QUALITY MANAGEMENT SYSTEM

GRI Standards :

416-1, 416-2 : Customer Health and Safety

102: General Disclosures

103: Management approach

416: Customer Health and Safety

EXECUTIVE SUMMARY

Hereafter is described a concise overview of the Sanofi Quality Management System structure, aligned our Company objective of focus and simplification.

The Sanofi Quality Management System is elaborated on the fundamentals delineated in our Company Global Quality Policy revised in September 2019.

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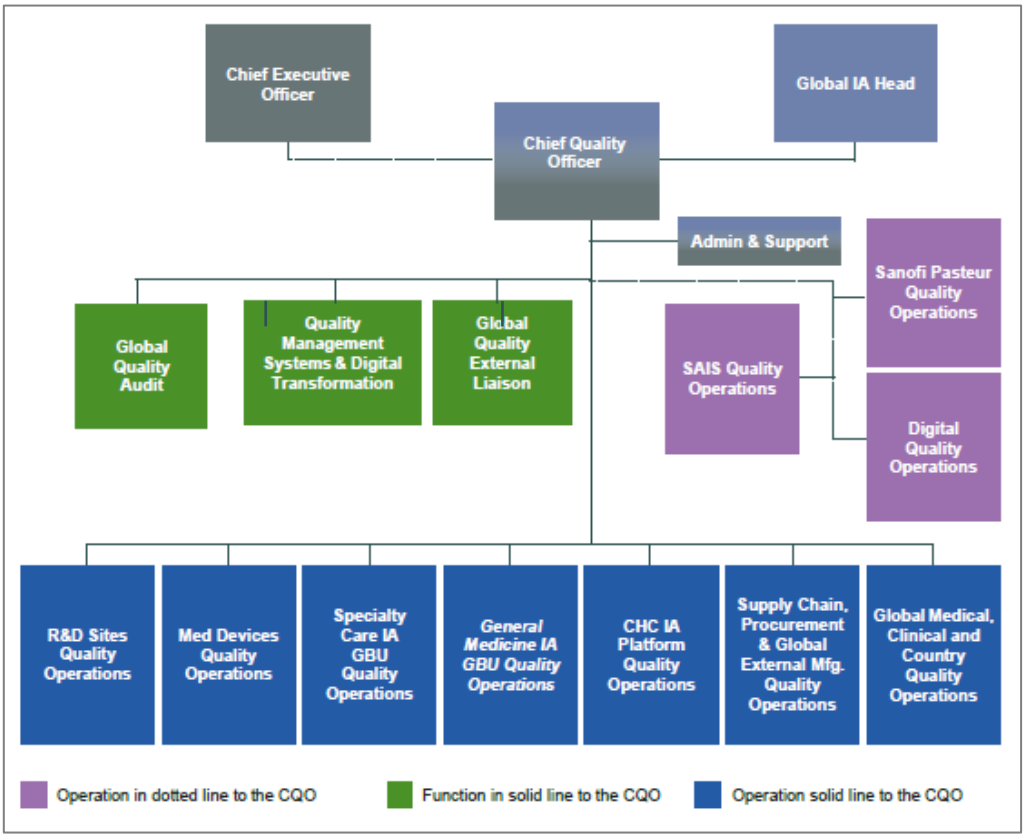
1.1. Commitment

Quality commitment to patients leads Sanofi 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 the Sanofi Quality Management System (QMS).

1.2. Quality Organization



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.

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.

1.3. Quality Management System

The Sanofi Quality Management System (QMS) framework and principles are fully aligned with the ICH Quality Guideline Q10 on 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 GxP regulations (GCP, GDP, GLP, GCLP, GMP, GRP & GVP) and other health-related requirements.

This is One Quality System that applies to all types of Sanofi products and services throughout their life-cycle from research 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 ensure continuous improvement and anticipate regulatory developments, to support the needs of our Global Business Units and Global Functions.

The electronic tools supporting the Sanofi QMS are also evolving to leverage the new technologies. This digital transformation program is meant to strengthen our capabilities to continuously improve our systems and processes.

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

1.4. Quality Policy

SANOFI

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. Advanced digitalized data management allows us to improve our knowledge of our products, services, patients and environment and contributes to the promotion of innovation within Sanofi.

The Quality Culture, made real by each member of Sanofi, assists with the development of people 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 2019

Paul Hudson
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 Unités Commerciales 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. Une gestion moderne et digitalisée des données nous permet d'améliorer notre connaissance de nos produits, services, patients et environnement, et participe à promouvoir l'innovation au sein de Sanofi.

La Culture Qualité, vécue par chaque membre de Sanofi, participe au développement des collaborateurs 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.

Septembre 2019

Philippe Germanaud
Chief Quality Officer

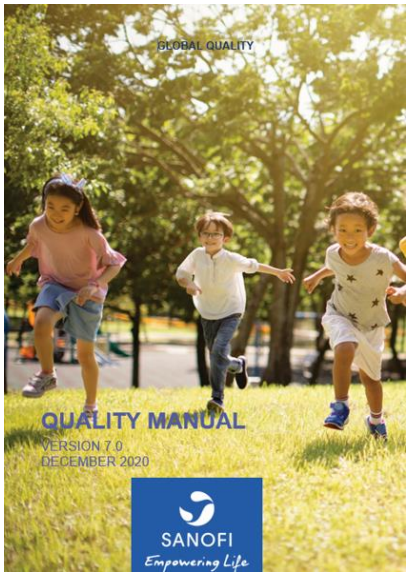
The Sanofi Quality Policy signed by Paul Hudson and Philippe Germanaud, respectively Chief Executive Officer and Chief Quality Officer delineates the fundamentals and gives the vision of what Quality is for Sanofi people, products and services, for the benefit of our patients and customers.

Available at the Sanofi Document Center

1.5. Quality Manual

In line with our Company objective of focusing on growth, leading with innovation, accelerating efficiency and reinventing the way we work, the Sanofi Quality Manual provides to all Sanofi personnel as well as external partners and regulators a concise and useful overview of the Sanofi QMS structure and related key processes.

Available at the Sanofi Document Center



1.6. Abbreviations and Acronyms

CHC	Consumer HealthCare
GCP	Good Clinical Practices
GDP	Good Distribution Practices
GLP	Good Laboratory Practices
GCLP	Good clinical and Laboratory Practices
GMP	Good Manufacturing Practices
GVP	Good Pharmacovigilance Practices
GxP	Combined term for GCP, GDP, GCLP, GLP, GMP, GRP, GVP
IA	Industrial Affairs
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.
QMS	Quality Management System
SAIS	Sanofi Active Ingredient Solution