

GLOBAL QUALITY

# QUALITY MANUAL

VERSION 5.0

NOVEMBER 2017



SANOFI

*Empowering Life*

## Abbreviations and Acronyms

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CMC	Chemistry, Manufacturing and Control
GBU	Global Business Unit
GCP	Good Clinical Practices
GDP	Good Distribution Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GVP	Good Pharmacovigilance Practices
GxP	Combined term for GCP, GDP, GLP, GMP, GVP
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
PQS	Pharmaceutical Quality System
QMS	Quality Management System
QM	Quality Manual

## Foreword

*We are pleased to share with you the Global Quality Manual 5.0 edition.*

*This edition reflects the most recent changes to the Quality organization aligned with Global Business Units, Global Functions, Country organizations, the Sanofi Industrial Platforms, and finally Sanofi Values.*

*New points of focus are described and are enablers for an effective and successful implementation of the Quality Management System. The Quality Academy is highlighted as it provides training resources and is a promotor for continuous learning and education of our people at all levels.*

*Our Quality Management System was implemented in 2009 and is based upon our strong commitment to improve the life of our patients and the public health needs that we are privileged to serve. It is One Quality System applied to ensure the Quality of all the Sanofi products and services throughout their life-cycle from discovery to development, manufacturing, distribution and discontinuation for established and innovative products. It is operated in a flexible and adaptable model to include quality standards specific to each profile class of the Sanofi product portfolio. It is constantly evolving to anticipate regulatory developments and to support the needs of our Global Business Units and Global Functions.*

*In line with our Company objective of focus and simplification, the Quality Manual provides to all Sanofi personnel as well as to external partners and regulators a concise and useful overview of our Quality System structure and related key processes. It elaborates on the fundamentals delineated in our revised Global Quality Policy approved in September 2017. The Quality Policy and Quality Manual constitute the hallmarks of our Quality Documentation pyramid, and serve as vectors to ensure a full deployment of our Quality management principles across the organization.*

*They are an important part of our desired Quality Culture focused on patient centricity and contribute to our innovation and continuous improvement strategic goals.*

*We are convinced that, thanks to the commitment to this Quality Manual of each individual at all levels of Sanofi, we will be empowering life.*



*O. Brandicourt*

**Olivier Brandicourt**  
Chief Executive Officer

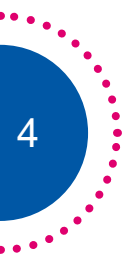


*P. Germanaud*

**Philippe Germanaud**  
Chief Quality Officer

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# 1. Introduction to the Global Quality Manual

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## 1.1 Purpose

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

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, GMP & GVP) and other health-related requirements.

## 1.2 Scope

This Global QM applies to all activities related to the research, discovery, development, manufacturing, distribution and discontinuation of Sanofi products and services, regardless of where these activities take place.

## 1.3 Sanofi at a Glance

Sanofi is a global life sciences company committed to improve 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 and cardiovascular solutions, and consumer healthcare.

More than 100,000 people at Sanofi are dedicated to make a difference on patients' daily life, wherever they live and enable them to enjoy a healthier life.

## 1.4 Our Business Strategy

The Sanofi business strategy is built upon four key pillars to deliver sustainable long term growth:

- Reshape the product portfolio, through focus on the contribution of treating the global epidemic of diabetes and cardiovascular diseases, as well as through building strategic positions in multiple sclerosis, oncology, immunology and consumer health.
- Deliver outstanding launches of innovative medicines and vaccines to the market.
- Sustain innovation in R&D by strengthening the R&D pipeline, increasing the number of high-quality projects in the early stage pipeline and replenishing the late development pipeline as products launch.
- Drive focus and simplification within the organization by enabling to be more closely aligned with the strategy and to be more effective in execution, from R&D to commercial, from global to country level.

