the representative of the Sanofi senior management for quality-related matters.

In addition, the Sanofi Chief Quality Officer reports operationally to the Executive Vice President of Global Manufacturing & Supply, and is a core team member of the Sanofi Global Manufacturing & Supply Leadership team and the Sanofi Global Compliance Committee.

3.3 Global Quality Functions

Three Global Quality Functions directly report to the Sanofi Chief Quality Officer:

Global Quality Management System

The mission of the QMS group is to maintain the Sanofi QMS foundational elements, based upon the strategic orientations of the Company and applicable health-related regulations, and drive the key compliance activities to assure patient safety and product quality and services across the entire organization

This mission is achieved through the following Global Quality functional areas reporting to the Head of QMS:

- Qualified Persons & Pharma Affairs
- Industrial CMC Compliance & Pharmacopoeia
- Quality Alert Management, including Product Recall, Quality Alerts, Product Alerts of quality origin, and Product Shortage reporting
- Quality Risk Management
- Quality Training, Communication, and Culture
- Quality Documentation
- Quality Strategy

Global Quality Performance, Digital Transformation, and Support to Operations

The mission of the Global Quality Performance, Digital Transformation, and Support to Operations is to drive the transformation of the quality systems across all entities to operational level, to lead the evolution and implementation of Sanofi quality standards and digital solutions, to drive the quality performance, and to provide expertise to quality operations on technical topics.

This mission is achieved through the following Global Quality functional areas reporting to the Head of Quality Performance, Digital Transformation, and Support to Operations:

- Quality Performance
- Quality Assurance BPO
- Quality Programs
- QC Excellence
- Technical expertise and site support

Global Quality Audit and External Liaison

The mission of Global Quality Audit and External Liaison is to:

- Provide Senior Management accurate, independent assessments of compliance to the Sanofi QMS through regular surveillance audits of Sanofi entities and key third parties
- Support Pre-Approval Management Group (PMG) activities and entity regulatory inspections
- Lead the Quality external strategy and influence external pharmaceutical industry associations and regulatory agencies to advocate and promote the Sanofi Global Quality "One-Voice" strategy
- Perform quality assessments in support of due diligence
- Deliver auditor qualification and technical training

3.4 Operational Quality Units

Nine Operational Quality Units report to the Sanofi Chief Quality Officer.

The mission of the Heads of the Operational Quality Units is to lead and coordinate quality and compliance in their Operational Units to ensure that all products and services are designed, developed, manufactured, and distributed in compliance with the applicable regulatory and Company requirements.

This includes the following responsibilities, as a minimum:

- Accountable for GxP compliance and quality performance for products and services in the GBUs
- Ensure and harmonize consistent implementation of the Sanofi QMS in their Operational Unit
- Ensure continuous improvement of the quality concepts, promote innovation and systems performance in their Operational Unit
- Provide support to the local entities of their Operational Unit on quality and compliance topics
- Integrate risk management principles into quality systems
- Review and approve quality organizations of their Operational Unit
- Assess performance of quality management in conjunction with operational management
- Ensure inspection readiness and strict follow-up to GxP regulatory inspections

The Heads of the Operational Quality Units report operationally to the Chief Quality Officer, except for the Head of the CHC Quality Operations and the Head of Digital Quality

Operations who report functionally to the Sanofi Chief Quality Officer. The head of R&D SQO reports also functionally to the R&D Operations Head.

3.5 Site Quality Management

At each site involved in research & development, manufacturing, and distribution activities, a Site Quality Head or Manager is appointed to define, implement, manage, and control the Quality Systems at the site to ensure the quality of products and services and to guarantee compliance with applicable regulatory requirements and the Sanofi QMS.

For M&S, the SQM reports to the Head of the Operational Quality Unit and to the Senior Site Director or General Manager. For R&D, the SQM reports to the R&D Operations Units Head.

3.6 Country Quality Management

At each Country Commercial office within Sanofi, a Country Quality Head is appointed to define, implement, manage, and control the Country Quality System to ensure the quality of products and services at market level and to guarantee compliance with applicable regulatory requirements and the Sanofi QMS.

The Country Quality Head reports to the Regional Quality Head and to the Country Lead.

In countries where local regulations require a Responsible/Qualified Person, the Country Quality Head is either the Qualified Person or delegates this responsibility to a designated person.

3.7 Senior Management

Senior Management is a team of individuals at the highest level of authority in their respective organization who have the day-to-day task to manage that organization.

Senior Management at operational unit, site, and country level has the ultimate responsibility for the overall effectiveness of the QMS. Senior Management ensures that roles, responsibilities, and authorities related to the QMS are defined, communicated, and implemented throughout the Sanofi Company.

