I. COMMITMENT

Patient safety is an absolute priority for Sanofi. With this in mind, Sanofi’s approach consists of implementing standards to ensure quality and continuous improvement that applies to all types of products and services, whether established or innovative, at all stages of their life cycle.

The senior management of Sanofi is committed 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.

The Sanofi Quality Management 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.

1. How Global Quality is organized at Sanofi

Implemented in 2009, the Sanofi Quality Management System 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 as well as medical, clinical and commercial activities 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 Sanofi Global Business Units and Global Functions.

A 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 Chief Quality Officer is the representative of the Sanofi Senior Management for quality related matters. In addition, the Chief Quality Officer is a core team member of the Sanofi Global Industrial Affairs Council, the Sanofi Global Risk Committee and the Sanofi Global Compliance Committee.

Philippe Germanaud’s quote:

“Quality is a way of living and thinking. Quality is a Top Priority, Whatever we do, Wherever we are. Quality is a Culture and a Key Driver of Performance and Reputation for Sanofi.”

Phillipe Germanaud
Chief Quality Officer
Quality managers are appointed in each of the Sanofi operational units, sites, and country organizations involved in activities that may impact product quality, patient safety, or data integrity. These quality managers conduct and coordinate quality and compliance activities, and they contribute to compliance with regulatory requirements and continuous improvement of Sanofi’s performance.

2. Quality governance

The objective of the Quality governance is to ensure that the Sanofi quality policy is adhered to and endorsed by all employees throughout the Company, and to promote continuous improvement and innovation through leadership and networking.

Across Sanofi, Global Quality brings together all quality teams, which represent up to 9,000 employees including those involved in the quality control of materials and products.

Both, Global Quality functions and Operational Quality units, are responsible for implementing and maintaining an efficient and consistent Sanofi Quality Management System in order to ensure the quality of products and services, and to guarantee compliance with applicable regulatory requirements and Company requirements.

The role of the Sanofi Senior Management is also to demonstrate a strong and visible commitment to the Sanofi Quality Management System by taking accountability and responsibilities for its overall effectiveness. Senior Management ensures that roles, responsibilities and authorities related to the Sanofi Quality Management System are defined, communicated and implemented throughout the Company.

3. Sanofi Quality Management System

The Sanofi Quality Management System framework and principles are fully aligned with the ICH (International Council on Harmonization) Quality Guideline Q10 on Pharmaceutical Quality System.

The Sanofi Quality Management System 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 GxP regulations (GCP, GDP, GLP, GMP & GVP) and other health-related requirements.

The Sanofi Quality Management System is structured in a such way as to cover 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 Management System, by providing consistent directions and adequate support.

4. Sanofi Quality Documentation System

The documentation hierarchy supporting the Sanofi Quality Management System is displayed in the following diagram:
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.

The Sanofi Quality Management System is documented in:

- Global Quality Directives applicable across all product categories and activities
- Operational Quality Standards and Guidance ordered by activities and product ranges
- Global Standard Operating Procedures which give instructions for performing operations which are transversal across different activities
- Local Quality Documents which give instructions for performing operations which are specific to an activity

Sanofi 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.

By 2017 more than 300 global quality directives, operational quality standards and guidances have been produced and updated as necessary to support the Sanofi Quality Management System.

II. POLICY

Sanofi Quality Policy

The Sanofi Quality Policy signed by Olivier Brandicourt and Philippe Germanaud, respectively Chief Executive Officer and Chief Quality Officer delineates the fundamentals and gives the vision of what Quality is for Sanofi people, products and services, for the benefit of our patients and customers.

For more information, see: Sanofi Global Quality Policy in the Documents Center.
The Sanofi Quality Manual provides to all Sanofi personnel as well as external partners and regulators a concise and useful overview of the Sanofi Quality Management System structure and related key processes.

1. Quality audit and regulatory inspection readiness

Within the Global Quality organization, a dedicated department, Global Quality Audit, is responsible for providing an accurate and independent assessment of the compliance of the operational units, sites, country organizations, and global functions to the Sanofi Quality Management System.

Global Quality Audit aims to foster a culture of proactive continuous improvement across all Sanofi sites and country organizations, in order to achieve successful regulatory inspection outcomes and secure GxP compliance through effective self-assessment.

All Sanofi operational units, sites and country organizations facilitate inspection of their facilities at the request of regulatory authorities, and coordinate all activities related to these inspections.

When deviations from internal or external requirements are identified during audits and 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.

2. Quality risk management

Quality risk management is an integral part of the Sanofi Quality Management System, enabling effective decision-making and allowing to build regulatory authorities’ confidence in our ability to address any potential issues that may arise.

In order to facilitate continuous improvement of process performance and product & service quality throughout product lifecycle, Sanofi quality risk management approach is both reactive and proactive.

In reactive mode, any quality issue identified is handled in a timely and effective manner with the necessary corrective and preventive actions.

In proactive mode, potential risks, not yet materialized, are detected from both internal and external sources, and all necessary measures are implemented to prevent any negative impact for Sanofi or on patient safety.

At a global level, quality risks are consolidated, reported and followed through the Quality Risk Profile.
3. Quality across the entire supply chain

Sanofi maintains the quality, security and traceability of all its materials and products throughout their physical flows.

To reduce the risk of fraud, falsification and diversion of our products, Sanofi adopts innovative technological solutions to ensure traceability, identify fake products and secure the supply and distribution chain. These include the use of tamper-evident packaging to guarantee the integrity of the packs, anti-counterfeit security labels to authenticate our products, and data matrix codes for serialization, which improve the traceability and identification of our products.

In addition, Sanofi has a central anti-counterfeit laboratory in Tours (France) dedicated to the analysis of medicines or products suspected of being counterfeit.

Throughout the entire supply and distribution chain, Sanofi ensures appropriate conditions of storage, transport and delivery of materials and products in order to maintain the quality attributes of materials and products in compliance with applicable regulatory and Sanofi Quality Management System requirements.

4. Quality culture

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

To promote this quality culture initiative, Sanofi puts in place a Quality Academy that provides training resources and fosters continuous learning and education of our people. There are also established communities of practices for our people to connect and share around specific quality topics and processes.

III. INTEGRATION OF NEW ENTITIES IN THE SANOFI QUALITY MANAGEMENT SYSTEM

In the best interest of patients, and to guarantee that the highest quality standards are met across the entire Company, a clearly defined process supports and facilitates the integration of the Sanofi Quality Management Systems into all new entities.

The quality function is involved as a partner in the process of acquisition of new entities, from the process of due diligence. This integration process is designed to drive the successful integration of the Sanofi Quality Management System for both large multi-national companies and smaller companies.