## 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 eApplications, and combination products
- Medicinal products (including Generics and OTC products)
- Nutraceuticals
- Vaccines

## 1.6 Our Values

Sanofi is a company committed to high standards of business integrity and ethics based on these shared values:



## 1.7 Sanofi Organization & Activities

The Sanofi Company is organized in:

- Five Global Business Units (GBUs) integrating global franchises and country level commercial and medical organizations for each of our major businesses:
  - Specialty Care (Sanofi Genzyme) - Rare Diseases, Multiple Sclerosis, Oncology & Immunology
  - Diabetes and Cardiovascular
  - General Medicines and Emerging Markets (established products, generics and all pharmaceutical sales including Sanofi Genzyme and Diabetes and Cardiovascular, in emerging markets)
  - Vaccines (Sanofi Pasteur)
  - Consumer Healthcare
- Various Global Functions
  - Chief Medical Office & Medical Function
  - Communication
  - External Affairs
  - Finance
  - Global Business Services
  - Global Industrial Affairs, aligned with the GBUs
  - Global Research & Development organized by therapeutic area, aligned with the GBUs for late stage products
  - Human Resources
  - Internal Audit & Risk Management
  - Legal, Business Integrity & Ethics
  - Strategy, Alliances & Business Development



## 2. Sanofi Quality Policy



### QUALITY POLICY

#### Empowering Life

Our Quality commitment to patients leads us to provide safe and effective products and services throughout the world that are developed, manufactured, distributed and marketed in compliance with the regulatory requirements and our Company values: integrity, courage, respect and teamwork.

Our Quality System is described in our Quality Manual and must be deployed by all, at all levels of Sanofi. This Quality System is both integrated and segmented. Integrated, it ensures patient safety and is meeting the expectations of our customers in a coherent and harmonized way. Segmented, it includes standards specific to each field, allowing the adaptation to the specific rules of our various activities and fostering their competitiveness. It applies to all types of products and services, whether established or innovative, at all stages of their life cycle. It is constantly evolving to anticipate regulatory developments and to support the needs of our Global Business Units and activities.

Regulatory compliance is a prerequisite for our Quality System, which is based on the principle of quality risk management and continuous improvement. This helps to promote innovation within Sanofi. The effectiveness of the implementation of the Quality System is specifically verified by quality audits.

The Quality Culture, promoted through the Quality Academy to each member of Sanofi, assists with the development of the men and women within our Company.

Thanks to the individual commitment of all to this Quality Mindset, combining collective ambition and individual humility at all levels of Sanofi, we will be empowering life.

September 2017

Olivier Brandicourt  
Chief Executive Officer

### POLITIQUE QUALITÉ

#### Donner toute sa force à la vie

Notre engagement Qualité envers les patients nous conduit à mettre à disposition, partout dans le monde, des produits et des services sûrs et efficaces qui sont développés, fabriqués, distribués et commercialisés dans le respect des exigences réglementaires et des valeurs de notre Compagnie : intégrité, courage, respect et travail en équipe.

Notre Système Qualité est décrit dans notre Manuel Qualité et doit être déployé par tous, à tous les niveaux de Sanofi. Ce Système Qualité est à la fois intégré et segmenté : intégré, il permet de garantir la sécurité des patients et de répondre aux attentes de nos clients de façon cohérente et harmonisée ; segmenté, il comprend des standards propres à chaque domaine, afin de s'adapter aux règles spécifiques de nos différentes activités et de favoriser leur compétitivité. Il s'applique à tous les types de produits et de services, bien établis ou innovants, à toutes les étapes de leur cycle de vie. Il évolue constamment pour anticiper les évolutions réglementaires et répondre aux besoins de nos Business Units Globales et de nos activités.

Notre Système Qualité tient pour prérequis la compliance réglementaire et est basé sur le principe de la gestion du risque qualité et de l'amélioration continue. Ceci permet de promouvoir l'innovation au sein de Sanofi. L'efficacité de la mise en œuvre du Système Qualité est vérifiée en particulier par des audits qualité.

