Position on Quality and Compliance

We maintain our commitment to quality through our quality management approach, which is based on the following proactive measures that help ensure end-to-end quality excellence across all stages of a product lifecycle—from R&D to manufacturing, to commercialization:

- Adherence to Johnson & Johnson Quality Policies and Quality Standards;
- Quality risk management principles;
- Compliance monitoring through audits and inspections;
- Rigorous internal communications and escalation procedures;
- Continuous improvement;
- Integration of new acquisitions; and
- Ongoing and consistent enhancement of talent and capabilities through training and education.

Governance

Our commitment to quality is driven by our Chairman and Chief Executive Officer, as well as our Executive Committee. They are supported by a global Quality & Compliance (Q&C) organization, which is functionally independent from commercial interests.

The Johnson & Johnson Quality & Compliance (J&J Q&C) organization has a worldwide presence in our segments to ensure that products are designed, manufactured, and delivered effectively. Quality management has a significant role within Johnson & Johnson and is represented on each segment's senior leadership team and within each Business and Functional unit. Quality Management has the responsibility and authority to ensure that quality system requirements are effectively established and maintained within the respective organization.

The Johnson & Johnson Chief Quality Officer (CQO) leads the Johnson & Johnson Quality & Compliance organization and is responsible for 1) Providing strategic direction and oversight of quality and regulatory compliance for the Johnson & Johnson companies end-to-end across all our business and functions; 2)

Establishing the Quality and Compliance Vision, and Strategic Priorities, and communicating these to employees; 3) Establishing Johnson & Johnson Quality Policies and Standards that will promote consistency in quality requirements across all Business and Functional units; 4) Assuring transparency of risk and decision-making with executive management, including governance oversight through a Johnson & Johnson Regulatory Compliance group independent of Business and Functional units; and 5) Reporting quality and regulatory compliance metrics and issues to executive management.

The Quality organization for each Segment is led by a Chief Quality Officer (Segment CQO) who reports directly to the Johnson & Johnson CQO and monitors the individual Quality Management Systems for their respective Segments. The Segment CQO responsibilities include 1) Assuring Segment procedures are in place that align with Johnson & Johnson Quality Policies and Standards; 2) Establishing quality plans and goals/objectives for the Segment; 3) Managing resources to effectively execute and monitor the quality plan and goals/objectives for effectiveness throughout the Segment; and 4) Communicating quality needs, performance, and risks to the relevant Segment Group Operating Committees and to the Johnson & Johnson CQO.

Enterprise-wide Quality Functions provide quality governance and services to support Business and Functional units throughout the Enterprise. These functions consist of Regulatory Compliance, R&D Quality, Microbiological Quality & Sterility Assurance, and Enterprise Quality. At our operating companies, the scope of Q&C responsibilities includes quality management activities at all stages of a product lifecycle—from R&D, to manufacturing and commercialization. Our R&D and manufacturing sites have designated Quality leaders to establish, implement and maintain quality systems at our sites and ensure quality regulatory compliance.

All employees must contribute to our enterprise-wide commitment to quality and compliance, following laws, regulations and Company policies and procedures, and must participate in an annual enterprise-wide training on our Quality Management Framework. It is the responsibility of every employee to adhere to our quality and compliance principles, which are embedded in our evaluation and compensation processes.

Our Quality Policies and Quality Standards: Our Quality Policies and Quality Standards define the requirements that our operating companies across Johnson & Johnson must achieve in order to design, make and deliver our products, and if needed, take actions to correct or recall products in the market.

They provide a common foundation for quality systems across Johnson & Johnson. The requirements are based on national and international standards such as current Good Manufacturing Practices (cGMPs), International Organization for Standardization (ISO) series, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Johnson & Johnson best practices. Our Quality Policies and Quality Standards apply worldwide, requiring our businesses to maintain the quality of our products for our customers and to operate in compliance with current regulations while anticipating and preparing for changes in regulations in the future. For additional information on the implementation of international standards for GMPs, see our Johnson & Johnson Quality Management Framework.

Quality risk management: Risk management requirements are part of the Johnson & Johnson Quality Policies. They require that quality risks throughout the product lifecycles be identified, assessed, and mitigated or minimized. This includes ensuring we have appropriate business continuity plans in place. In addition to mandatory product risk management principles, we developed a proprietary risk mapping tool to identify, assess and thereby help mitigate risks across the entire manufacturing value stream. Based on a comprehensive data-driven methodology, the tool helps identify opportunities for strengthening quality controls at every phase of a product lifecycle, thereby enabling continuous process improvement and proactive quality control.

