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Quality Management System

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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 with 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.

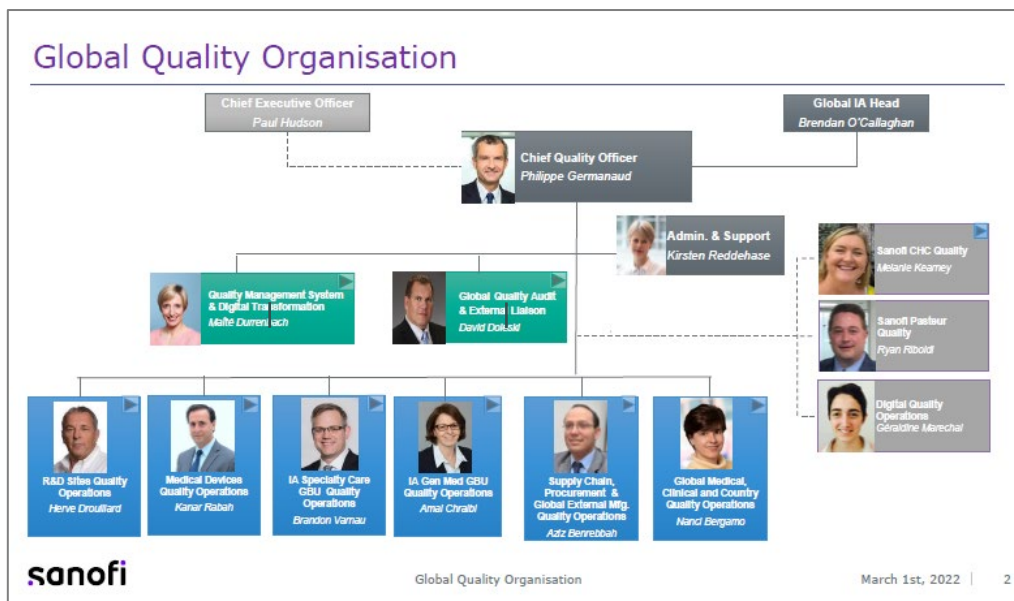
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1. Commitment

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).

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.

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 and 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.

4. Quality Policy



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

Available in our [Document Center](#).

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 in our [Document Center](#).



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