In practice, Senior Management:

- Participates in the design, implementation, monitoring, and maintenance of the QMS throughout their organization
- Demonstrates strong and visible commitment to the QMS
- Ensures a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management
- Conducts management reviews of process performance, product quality, and the QMS effectiveness
- Advocates continuous improvement
- Determines and provides adequate and appropriate resources to implement,

maintain, and continuously improve the QMS

3.8 Process and Systems Owners

Process owners are accountable for the end-to-end process and from the standard and process design to its performance measurement. The process owners ensure the GxP compliance of the process and its continuous improvement and establish the quality standard and training requirements related to the system.

System owners are accountable for the alignment of the computerized solution with the process and strategy defined by the process owner and ensure the GxP compliance of the computerized solution and associated data.

3.9 Responsibilities for Third Parties (Services Providers, Suppliers, and Subcontractors)

Development (including clinical and/or laboratory study activities), manufacturing, and distribution of Sanofi products, as well as GxP-related services and medical and commercial activities, may be with an alliance partner or subcontracted to third parties, under the responsibility of an operational unit, site, external manufacturing, or country.

The acceptability of these partners (and their third parties) and our third parties (service providers, suppliers, and subcontractors) is verified through a formal process including initial assessment (including due diligence), qualification, and routine evaluation of their compliance with applicable regulatory requirements and the Sanofi QMS.

In addition, GxP-related materials, equipment, and services are purchased from approved or certified suppliers using predefined acceptance criteria, including compliance with technical specifications and quality requirements.

The quality oversight of partners and all third parties is under the responsibility of the relevant operational quality unit, site quality management, external manufacturing quality, or country quality management.

3.10 Responsibilities for Supply Chain

Operational units, sites, external manufacturing, and countries are responsible for maintaining the quality, security, and traceability of all Sanofi materials and products throughout their physical flows. This responsibility includes the implementation of appropriate technologies to protect the materials and products against diversion, counterfeit, and falsification.

Throughout the entire supply chain, appropriate conditions of storage, transport, and delivery of materials and products ensure that the quality attributes of materials and products are maintained in compliance with applicable regulatory and Sanofi QMS requirements.

3.11 Responsibilities for Computerized Systems

Computerized systems in support of development (including laboratory studies and clinical trials), manufacturing, distribution, and medical and commercial activities, and

the electronic data they contain, are subject to specific regulatory requirements. Computerized systems that are part of the products and services, such as software embedded in medical devices, are also subject to such requirements.

These requirements apply during the whole system life-cycle, including design, development, validation, use, support, maintenance, and decommissioning.

The Digital Quality Operation Unit ensures that computerized systems are built, supported, and maintained in compliance with applicable regulations and expected business performance (including data integrity) during their entire life-cycle.

Global Quality, Operational Quality Units, Site Quality Management, and Country Quality Management ensure that computerized systems are fit for their intended use and comply with applicable regulations and expected performance, so that the business process and system do not adversely impact the product quality, patient and consumer safety, and related data integrity.

3.12 Responsibilities for Personnel Qualification and Training

All Sanofi employees who are directly or indirectly operating within the Sanofi QMS and are engaged in the research, development, manufacturing, distribution, and discontinuation of the Sanofi products and services, are assured to have the right education, skills, training, and experience, or any combination thereof, to enable them to perform their assigned roles.

Training in the applicable regulations and Sanofi QMS is mandatory for all Sanofi employees and is regularly conducted within their functional areas and with sufficient frequency to assure that employees remain familiar with the applicable requirements and processes.

The quality training is an important enabler of Personnel Qualification and Training as it provides training resources and fosters continuous learning and education to our people. Together with representatives of global functions and operational platform units, the quality training governance prioritizes and rationalizes training related to quality competencies.

3.13 Responsibilities for Quality Documentation

The site, platform, and country quality management are responsible to ensure the roll-out and the enforcement of the requirements of the Sanofi global quality documentation system at local level. Consistency and continuity between both systems are critical.

4 Management Responsibilities

Senior management has the responsibility to demonstrate strong and visible commitment to the Sanofi QMS by taking accountability and responsibilities for the following activities. The participation and commitment of all personnel to the Sanofi QMS is effectively achieved through Senior Management leadership and action.

Senior management and their teams are responsible for implementing and maintaining the Sanofi QMS within their respective operational unit, site, or country. Therefore, management must commit to the principles described below.

4.1 Planning

Senior management fully integrates quality into the organization's strategic and operational planning and business processes.

The Global Quality Senior Leadership Team establishes a Companywide vision as a basis for the quality strategy, goals, and objectives and cascades them throughout the organization with the purpose of involving personnel at all levels of the Company in quality improvement. Quality objectives are aligned with the Company's strategy and are consistent with the Quality Policy.

