
●

Quality Management System

●

GRI Standards:

416: Customer Health and Safety

EXECUTIVE SUMMARY

Hereafter is described a concise overview of the Sanofi Quality Management System structure, connected to the Play to Win pillars of the Company.

The Sanofi Quality Management System (QMS) is elaborated on the fundamentals delineated in our Company Global Quality Policy revised in September 2022.

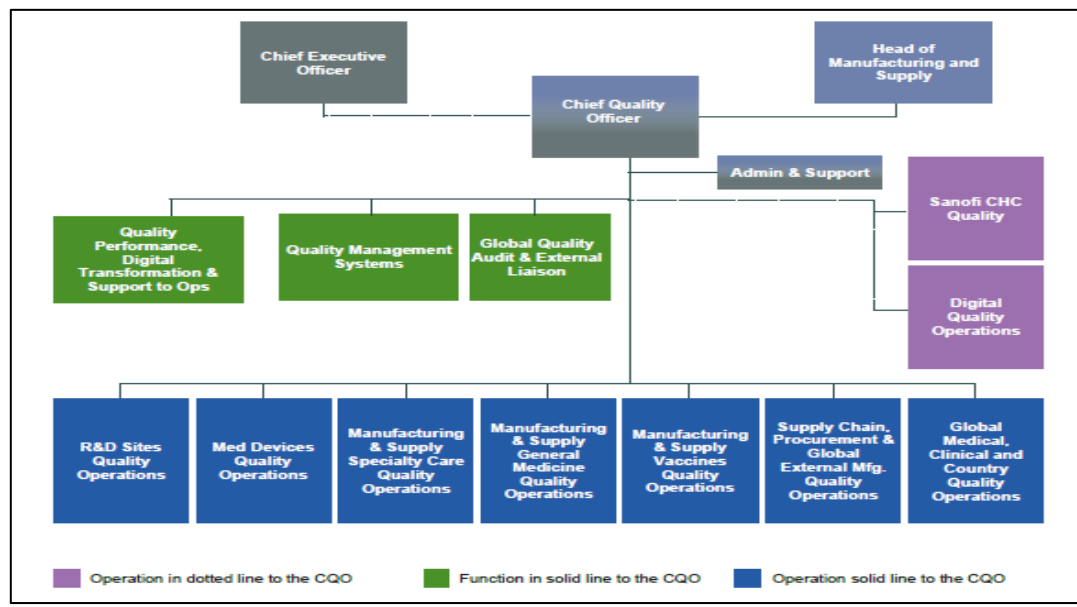
TABLE OF CONTENTS

| | |
|--|---|
| <i>1. Commitment</i> | 3 |
| <i>2. Quality organization</i> | 3 |
| <i>3. Quality Management System</i> | 3 |
| <i>4. Quality Policy</i> | 4 |
| <i>5. Quality Manual</i> | 4 |
| <i>6. Abbreviations and acronyms</i> | 5 |

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 Manufacturing & Supply and is a core team member of the Sanofi Global Manufacturing & Supply Leadership team and the Sanofi Global Compliance Committee.

3. Quality Management System

The Sanofi Quality Management System (QMS) is based upon a 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.

It 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.

It is operated with standards reflecting Sanofi 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.

It is constantly evolving to ensure continuous improvement and alignment with regulatory developments and to support the needs of Sanofi Global Business Units and Global Functions.

The Sanofi QMS framework and principles are fully aligned with the ICH Quality Guideline Q10 on Pharmaceutical Quality System.

The electronic tools supporting the Sanofi QMS 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.

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 System 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 Maïté Durrenbach, 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

The Quality Manual remains closely connected to the Sanofi Play to Win pillars. It provides a concise and useful overview of the Sanofi Quality System structure and related key processes to all Sanofi personnel, external partners and regulators.

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 |
| 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 |