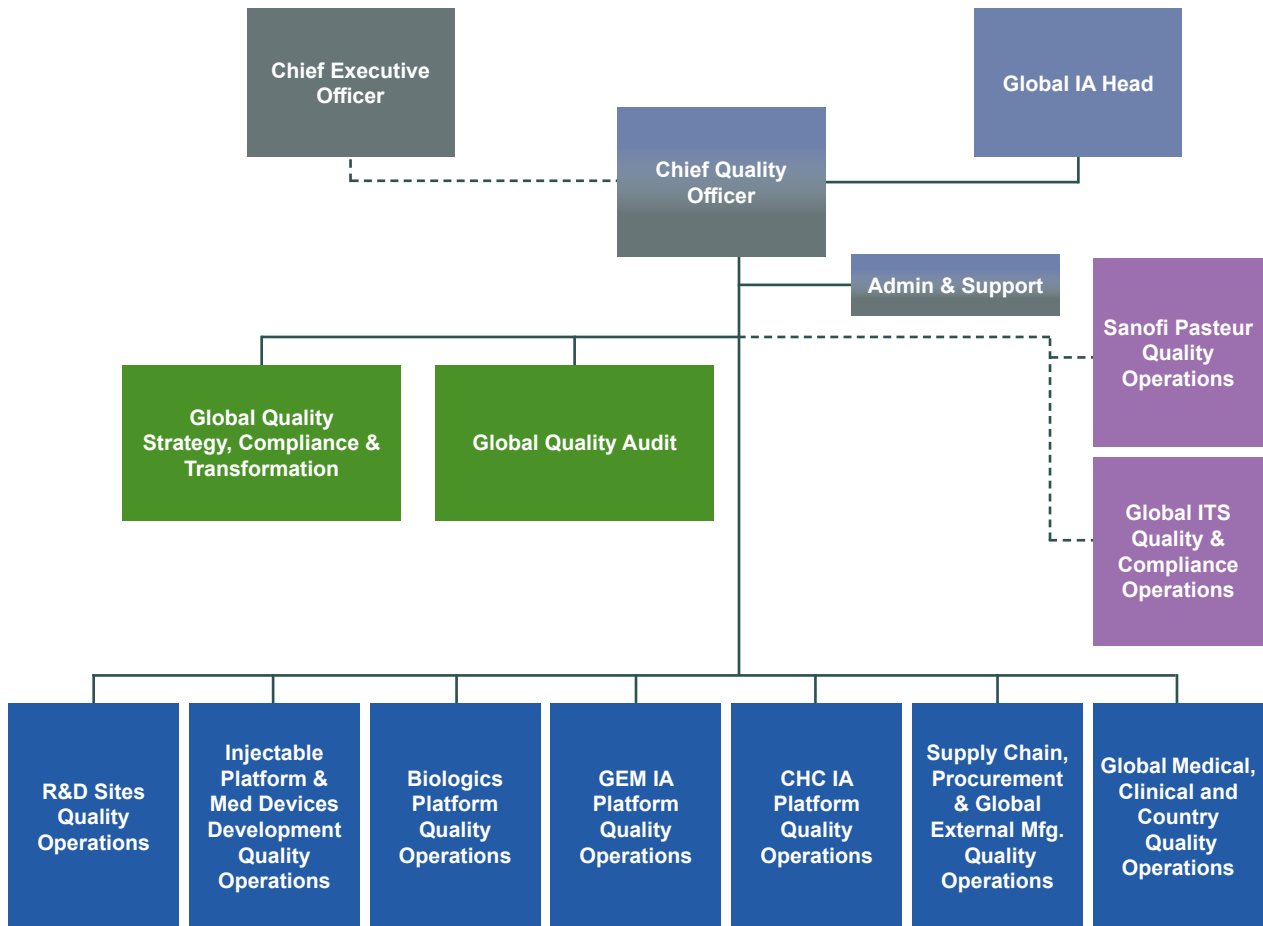
La Culture Qualité, promue au moyen de l'Académie Qualité auprès de chaque membre de Sanofi, participe au développement des hommes et des femmes de notre Compagnie.

Grâce à l'engagement individuel de tous pour cet état d'esprit Qualité, alliant ambition collective et humilité individuelle, à tous les niveaux de Sanofi, nous serons en mesure de donner toute sa force à la vie.

Philippe Germanaud  
Chief Quality Officer

# 3. Quality Organization and Responsibilities

## 3.1 Organization Chart



■ Operation in dotted line to the function    
 ■ Operation in solid line to the function    
 ■ Solid line to the function

## 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 Industrial Affairs, and is a core team member of the Sanofi Global Industrial Affairs Council, the Sanofi Global Risk Committee and the Sanofi Global Compliance Committee.

## 3.3 Global Quality Functions

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

### Global Quality Strategy, Compliance & Transformation:

The mission of the Global Quality Strategy, Compliance & Transformation (GQ SC&T) is to drive the Sanofi Global Quality strategy built upon the strategic orientations of the Company, the principles defined in ICH Q10 Pharmaceutical Quality System and applicable health-related regulations to assure patient safety and product quality.