4.2 Organizing

Senior management provides the required capital and human resources to guarantee complete and timely delivery of the strategic and operational plans and to implement, maintain, and continuously improve the QMS. This includes sufficient numbers of personnel that have the necessary competencies to fulfil their roles and responsibilities, appropriate facilities and equipment, and ways of working operating effectively across the entire Sanofi Company.

4.3 Communicating

Senior management provides effective communication and related communication processes to promote the Quality Policy and quality objectives to increase awareness, engagement, and involvement of everyone in Sanofi.

The Sanofi Quality Alert process ensures a timely and effective communication and escalation of product quality and quality system issues to the appropriate levels of management.

4.4 Measuring

Senior management has a performance measurement and reporting system for quality

results, quality issues, and progress against quality objectives. Measures are used to identify areas for continuous improvements.

4.5 Reviewing

Senior management has quality performance metrics reviewed as a key requirement in relevant senior management meetings.

As quality governance, progress against the strategic and operational plans is evaluated regularly, and the overall process performance, product quality, and effectiveness of the QMS is reviewed actively. These reviews are intended to identify areas for continuous improvement.

4.6 Improving

Senior management sets continuous quality improvement as an objective throughout Sanofi.

4.7 Other Areas of Management Responsibilities

4.7.1 Management of Change in Product Ownership

Management takes responsibility for the integration of a new entity into the Sanofi Company and the Sanofi QMS in accordance with the selected integration model.

4.7.2 Monitoring of Internal and External Factors impacting the QMS

Management monitors internal and external factors that have a potential to impact the Sanofi QMS. Monitored factors include the following:

- Emerging regulations and guidance
- Quality issues that can impact the QMS
- Innovations that may enhance the QMS
- Changes in the business environment and business objectives

5 Enablers

5.1 Quality Risk Management

Quality risk management is an integral part of the Sanofi system of control and governance.

A systematic risk management process provides a proactive means to identify, assess, remediate, mitigate, escalate, monitor, review, and communicate potential quality risks applicable to products and services, processes, systems and projects, operational units, sites, and countries. This process includes review and escalation of both proactive and reactive risks at local and global levels that incorporate the review of risks.

Quality risk management facilitates continuous improvement of process performance and product and services quality. Mechanisms, including the establishment of a Site Risk Profile and the escalation of quality alerts, are means to identify, track, and trend risks throughout the product life-cycle.

A Quality Risk Representative is designated by the Operational Quality Units to lead and provide oversight of the quality risk management of their unit. This oversight is achieved in accordance with the requirements set in the Global Quality Risk Management documentation.

At a global level, quality risks are further consolidated, ranked, and managed following the Global Quality Risk Profile process.

5.2 Knowledge Management

There are several systematic processes within Sanofi that are designed to formally acquire, analyze, store, and disseminate product and process knowledge throughout the product life-cycle.

These processes, which are explained within our Global Quality documents, help to ensure effective product development, scale up, technology transfer, process validation, continual improvement, and post-approval change management that meet all the applicable regulatory and Company requirements.

5.3 Quality Culture

Quality culture is the mindset and behavior to consistently perform the right things in the design and execution of the quality management principles right first time. It applies to people from all entities, GBUs, and businesses in Sanofi. Within Sanofi, the quality culture is critical for the successful execution of our business performance and strategy. In this context, Global Quality has defined the quality culture as "*an environment where employees can hear, see, and feel quality all around them*".

5.4 Data Integrity

Data integrity is paramount to support the quality, safety, and efficacy claims of our products. Global Quality is, therefore, engaged in fostering data integrity assurance at all levels of the Company through implementation of our quality standards during data life-cycle. A dedicated training program is also in place to reinforce this critical concept to all employees handling GxP data.

6 Sanofi Global Quality Documentation System

Sanofi Global Quality Documents are classified in alignment with the Sanofi Global Process Framework.

