



CATALENT, INC.

QUALITY AND REGULATORY COMPLIANCE COMMITTEE CHARTER

(LAST REVISED AUGUST 24, 2017)

I. PURPOSE

The Quality and Regulatory Compliance Committee (the “Committee”) of the Board of Directors (the “Board of Directors”) of Catalent, Inc. (the “Company”) shall provide assistance to the Board of Directors by, among other things:

- A. Reviewing and overseeing the personnel, activities, processes and procedures by which the Company assures the quality of the products and services it delivers;
- B. Reviewing and overseeing the Company’s compliance with relevant laws, regulations and internal procedures governing the quality of the products and services the Company delivers;
- C. Providing guidance on the inspiration and maintenance of a culture of compliance; and
- D. Reporting on significant audits and inspections, and performing follow-up oversight of corrective and preventive actions (“CAPAs”).

II. STRUCTURE AND OPERATIONS

Composition and Qualifications

The Committee shall be comprised of three or more members of the Board of Directors. The chair of the Committee (the “Chair”) shall be determined by the Board of Directors to be “independent” under the applicable rules of the New York Stock Exchange.

Appointment and Removal

The members of the Committee shall be appointed by the Board of Directors and each member shall serve until such member’s successor is duly elected and qualified or until such member’s earlier resignation, removal, disqualification or death. The members of the Committee may be removed, with or without cause, by action of the Board of Directors.

Chair

Unless the Chair is selected by the Board of Directors, the members of the Committee shall designate a Chair by the majority vote of the full Committee membership. The Chair of the Committee will preside over all regular sessions of the Committee and is responsible for setting the agendas for Committee meetings. In the absence of the Chair of the Committee, the Committee shall select another member to preside.

Delegation to Subcommittees

The Committee may form subcommittees composed of one or more of its members for any purpose that the Committee deems appropriate and may delegate to such subcommittees such power and authority as the Committee deems appropriate.

III. MEETINGS

The Committee shall meet periodically as circumstances dictate. The Chair of the Board of Directors or any member of the Committee may call meetings of the Committee. Unless otherwise restricted by the Company's certificate of incorporation or bylaws, all meetings of the Committee may be held telephonically. In addition, unless otherwise restricted by the Company's certificate of incorporation or bylaws, the Committee may act by unanimous written consent in lieu of a meeting.

All non-management directors that are not members of the Committee may attend meetings of the Committee but may not vote. Additionally, the Committee may invite to its meetings any director, management of the Company and such other persons as it deems appropriate in order to carry out its responsibilities. The Committee may also exclude from its meetings any persons it deems appropriate in order to carry out its responsibilities.

A majority of the Committee shall constitute a quorum for the transaction of business and the act of a majority of those present at any meeting at which there is a quorum shall be the act of the Committee.

The Committee shall coordinate with the Audit Committee of the Board of Directors in order to minimize any overlap in the work of the two committees.

IV. RESPONSIBILITIES AND DUTIES

The following functions shall be the common recurring activities of the Committee in carrying out its responsibilities. These functions should serve as a guide with the understanding that the Committee may carry out additional functions and adopt additional policies and procedures as may be required or appropriate in light of business, legislative, regulatory, legal or other conditions or changes. The Committee shall also carry out any other responsibilities and duties delegated to it by the Board of Directors from time to time. Nothing in this Charter shall expand the duties or liabilities of any director or officer of the Company beyond any duties or liabilities otherwise imposed by applicable law.

The Committee, in discharging its oversight role, is empowered to study or investigate any matter of interest or concern that the Committee deems appropriate and shall have the authority to retain and terminate outside legal counsel or other advisors for this purpose, including the authority to approve the fees payable to such outside legal counsel or other advisors retained by the Committee and any other terms of retention. The Committee also shall have authority to retain and to terminate any regulatory or quality consultant of the Company, including the authority to approve the fees payable to such regulatory or quality consultant who may provide services to the Committee and any other terms of retention. The Company shall provide appropriate funding, as determined by the Committee, for payment of compensation to any consultant, outside legal counsel or other advisers retained by the Committee, as well as funding for the payment of ordinary administrative expenses of the Committee that are necessary or appropriate in carrying out its duties.