This mission is achieved through the following Global Quality functional areas reporting to the Head of GQ SC&T:

- Governance, Projects & Expertise Management Office
- Qualified Persons Responsibilities & Industrial CMC Compliance
- Quality Alert Management including Product recall, Quality Alerts, Product Alerts of quality origin, and Product Shortage reporting
- Quality Systems Documentation & Training
- Quality Strategy, Culture & External Liaison including Proactive Quality Risk management, Communication and Quality Academy
- Computerized Systems GxP Compliance

### Global Quality Audit:

The mission of Global Quality Audit is to provide to the Senior Management an accurate, independent assessment of the compliance to the Sanofi Quality Management System through regular surveillance audits of the Operational Units, Sites (R&D, Manufacturing and Distribution), Country Offices, Global Functions and key third parties including due diligence assessments. GQA also supports regulatory inspection readiness.

## 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 cGxP 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 strictly 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 Operational Quality Unit in charge of Vaccines GBU (Sanofi Pasteur) and Information Technology & Solutions who report functionally to the Sanofi Chief Quality Officer. The head of the Operational Quality Unit in charge of Medical, Clinical and Country Quality Operations reports also functionally to the Chief Medical Officer.

## 3.5 Site Quality Management

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

The SQM reports to the Head of the Operational Quality Unit and to the Senior Site Director or General Manager.

## 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 Systems, in order to ensure the quality of products and services at market level and to guarantee compliance with applicable regulatory requirements and the Sanofi Quality Management System.

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

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

### 3.7 The Role of 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 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, may be subcontracted to third parties, under the responsibility of an Operational Unit, Site, External Manufacturing or Country.

The acceptability of these third parties (service providers, suppliers and subcontractors) is verified through a formal process including initial assessment, 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 pre-defined acceptance criteria, including compliance with technical specifications and quality requirements.

The quality oversight of these third parties is under the responsibility of the relevant Operational Quality Unit, Site Quality Management, External Manufacturing Quality or Country Quality Management.

### 3.9 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 includes the implementation of appropriated 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.

### **3.10 Responsibilities for Computerized Systems**

Computerized systems in support of development (including laboratory studies and clinical trials), manufacturing, distribution, medical and commercial activities, and the electronic data they contain, are subject to specific regulatory requirements. Computerized systems which 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 Information Technology & Systems Operational Quality Unit ensures that computerized systems are built, supported and maintained in compliance with applicable regulations, during their entire life-cycle.

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

### **3.11 Responsibilities for Personnel Qualification & Training**

All Sanofi employees who are directly or indirectly operating within the Sanofi QMS and are engaged in the discovery, 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.

### **3.12 Responsibilities for Quality Documentation**

The Site and Country Quality Management are responsible to ensure the roll-out and the enforcement of the requirements of the Sanofi Global Quality Documentation System through their own local quality documentation. Consistency and continuity between both systems are critical.

## 4. Management Responsibilities

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Senior management has the responsibility to demonstrate strong and visible commitment to the Sanofi QMS by taking accountability and responsibilities for these 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 following principles:

### 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 down throughout the organization with the purpose to involve 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 personnel with 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 matrices 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 Quality Management System in accordance with the selected integration model.

### **4.7.2 Monitoring of Internal and External Factors impacting the Quality Management System**

Management monitors internal and external factors with a potential to impact the Sanofi Quality Management System. Monitored factors are:

- Emerging regulations and guidance;
- Quality issues that can impact the Quality Management System;
- Innovations that may enhance the Quality Management System;
- Changes in the business environment and business objectives.



## 5. Enablers

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### 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 includes management governance processes at global and local levels which incorporate the review of risks that have been identified and classified.

It facilitates continuous improvement of process performance and product & services quality throughout the product lifecycle. An effective proactive quality risk management process can facilitate better and more informed decisions and can provide regulators with greater assurance of the Company's ability to foresee and avoid potential crisis.

A Quality Risk Representative is designated by the involved Operational Quality Units to manage the quality risk management process of their unit. This is achieved in accordance with the requirements set in the Global Quality Directive Quality Risk Management.