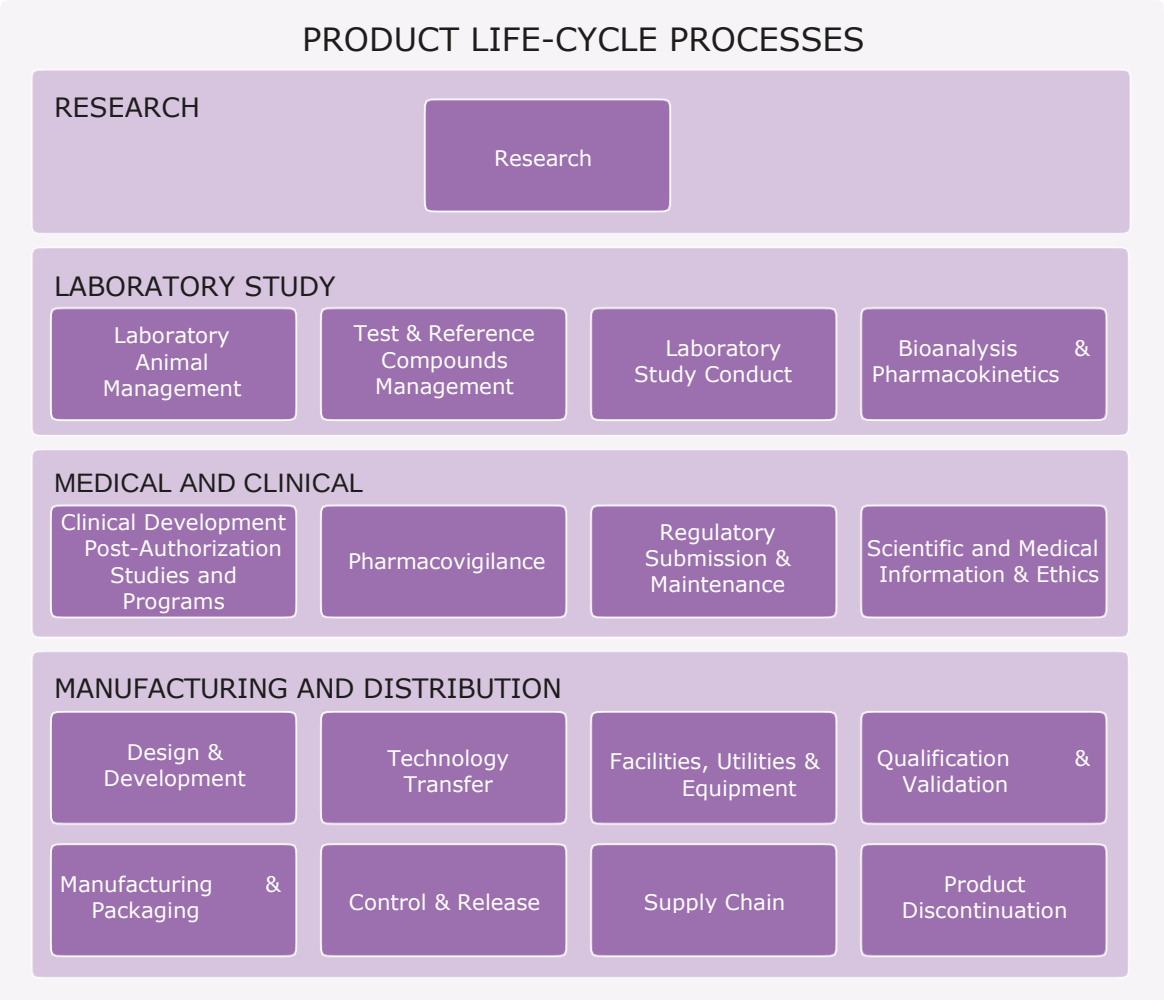
6.1 Quality Processes

The Global Quality documents are grouped in alignment with the Quality processes covering the GxP-regulated activities, as well as other health-related regulations.

There are three categories of Quality processes:

- **Product Life-Cycle Processes:** directly contribute to the design, development, and realization of effective and safe products and services for the benefit of patients and consumers
- **Transversal Processes:** support the Product Life-Cycle Processes to ensure their proper management, control, and continuous improvement
- **Organizational Processes:** contribute to the organization and management of the Sanofi Quality System by providing consistent directions and adequate support

6.1.1 Product Life-Cycle Processes



Research Process:

PROCESS	OBJECTIVE
Research	Ensure that the first stages of product development - including basic scientific exploration and discovery as well as studies and analysis of early development that are not covered by GxPs - are properly organized, performed, documented, and archived to ensure the integrity of data, the protection of intellectual property, and adequate dossiers submission.

Laboratory Study Process:

PROCESS	OBJECTIVE
Laboratory Animal Management	Manage all aspects related to the care and use of laboratory animals in alignment with the fundamental principles of animal welfare.
Test & Reference Compounds Management	Manage any article that is either the subject of a laboratory study or provides a basis for a comparison with the study object.
Laboratory Study Conduct	Ensure the proper management of laboratory studies, starting from the protocol, continuing through the generation of study data and the production of the report, and ending with the data archiving.
Bioanalysis & Pharmacokinetics	Analyze biological samples with the aim to provide knowledge and understanding of the disposition of the product in animals and humans.