Responsibilities

1. Review and oversee the activities, processes, and procedures by which the Company assures the quality of the products and services it delivers, as well as oversee any related personnel policy or matter that may affect quality and regulatory compliance, all in comparison to industry best practices.
2. Review the status of the Company's compliance with laws, regulations, and internal procedures relating to quality, safety, efficacy, or handling with regard to the Company's products and related services and their consistency with industry best practices (e.g., compliance with the U.S. federal Food, Drug and Cosmetics Act, as amended, all related U.S. Food and Drug Administration ("FDA") requirements, and the comparable laws and regulations of states, localities, and foreign countries in which the Company operates or in which its products or services are used, including laws and regulations relating to current good manufacturing practices ("cGMP"), current good laboratory practices ("cGLP"), and current good distribution practices ("cGDP"), as applicable; compliance with other U.S. and ex-U.S. laws and regulations relating to the manufacture, handling, distribution, sale, or use of pharmaceutical and consumer health products, and related services; and compliance with the laws and regulations relating to claims as to the safety, efficacy, or superiority of such products).
3. Review and evaluate internal reports and external data, based on criteria to be developed by the Committee, to assess whether there is any significant concern regarding the Company's regulatory and/or compliance practices, including:
 - a. Receive details and factual reports on relevant governmental investigations, including the conduct at issue and whether it reflects a regulatory or compliance issue at the Company.
 - b. Receive relevant *qui tam* lawsuits unsealed by the government and/or made known to the Company relating to quality or regulatory compliance, and receive an analysis of the factual allegations of the claims, a review of any potential legal exposure the claims present for the Company, and whether the claims reflect a regulatory or compliance issue for the Company.
 - c. Receive all material FDA Form 483 reports and warning letters (and comparable notifications from other agencies) and the responses to such, as well as reports on the steps taken to implement the responses and an evaluation of whether the reports or letters, together with the Company's responses, raise any product-related regulatory and compliance issue.
 - d. Receive, in its discretion, reports from management on internal messaging to employees regarding the Company's commitment to behavior and practices that assure quality and compliance with related legal standards, as well as the Company's efforts to promote a culture of compliance.
 - e. Receive reports from management with respect to any significant disciplinary action against any of the Company's quality and regulatory personnel or internal audit personnel, including the nature of the conduct that led to the disciplinary action, the disciplinary action and the reason for it, and an analysis of whether the underlying conduct reflects any compliance or regulatory concern or issue.

4. Oversee the prompt implementation of the Company's quality and regulatory compliance program with respect to companies acquired by the Company and in which the Company exercises a controlling interest.
5. Require, in its discretion, management or any third-party expert it may retain to conduct audits on quality and related regulatory compliance concerns. The Committee may also, in its discretion, direct whether the Committee should be the direct recipient of the results of any such audit.
6. Conduct, in its discretion, on-site visits to the Company's operating facilities in order to facilitate its own evaluation or audit of any matter within the Committee's oversight role.
7. Report regularly to the Board of Directors including:
 - (i) following meetings of the Committee; and
 - (ii) with respect to such other matters as are relevant to the Committee's discharge of its responsibilities.

The Committee shall provide such recommendations to the Board of Directors as the Committee may deem appropriate. The report to the Board of Directors may take the form of an oral report by the Chair or any other member of the Committee designated by the Committee to make such report.

8. Maintain minutes or other records of meetings and activities of the Committee.

V. ANNUAL PERFORMANCE EVALUATION

The Committee shall perform a review and evaluation, at least annually, of the performance of the Committee and its members, including by reviewing the compliance of the Committee with this Charter. In addition, the Committee shall review and reassess at least annually the adequacy of this Charter and recommend to the Board of Directors any improvement to this Charter that the Committee considers necessary or appropriate. The Committee shall conduct such evaluations and reviews in such manner as it deems appropriate.