Compliance monitoring: We have established a closed-loop, independent audit approach to help ensure our facilities and external manufacturing sites operate in compliance with our internal Johnson & Johnson Quality Standards, as well as global health authority requirements. Closed-loop quality processes, or feedback loops, continuously correct and help prevent quality issues. Our Quality Audit Program applies to all Johnson & Johnson facilities that manufacture, store or distribute product. It also applies to external manufacturers that provide materials, products and services to our businesses. Through this Quality Audit Program, we monitor, assess and identify opportunities to continuously improve the effectiveness of our quality systems. Suppliers of Johnson & Johnson are audited to ensure compliance with our Quality Agreements and with the regulations under which they operate. The audits are performed by representatives of Johnson & Johnson and/or third parties, including nonprofit industry associations such as Rx-360.
In addition to our monitoring programs, we maintain a Management Review process that is built into the quality system of each operating company, mandating its executive management to review the quality

system, and to require improvements where necessary. These Management Reviews are conducted every six months.

Internal communications and escalation procedures: As part of our Quality Policies and Quality Standards, we maintain detailed Standard Operating Procedures governing escalation procedures for product quality issues that may arise. These procedures set out specific criteria that define when a quality or product issue should be escalated. If the issue meets any of these criteria, an Escalation ALERT, which is a written communication used to inform management about a potentially serious product quality or compliance issue, is sent to the appropriate level of management, and to higher levels of management for information. An Escalation Lead is appointed to manage the entire process through to resolution, including the prescribed convening of Quality Issue Management Teams to investigate and classify the severity of the issue and determine and initiate required action. This includes additional escalation procedures such as external notification to relevant health authorities if required.

Product recall: As required by the Quality Standards, each operating company has a formal Quality Review Board (QRB), which convenes when necessary to evaluate concerns with the quality of product in the market. The QRBs consist of leaders from Quality, Medical Affairs, Medical Safety and Regulatory Affairs. The QRBs decide independently of commercial considerations whether actions need to be taken to correct or recall a product from the market. Patient and consumer safety supersedes any other factor in this decision-making.

Continuous improvement: We proactively monitor and evaluate our systems, standards, industry landscape and regulatory environment, incorporating changes where necessary to drive continuous improvement. Further, when appropriate, sites develop corrective action plans to systematically improve their quality systems and to prevent a recurrence of any deficiencies. Such ongoing proactivity helps us detect and correct potential issues independently to ensure compliance with regulatory requirements. Results, status and progress are all reported to business leaders and the Johnson & Johnson operating company governing bodies. Regular updates on this topic are provided by the Johnson & Johnson CQO to the Regulatory Compliance & Sustainability Committee.

Integration of new acquisitions: Patient and customer safety and product quality are paramount considerations in our approach to integrating new acquisitions. We have a well-defined process in place to ensure that when a new company joins our Johnson & Johnson Family of Companies, we take prompt

measures to align that company's quality system to our Johnson & Johnson Quality System framework. Our Quality teams participate in the due diligence activities during the acquisition process and conduct detailed risk assessments of quality systems and processes. The risks are prioritized, and action plans are developed to ensure compliance with our internal Quality Policies and Quality Standards.

Training and education: Continuous improvement of the skills and capabilities of our employees is essential for ensuring they have the competence needed to perform the requirements of their job in a health-authority-regulated industry. All Quality & Compliance employees are assigned extensive trainings throughout the year, based on their job responsibilities, and as required by their business's Quality System. This training ensures all associates are knowledgeable about the Current Good Practice (cGxP) requirements for their work.

Further, we educate our workforce and partners to develop their skills and capabilities beyond GxP regulatory requirements as follows:

- Our Quality Academy provides all employees (not just those in our Quality & Compliance organization) with access to educational and development opportunities and over 85 self-paced, interactive, professionally developed e-learning modules and case studies covering over 40 quality-related end-to-end topics. Among these topics are audit readiness, error reduction skills, investigation skills, root cause problem solving, data integrity, continuous improvement and change management to support our proactive manufacturing quality and goals.
- Our Johnson & Johnson Certified Quality Engineer learning journey provides additional learning opportunities for employees committed to enhancing their quality knowledge and skills, and is aimed at accelerating the generation, expansion and exchange of knowledge in applied statistics, quality engineering and quality improvement topics.
- Sterility Assurance courses, which include the Microbiology Analyst Training Certification and Laboratory Analyst Training Certification programs.
- Over the years, we have identified many best practices that improve the quality of our products and processes at our sites. We share those learnings free of charge with our suppliers, external manufacturers, distributors, transportation providers and other external partners through our Supplier Quality Academy.

We apply the same educational philosophy to our work with external business partners. Through our Supplier Quality Academy, we provide high-quality training to suppliers and supplier-facing Johnson & Johnson employees to build and strengthen strategic competencies that impact the overall quality and performance of the end-to-end supply chain. Over years, we have identified many best practices that improve the quality of our products and processes at our sites. The Supplier Quality Academy enables us to share those learnings free of charge with our suppliers, external manufacturers, distributors, transportation providers and other partners.

For additional details on our quality management system across our Innovative Medicine and MedTech business segments see the Johnson & Johnson Quality Management Framework.

Application

This Position is relevant for the Johnson & Johnson Family of Companies, as detailed in our governance materials. We provide updates, where relevant, relating to quality and compliance in our annual Health for Humanity Report. Johnson & Johnson's Policies and Positions on these and other issues are available in full here.

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