

INTERNAL CONTROL & PROCESSES

GRI Standards :

N/A

EXECUTIVE SUMMARY

Sanofi is an international company with operations in more than 100 countries and the need to obtain reasonable assurance that the organization is achieving its objectives is paramount. Sanofi's audit and internal control procedures ensure that the risks related to its activities are controlled, in compliance with laws and regulations and aligned with the Board instructions in order to improve the company's performance. To achieve this objective, the Global Processes and Standards (GPS) program combines elements of internal control into a unified enterprise-wide approach. Maintaining and improving its internal control and risk management systems worldwide is a key commitment of Sanofi's Executive management.

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1. INTERNAL CONTROL AND PROCESSES DEPARTMENT MISSION

The Committee of Sponsoring Organizations of the Treadway Commission (COSO) defines Internal Control as a process, carried out by an entity's Board of Directors, management, and other personnel, designed to provide reasonable assurance regarding the achievement of objectives, in the following categories :

- Effectiveness and efficiency of operations ;
- Reliability of financial and management information/reporting ;
- Compliance with applicable laws, regulations and Sanofi policies.

Although the risks associated with the Company activities cannot be totally eliminated, Internal Control aims at providing reasonable assurance that the organization achieves its objectives.

The mission of the Sanofi Internal Control and Processes (IC&P) Department is to support the company with its objectives to have an Internal Control adapted to its organization and activities, by:

- Defining and maintaining company-wide standards.
- Providing support to management for improving controls and remediating failures.
- Coordinating the evaluation of Internal Control over Financial Reporting, program effectiveness.

2. GROUP PROCESSES & STANDARDS – “GPS”

The Global Process Framework is the official process model of Sanofi also used as a backbone by the Sanofi Operating Model. The initial version of the framework was formally approved by the Executive Committee and the Audit Committee of the Board. For its first revision in 2020, operational stakeholders at Global Business Units and Global Functions levels were involved. It provides a common view of Sanofi's value chain and support functions processes and brings consistency and efficiency to our control activities across Sanofi.

GPS comprises the following elements :

- A Global Process Framework, presenting the Sanofi's operational and support processes with a three-level hierarchy : processes, sub-processes and topics.
- An Internal Control Manual, made up of three parts. The first part describes the overall internal control organization and requirements, the second part details controls (which include the Severe Impact Controls SIC) that are expected to be in place in all Global Business Units and Global Functions in countries and regions and the third part provides the detailed mandatory controls that are applicable at Global / Corporate level only.
- A Financial Controls Framework, presenting Sanofi's internal control over financial reporting (used to comply with Section 404 of the Sarbanes-Oxley Act, “SOX”). This framework is an integral part of the Internal Control Manual.
- An Internal Control Self-Assessment process to be completed annually by all the Global Business Units and Global Functions in countries, based on a risk and materiality assessment. In addition, a quarterly testing is performed to screen the integrity of self-assessments by IC&P, Finance Business Partners for industrial sites and Digital Quality for Manage Information Systems controls. Both outcome can be reviewed by Sanofi Internal Audit during its periodic audits, as well as senior management in their monitoring of activities and decision making process.

The GPS applies to all business units, functions and activities, in all countries.

3. INTERNAL CONTROL RESPONSIBILITIES

The Executive Committee sets principles and policies for the Sanofi's Internal Control, allocates resources, and monitors adherence to the company's Internal Control by local management teams.

The Audit Committee of the Board of Directors is responsible for monitoring the effectiveness of the enterprise's risk management and internal control systems including Internal Control over Financial Reporting.

- The IC&P Department assists the company to implement its Internal Control, and as such :
 - > Maintains the Sanofi Internal Control Manual and respective tools ;
 - > Follows up and provides guidance on the local implementation of policies, processes and controls developed at Global level ;
 - > Monitors the GPS implementation and reports deviations to the Executive Committee and the Audit Committee ;
 - > Supervises and monitors implementation of action plans on internal control issues including internal audit recommendations and escalates when needed ;
 - > Acts as subject matter experts in projects and other initiatives ;
 - > Coordinates and prepares the self-assessment, testing campaigns and the SOX assessment;
 - > Performs quarterly testing to screen the integrity of self-assessments, in coordination with Finance Business Partners for industrial sites and Digital Quality for Manage Information Systems controls.

- Management :
 - > Is accountable for internal control environment within their area of responsibility ;
 - > Ensures that an internal control system including organization, procedures exists in all operations, and that such a system is documented, understood and adhered to by all employees. Ensures roles and responsibilities and control ownership are defined and communicated through RACI or other means ;
 - > Takes corrective and disciplinary actions in case of non-compliance with internal control requirements.

- Sanofi Internal Audit :
 - > Provides the Executive Committee and the Audit Committee with reasonable assurance as to Sanofi's ability to exercise control over the risks associated with its operations ;
 - > Performs periodic audits of controls and processes (including but not limited to those described in the Internal Control Manual) and monitors that action plans identified during their assignments are implemented within the specified timeframes.