At a global level, quality risks are consolidated, reported and followed through the Quality Risk Profile.

### 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. Within Sanofi the quality culture is critical for the successful execution of our business performance and strategy.

The Quality Academy is an important enabler of our Quality Culture as it provides training resources and fosters continuous learning and education of our people. There are established Communities of Practices for our people to connect and share around specific Quality topics and processes.

## 6. Sanofi Global Quality Documentation System

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

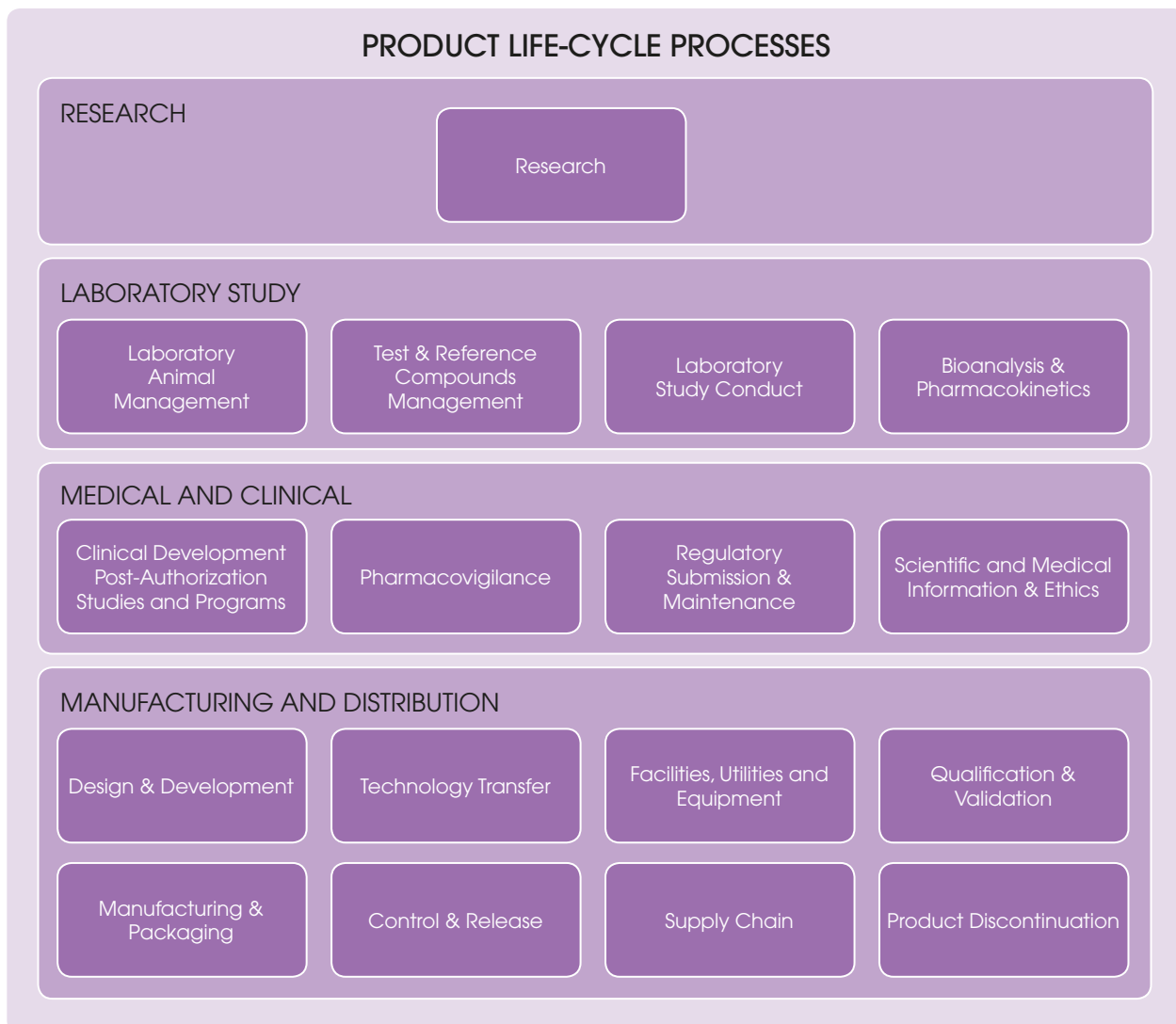
### 6.1 Quality Processes

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 contributing to the design, development and realization of effective and safe products and services for the benefit of patients and consumers.
- **Transversal Processes**, supporting the Product Life-Cycle Processes, in order to ensure their proper management, control and continuous improvement.
- **Organizational Processes**, contributing 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
<b>Research</b>	Ensure that the first stages of product development, including basic scientific exploration and discovery as well as studies and analysis of early development which are not covered by GxPs are properly organised, performed, documented and archived.