Medical and Clinical Process:

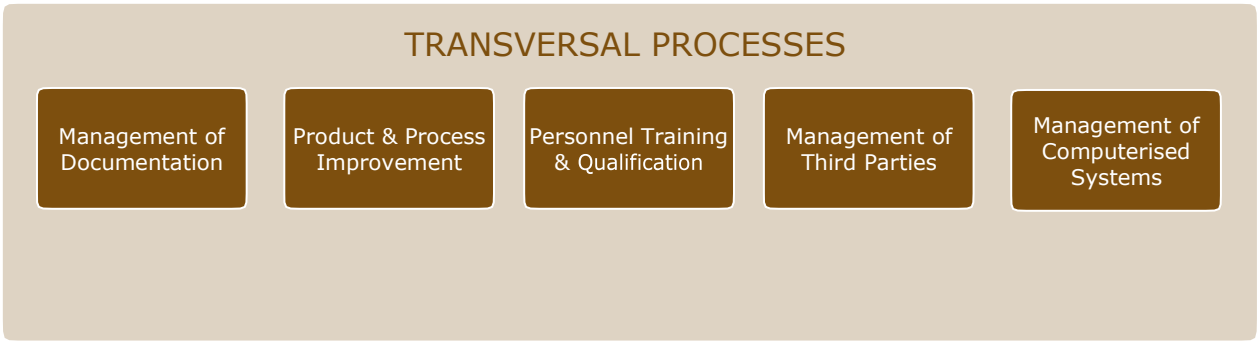
PROCESS	OBJECTIVE
Clinical Development, Post-Authorization Programs	Conduct studies and programs in humans for all products in clinical development and post-authorization to provide knowledge and documentation necessary for the worldwide registration of new products or new indications or line extensions, as well as medical and clinical knowledge throughout the product life-cycle.
Pharmacovigilance	Ensure establishment of the safety profile and contribution to evaluation of the therapeutic value for all products in clinical development. Ensure continuous monitoring and management of the safety profile and risk minimization of all products marketed by the Company. Coordinate and ensure Benefit-Risk assessment throughout the product life-cycle for continuous monitoring of risks and benefits of medicinal products
Regulatory Submission & Maintenance	Manage regulatory activities required to submit information to the regulatory authorities, obtain approval, and maintain the Sanofi portfolio.

Scientific and Medical Information & Ethics	Ensure ethical and responsible conduct when dealing with patients, consumers, and subjects participating to studies and programs. Ensure scientific and medical information is provided according to international standards to patients, healthcare professionals, and consumers.

Manufacturing and Distribution Process:

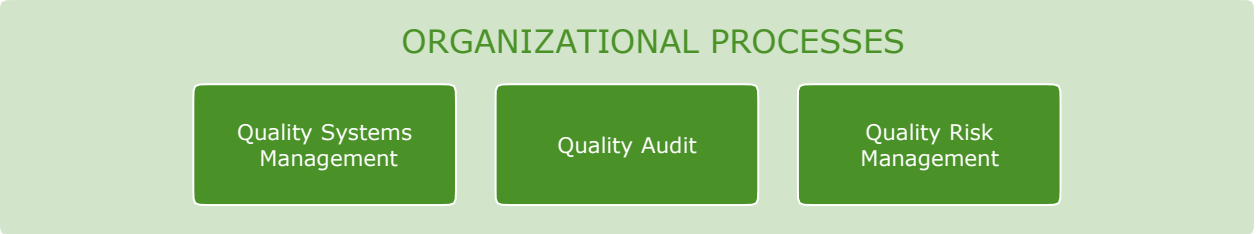
PROCESS	OBJECTIVE
Design & Development	Ensure the product and process design and development is suitable for routine commercial manufacturing that can consistently deliver a product that meets its quality attributes. Build quality by design and define the control strategy to ensure adequate product quality, purity, and strength for its intended purposes and to satisfy patient needs and costumer expectations.
Technology Transfer	Ensure that product transfers result in robust, reliable, cost-effective, and appropriate manufacturing, packaging, and testing controls and that the transferred products comply with applicable regulatory and Company requirements.
Facilities, Utilities, and Equipment	Design, manage, maintain, and decommission facilities, utilities, and equipment used to conduct laboratory, manufacturing, and distribution activities related to Sanofi products to ensure the quality of the studies and products and to minimize the risk of contamination.
Qualification & Validation	Demonstrate compliance of the critical aspects of the development, manufacturing, control, and distribution of Sanofi products with pre-established requirements.
Manufacturing & Packaging	Manufacture and package products to consistently meet all the required quality attributes and specifications.
Control & Release	Ensure that materials, intermediates, and finished products are sampled, analyzed and formally released by quality management before use or distribution.
Supply Chain	Ensure the timely delivery to production of the right quantity and quality of materials for use in the manufacturing and packaging of Sanofi products. Manage the physical flows of Sanofi materials and products while maintaining their quality, security, and traceability. Ensure that Sanofi customers receive the right quality product at the right time. Ensure that, when a product is deemed unfit based on adequate investigation, product discontinuation actions are properly taken.
Product Discontinuation	Manage the activities associated with the terminal stage of the product life-cycle, such as retention of documentation and samples, and continued product assessment and reporting in accordance with regulatory requirements.

