

# Position on Quality and Compliance

## Background

Quality is a core responsibility of any company. Healthcare providers, patients, consumers and customers expect the level of quality they are promised. By building quality into processes, a company meets its responsibilities to those it serves while operating efficiently, minimizing waste and other risks and costs arising resulting from quality issues. Additionally, consistent delivery of high-quality products helps a company build and maintain a positive reputation and trust with all those who use its products.

## Relevance

As the largest, most diversified healthcare products company—reaching patients, consumers and customers each day with its medicines, medical technologies and consumer care products—Johnson & Johnson plays a major role in advancing human health and improving patient outcomes.

Quality is a fundamental value. We believe our patients and consumers deserve consistent, reliable and high quality every time they use or experience a Johnson & Johnson product. Specifically, in the healthcare industry, many of our products play a very significant role in improving people's lives—products that patients and consumers rely on every day. Focusing on quality and compliance throughout our product lifecycle is key to ensuring continuity of supply to those who need our products to achieve or maintain good health and well-being. On a day-to-day basis, attention to quality is just good business, creating cost and resource efficiencies, which in turn help us become a more sustainable company over the long term.

## Guiding Principles

As stated in [Our Credo](#), "... everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices."

## Our Quality & Compliance Organization

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 Company's Chief Quality Officer, who oversees Chief Quality Officers for each of our business segments, ensures harmonized quality management through consistent implementation of quality systems across our Johnson & Johnson Family of Companies. Q&C has oversight of quality and regulatory compliance across the Enterprise. Q&C leadership establishes the enterprise-wide Johnson & Johnson Quality Policies and Quality Standards. 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 Position

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.

**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 Chief Quality Officer 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 Pharmaceutical, MedTech and Consumer Health 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 relating to quality and compliance in our annual [Health for Humanity Report](#).

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