**Laboratory Study Process:**

PROCESS	OBJECTIVE
<b>Laboratory Animal Management</b>	Manage all aspects related to the care and use of laboratory animals, in alignment with the fundamental principles of animal welfare.
<b>Test &amp; Reference Compounds Management</b>	Manage any article that is either the subject of a laboratory study or provides a basis for a comparison with the study object.
<b>Laboratory Study Conduct</b>	Ensure the proper management of laboratory studies, starting from the protocol, the generation of study data, the production of the report, and ending with the data archiving.
<b>Bioanalysis &amp; Pharmacokinetics</b>	Analyse 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
<b>Clinical Development, Post-Authorization Programs</b>	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.
<b>Pharmacovigilance</b>	<p>Ensure establishment of the safety profile and contribution to evaluation of the therapeutic value for all products in clinical development.</p> <p>Ensure continuous monitoring and management of the safety profile, and risk minimization of all products marketed by the Company.</p>
<b>Regulatory Submission &amp; Maintenance</b>	Manage regulatory activities required to submit information to the regulatory authorities, obtain approval, and maintain the Sanofi portfolio.
<b>Scientific and Medical Information &amp; Ethics</b>	<p>Establish a governance model that ensures the continuous assessment of the medical benefit and risk balance of products throughout their life-cycle.</p> <p>Ensure ethical and responsible conduct when dealing with patients, consumers and subjects participating to studies.</p> <p>Ensure scientific and medical information is provided according to international standards to patients, healthcare professionals and consumers.</p>

**Manufacturing and Distribution Process:**

PROCESS	OBJECTIVE
<b>Design &amp; Development</b>	<p>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.</p> <p>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 customer expectations.</p>
<b>Technology Transfer</b>	<p>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.</p>
<b>Facilities, Utilities and Equipment</b>	<p>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 minimise the risk of contamination.</p>
<b>Qualification &amp; Validation</b>	<p>Demonstrate compliance of the critical aspects of the development, manufacturing, control and distribution of Sanofi products with pre-established requirements.</p>
<b>Manufacturing &amp; Packaging</b>	<p>Manufacture and package products to consistently meet all the required quality attributes and specifications.</p>
<b>Control &amp; Release</b>	<p>Ensure that materials, intermediates and finished products are sampled, analysed and formally released by Quality Management before use or distribution.</p>
<b>Supply Chain</b>	<p>Ensure the timely delivery to production of the right quantity and quality of materials, for use in the manufacturing and packaging of Sanofi products.</p> <p>Manage the physical flows of Sanofi materials and products while maintaining their quality, security and traceability.</p> <p>Ensure that Sanofi customers receive the right quality product, at the right time.</p> <p>Ensure when a product is deemed unfit based on adequate investigation, product discontinuation actions are properly taken.</p>
<b>Product Discontinuation</b>	<p>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.</p>

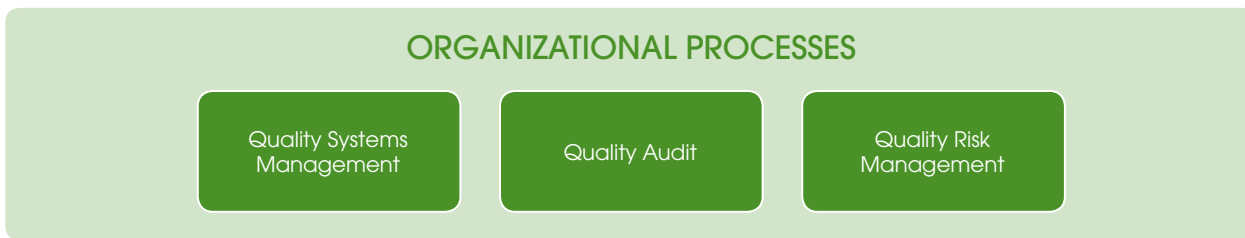
## 6.1.2 Transversal Processes:



Transversal processes are classified under the “G8-Quality Systems Management” sub-process of the Sanofi Global Process Framework.