6.1.2 Transversal Processes



PROCESS	OBJECTIVE
Management of Documentation	Ensure that documents and records supporting regulated activities are issued, managed, controlled, and archived in a way to accurately reflect the complete history of Sanofi products and services throughout their life-cycle.
Product & Process Improvement	Enhance products and improve processes to consistently and better meet the needs of customers and patients, and to promote innovation and enhance performance while respecting the related regulatory and Company requirements.
Personnel Training & Qualification	Ensure that the personnel involved in the Sanofi Quality Processes are trained and qualified for their assigned tasks.
Management of Third Parties	Ensure that service providers, suppliers, and subcontractors, who perform one or several steps in the life-cycle of Sanofi products and services and who supply materials and GxP services associated with this life-cycle, are selected and managed in accordance with business and quality requirements.
Management of Computerized Systems	Ensure that computerized systems and digital solutions used in support of regulated activities are designed, implemented, validated, and operated in a way to fulfil the applicable regulatory and Company requirements.

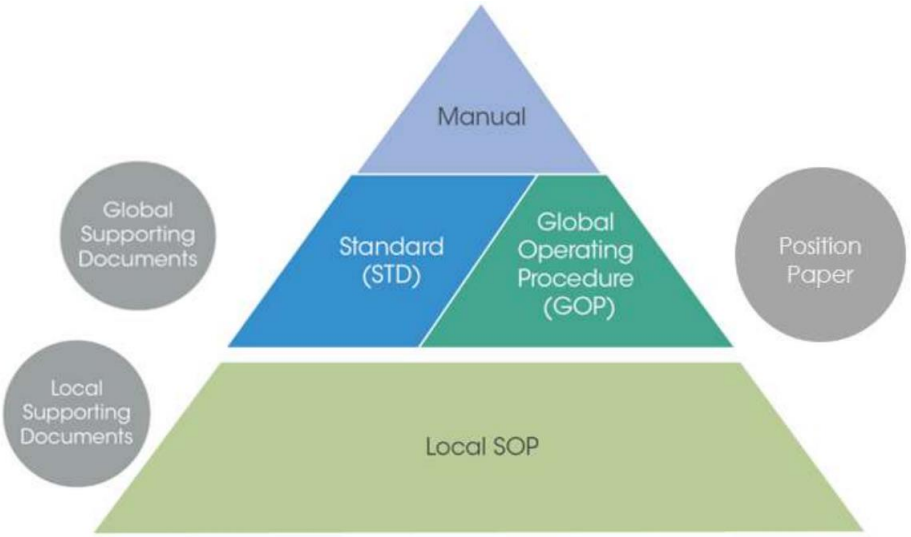
6.1.3 Organizational Processes



PROCESS	OBJECTIVE
Quality Systems Management	Deploy the Quality Policy across Sanofi through the implementation and monitoring of Quality Systems based upon the related regulatory and Company requirements.
Quality Audit	Provide an accurate, independent assessment of the compliance of the operational units, sites, countries, global functions, and third parties to the Sanofi QMS.
Quality Risk Management	Implement a systematic, consistent, and efficient process for the identification, assessment, remediation/mitigation, escalation, monitoring/review, and communication of risks related to the quality and compliance of the products, services, and activities by each operational unit, site, country, and functions throughout the product/services life-cycle.

6.2 Documentation Hierarchy

The Sanofi Global QMS documentation hierarchy is displayed in the following diagram:



The process to establish, review, approve, and distribute Global Quality documents as well as their supporting documents is detailed in the Global procedure "*Life-cycle Management of Global Functions Documents*".

Global Quality documents are developed for each type of GxP and public health-related regulation: research and laboratory studies, clinical and medical, manufacturing and distribution, commercial country activities, and information systems.

GxP documents used at all levels of the Sanofi Quality Documentation System are subject to the requirements set forth by the Global Quality document "*Management of GxP Documents and Records"* and are available for inspection by regulatory authorities.

