

Position on Quality and Compliance

Background

Quality is a core responsibility of any company. Healthcare providers, 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 because of 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 world's largest and most broadly based healthcare company, reaching patients, consumers and customers each day with its medicines, consumer care products and medical devices, 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 wellbeing. 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. It is our first responsibility to people around the world who use and trust Johnson & Johnson products. Every employee of our Company proudly accepts this responsibility every day.

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 has Chief Quality Officers in place for each of our three 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 Policy 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 heads 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. 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 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.

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. 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, thus 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 to our Quality

Agreements and to 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 Rx360.

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 all 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, independent of commercial considerations, whether actions need to be taken to correct or recall a product from the market. Patient and consumer safety supersede 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 “self-detect” and “self-correct” potential issues 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 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 in ensuring they have the competence needed to perform their responsibilities within health authority regulated activities. All applicable employees receive extensive trainings on their responsibilities under their business’ Quality System. Our Quality Training Academy is a centralized platform for our Quality employees to access training and development opportunities. In addition to mandatory trainings, we offer several learning and professional development courses. These include:

- Advanced training on quality improvement methodologies designed to support our manufacturing quality and goals;
- e-learning modules, arranged in four tiers (foundational, applied learning, integrating methods and leadership, which includes audit readiness training and change management). e-learning courses are integrated into annual employee objectives and are accessible anytime, anywhere;
- Johnson & Johnson Certified Quality Engineers learning track, to provide additional training for those who have achieved certification-level knowledge and skills; and
- Quality Engineering Communities of Practice that are aimed at accelerating the generation, expansion and exchange of knowledge in applied statistics, quality engineering and quality improvement topics. They take the form of case study webinars and practice forums on topics such as brand protection and effectively managing controlled substances, and seek to increase cross-business, end-to-end collaboration and teamwork.

We apply the same training and education philosophy to our work with suppliers. Through our Supplier Quality Academy, we provide 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 with our suppliers and external manufacturers. The platform offers a number of courses, delivered through a variety of training methods—from face-to-face instructor-led trainings to virtual instructor-led conferencing and self-led online modules.

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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