PROCESS	OBJECTIVE
<b>Management of Documentation</b>	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.
<b>Product &amp; Process Improvement</b>	Enhance products and improve processes to consistently and better meet the needs of customers and patients, and to promote innovation respecting the related regulatory and Company requirements.
<b>Personnel Training &amp; Qualification</b>	Ensure that the personnel involved in the Sanofi Quality Processes are trained and qualified for their assigned tasks.
<b>Management of Third Parties</b>	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.
<b>Management of Computerised Systems</b>	Ensure that computerised systems and eApplications, 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:



Organizational processes are classified under the “G9-Quality Systems Management” sub-process of the Sanofi Global Process Framework.

PROCESS	OBJECTIVE
<b>Quality Systems Management</b>	Deploy the Quality Policy across Sanofi through the implementation and monitoring of Quality Systems, based upon the related regulatory and Company requirements.
<b>Quality Audit</b>	Provide an accurate, independent assessment of the compliance of the Operational Units, Sites, Countries, Global Functions and third parties to the Sanofi Quality Management System.
<b>Quality Risk Management</b>	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 Directives, Operational Quality Standards and Guidances as well as the supporting documents associated to any of these documents is detailed in the Global Quality Directive Management of Global Quality 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.

All levels of the Sanofi Quality Documentation System are subject to the requirements set forth by the Global Quality Directive Management of GxP Documents and Records and are available for inspection by regulatory authorities.

## 6.3 Quality Documents Type

DOCUMENT TYPE	OBJECTIVE
<b>Quality Policy</b>	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 requirements and promotes continuous improvement. The Quality Policy is communicated to personnel at all levels of the Company.
<b>Quality Manual</b>	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 and by the Chief Executive Officer.
<b>Global Quality Directives</b>	Describe mandatory regulatory requirements for key processes which must be complied with across the Company. Apply to all activities and all product ranges.
<b>Operational Quality Standards</b>	Describe regulatory and Company requirements and current practices, 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.
<b>Operational Quality Guidances</b>	Describe the Sanofi detailed and current expectations on how to satisfy the requirements of applicable Operational Quality Standards and Global Quality Directives. Apply to one or several product ranges. Applicable to all entities of Sanofi involved in the activities they describe.
<b>Position Papers</b>	Describe the Sanofi position regarding a specific topic not associated with mandatory regulatory requirements. The position paper can be issued either for external communication or for internal use.
<b>Global Quality Supporting Documents</b>	Help to standardise the implementation of quality documents (typically templates, logs, checklists, etc.). Can be associated with Global Quality Directives, Operational Quality Standards, Operational Quality Guidances, Global Standard Operating Procedures or any local document. Mandatory document to be used, unless otherwise specified in the supported document.
<b>Global Standard Operating Procedures</b>	Give instructions for performing operations which are transversal across different entities or functions. Applicable to all Operational Units, Sites, Countries or Functions performing the described activity.
<b>Local Quality Documents</b>	Give instructions for performing operations which are specific to a Site, a Country or a Function.



## 7. Global Quality Audits and Regulatory Inspections

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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 is determined using a risk based model.

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 Quality Management System 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 Readiness evaluation tools are available for use by the entities to self-assess their state of inspection readiness; these tools cover manufacture, distribution, medical, clinical and country operations.
- Inspection Preparation can be provided from 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 either 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.

In addition, prior to the decision to enter a partnership or purchase of a product, a company, or process, Global Quality Audit is involved in the evaluation and selection through a due diligence process, to assess the state of compliance and associated risks to Sanofi.

## 8. Document Approvals

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This document is electronically approved in GEODE+.

## 9. Document History

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### December 2009 - V 1.0

- First version of this Global QM

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### June 2011 - V 2.0

- Creation of Global Operations Quality
- Creation of the Risk Committee
- Minor modifications of the process model:
  - Commercial activities is 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

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### 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

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### 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 countries 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

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### 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



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