6.3 Quality Document Types

DOCUMENT TYPE	OBJECTIVE
Quality Policy	Describes the overall intentions and direction of the Sanofi Company related to Quality. The Quality Policy is endorsed by the Sanofi Chief Quality Officer and by the Chief Executive Officer. The Quality Policy includes the expectation to comply with applicable regulatory and Company requirements and promotes continuous improvement. The Quality Policy is communicated to personnel at all levels of the Company.
Quality Manual	Contains the description of the QMS including the Quality Policy, the scope of the QMS, the Quality processes with their sequences, linkages, and interdependencies, and Management responsibilities. The Quality Manual is endorsed by the Sanofi Chief Quality Officer.
Standards	Describe mandatory regulatory and Company requirements for specific or transversal activities, which must be complied with. Apply to one or several product ranges. Applicable to all Sanofi entities involved in the activities described.
Position Papers	Describe the Sanofi position regarding a specific topic not necessarily associated with mandatory regulatory requirements. The position paper can be issued either for external communication or for internal use.
Supporting Documents	Help to standardize the implementation of quality documents (typically templates, logs, checklists, etc.). Can be associated with Standards, Global Operating Procedures, or any local document. Mandatory document to be used, unless otherwise specified in the supported document.
Global Operating Procedures	Give instructions for performing operations that are transversal across different entities or functions. Applicable to all operational units, sites, countries, or functions performing the described activity. The Global Operating Procedures are directly used at local level when applicable or cascaded in a platform or local document.
Local Quality Documents	Give instructions for performing operations that are specific to a site, country, or function.

7 Global Quality Audits and Regulatory Inspections

Sanofi operational units, sites, countries, and functions are periodically audited to verify compliance with the Sanofi QMS. These audits are performed by the Global Quality Audit team, and the audit frequency, duration, and number of auditors are determined using a risk-based model. The audit approach and audit system used have been accredited to ISO/IEC 17020:2012, which is an international standard specifying requirements for the competence of bodies performing audits as well as for the impartiality and consistency of the audit activities.

These audits also facilitate readiness of the Sanofi entities and functions for regulatory authority inspections, ensuring that Sanofi is meeting all regulatory obligations and commitments.

A key aspect of the QMS is to ensure that all relevant Sanofi entities are prepared at all times to receive Regulatory Authorities' inspections. To ensure on-going inspection readiness, the following tools and support are provided:

- Inspection Preparation can be provided by Global Quality Audit and Operational Quality Units. This support can be provided both prior to and during inspections.
- Mock Audits can be performed by Global Quality Audit at request of the entity, Global Quality functions, operation quality units, and site or country quality management. Mock audits are also used as part of the pre-approval inspection management process.

When deviations from internal or external requirements are identified during audits or regulatory inspections, corrective and preventive action plans are put in place and monitored until resolution.

Global Quality Audit is also responsible for coordinating (in partnership with R&D Sites Quality Operations) GxP evaluations in the due diligence for product, process, or Company acquisitions involving a cluster of countries, a single region, or multiple regions/global projects. In addition, Global Quality Audit is responsible to carry out a baseline audit within six (6) months of such acquisitions.

8 Document Approvals

This document is electronically approved in GEODE+.

9 Document History

December 2009 - V 1.0

- First version of this Global QM

June 2011 - V 2.0

- Creation of Global Operations Quality
- Creation of the Risk Committee
- Minor modifications of the process model:
  - Commercial activities are replaced by Scientific and Medical Information and Marketing activities
  - Support processes are renamed Transversal processes
  - Clinical development and post-Marketing studies are merged
  - Laboratory studies managed as a separated domain
- New section on Responsibilities for Computerized Systems
- New section on integration of new entities
- Integration of Merial and Genzyme
- Changes in the definition and applicability of Operational Quality Guidances
- Addition of a paragraph related to Quality Liaisons
- Added several regulatory references
- Minor editorial changes

July 2013 - V 3.0

- Seventh growth platform added for rare diseases
- Genzyme and Merial added to the group's organization
- Creation of the Executive Compliance Committee and Bioethics Committee
- Creation of the Global Quality Strategy Office
- Products containing software (e.g. iBGStar)
- Section added on the role of Senior Management
- Clarification that global quality documents are inspectable by regulatory authorities
- Clarification that Global Quality Directives apply immediately to integrated companies, regardless of the integration model
- Role of quality in the due diligence process
- Modifications of the process model:
  - New process for early Research
  - Detailed processes for Laboratory Studies (laboratory animals, test and reference compounds, study conduct, bioanalysis and pharmacokinetics)
  - Added process for Health Ethics and Transparency

- Minor update of glossary and references

February 2016 - V 4.0

- Combination product and sub-categories of veterinary products introduced
- 3 main business segments introduced (Pharma, Human vaccines and Animal Health replaced and the seven platforms for sustainable growth)
- New Sanofi organization and activities
- Introduction of the Global Business Units including diabetes and cardiovascular, general medicines and emerging markets, Sanofi Genzyme, Sanofi Pasteur, and Merial
- New Sanofi Quality Policy
- Update of the Global Quality Organization and functions
- The Affiliate Quality Officer was renamed Country Quality Head and precisions were given on the country's responsibilities
- The paragraph defining the responsibilities of Supply Chain was moved in section 4.7
- Sites involved in development and manufacturing of medical devices must establish a local Quality Manual
- Global Documents introduced
- Modifications of the process model:
  - Added process for Marketing and Sales in the new Marketing and Sales domain
  - Added process for Medical Benefit and Risk Governance in Clinical and Medical domain
  - Clinical Development & Post-Marketing Studies process renamed Clinical Development & Post-Authorization Studies
  - Scientific and Medical Information and Marketing process renamed Scientific and Medical
  - Information
  - Product discontinuation process removed from the Manufacturing and Distribution domain
- New section Personnel Training and Qualification
- Quality Intelligence, Quality Commissions, Risk Commissions and Quality Communication introduced in Continuous Improvement of the Quality System section
- Update of the Quality Risk Management section
- Minor update of glossary and references

November 2017 – V5.0

- Simplification of content and format in alignment with the Company objective of focus and simplification.
- New Sanofi Chief Quality Officer
- New Sanofi Quality Organization
- Clarification of the link between the Quality Processes and the Quality Documentation
- New section on enablers of the QMS, including Knowledge Management and Quality Culture

- New format of the QM
- Minor editorial changes

November 2019 – V6.0

- Update of the Sanofi Organization and Sanofi GBUs
- Updated the Quality Policy and Quality organization (chart and responsibilities). Introduction of 'Global Quality External Liaison' as well as 'Process and System Owners' responsibilities
- Updated 'Quality Risk Management' and 'Quality Culture' Enablers. Introduction of a new section 'Data Integrity'
- Updated 'Research' and 'Product and Process Improvement' processes objective in the section Global Quality Documentation System
- New documentation pyramid. Update of document types and few words about the transition period before the complete transition to the new pyramid.
- Global Quality Audits and Regulatory Inspections updated (ISO 17020 accreditation and due diligence process).
- Minor editorial changes

December 2020 – V7.0

- Update of the Forewords
- Update of Section *1.4 Our Business Strategy* with the new Sanofi Strategy
- Update of section *1.6 Our values* which becomes section *1.6 Our behaviors*
- Update of Section *1.7 Sanofi Organization and Activities*: Removal of Primary Care and China and emerging market, removal of the Chief medical office & Medical function, addition of General medicine as a GBU, SAIS as the unit in charge of API manufacturing and Digital office
- Update of Section *3.1 Organization Chart* with the new organization
- Update of Section *3.3 Global Quality Functions* with Global QMS and Digital transformation replacing Global Quality Strategy, Compliance and Transformation.
- Update of Section *3.4 Operational Quality Unit*: MCCQ head no longer reporting to Chief Medical Office, addition of SAIS and replacement of ITS QO by Digital Quality Operation
- Update of Section *3.6 Operational Quality Units*: removal of the delegation of a qualified person for R&D activities at country level
- Update of Section *6.1.1 Product life-cycle processes* for the process "Pharmacovigilance" with the addition of the coordination of the Benefit-Risk assessment and for the process "Scientific and Medical Information & Ethics" with the removal of the establishment of a governance for the medical benefit risk balance.
- Addition in section *3.3 Global Quality function* and section *7 Global Quality Audits and Regulatory Inspections* that R&D contribute with GQA to due diligence audits
- Minor editorial changes

February 2022 – V8.0

- Update to integrate new branding new logo, color, font and picture.
- Update Section *1.7 Sanofi Organisation and activities*, removal of "One unit in charge of API manufacturing: SAIS"
- Update of Section *2. Sanofi Quality Policy* with new branded Policy
- Update of Section *3.1 Organization Chart* with new organization
- Update of Section *3.3 Global Quality Functions* with GQA and External Liaison mission
- Minor editorial changes

February 2023 – V9.0

- Update of the Forewords
- Added in section *1.1 Purpose* "In addition, the activities performed by our people is also driven by the Sanofi Code of Conduct established by the Ethics and Business Integrity organization."
- Update of section 2 with the new Quality Policy
- Update of Section *3.1 Organization Chart* with the new organization
- Update of Section 3.3 Global Quality Functions with Global QMS and Global Quality Performance, Digital transformation and support to operations replacing Global QMS & Digital Transformation.
- Update of Sections *6.1.2 Transversal Processes* and *6.1.3 Organizational Processes*: Removal of the reference to the Internal Control Manual.
- Update of Section *6.2. Documentation Hierarchy* and *6.3 Quality documentation type*: Removal of the reference to the old documentation.
- Minor editorial changes

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