We blend heart, science and ingenuity...

Quality at Johnson & Johnson

...to profoundly change the trajectory of health for humanity.

Foreword

Quality at the Forefront

At Johnson & Johnson, ALL employees are responsible for Quality. We believe good health is the foundation of vibrant lives, thriving communities, and forward progress. That is why for more than 130 years, we have aimed to keep people healthy at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body, and environment within reach of everyone, everywhere. We blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. To continuously assure this vision, Johnson & Johnson puts high quality as a shared priority for all J&J associates.

Our approach to managing Quality is through the Johnson & Johnson Quality Management Framework or QMF. It includes our Commitment to Quality, as set forth in Our Credo, our Quality & Compliance organization, and our system of policies, standards, and procedures designed to achieve end-to-end compliance with customer and regulatory requirements for Quality Management Systems across Johnson & Johnson. The Johnson & Johnson Quality Policies & Standards across our Family of Companies cover the lifecycle of our products from research and development to the consumer and patient experience. These Policy Standards provide a common foundation of quality expectations and help to ensure a reliable supply of high-quality products across all our business segments. The Quality Policy Standards set expectations for all Johnson & Johnson companies to achieve.

In 2021, we continued to assess and improve our internal quality policies and standards to keep pace with the changing regulatory demands for our diverse portfolio of products. This positions Johnson & Johnson to leverage emerging technologies and better serve our customers, we undertook a program to improve clarity, map requirements to applicable regulatory requirements, and incorporate Health Authority expectations while enabling flexibility for our diverse business segments. This restructuring of our policy standards resulted in the addition of six new Quality Policies that better reflect the lifecycle of our products. These quality policies and standards focus on our commitment to continued **Compliance** to Regulations, **Simplification** of processes and procedures across our businesses, focused **Applicability** to the intended audience, **Traceability** to requirements, and **Flexibility** to enable innovation within the organization. These are the key elements that make our Quality Management Systems customer-centric, provide continuous improvement, and incorporate Quality as a universal discipline that raises the bar for all to attain.

As stated in Our Credo, "We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs, everything we do must be of high quality." Therefore, Quality is at the forefront of our strategic priorities and shapes the Quality culture at Johnson & Johnson for continued success now and in the future.

Joaquin Duato
Chairman and CEO
Johnson & Johnson

Jennifer Paine
Chief Quality Officer (CQO)
Johnson & Johnson

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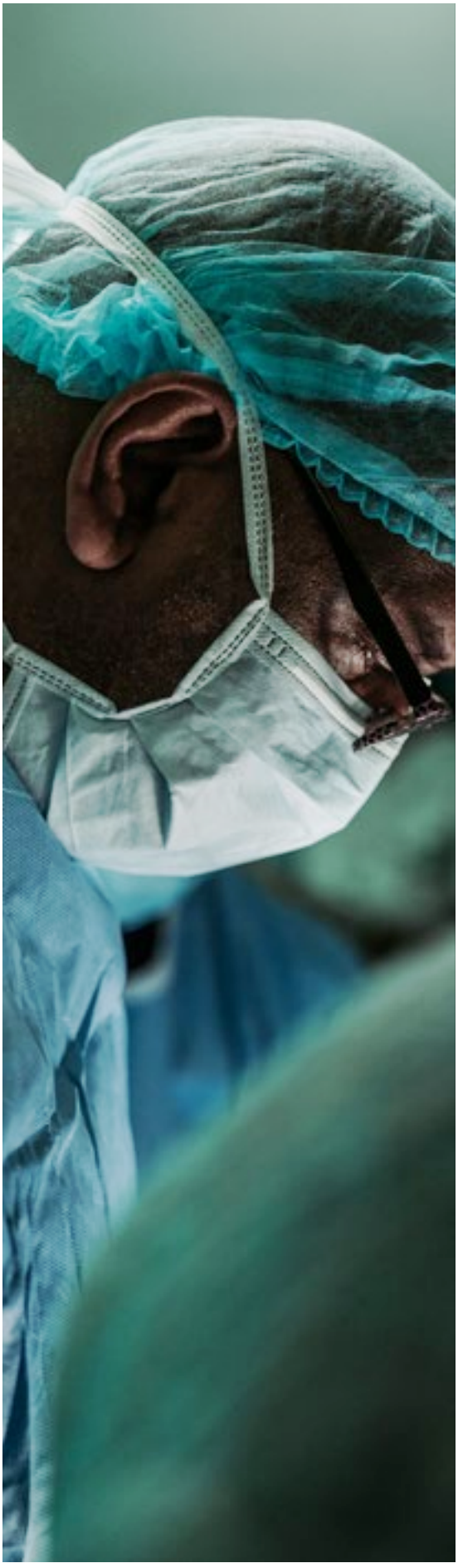


1. Introduction to the Johnson & Johnson Quality Management Framework

1.1 Purpose

This Johnson & Johnson Quality Management Framework provides an overview of the Quality architecture for Johnson and Johnson. Specifically, the QMF outlines how quality is managed within Johnson & Johnson and includes the Quality & Compliance organization, the roles and responsibilities, and the policies, standards, processes, and procedures that establish requirements for end-to-end compliance to the Quality Management Systems across Johnson & Johnson.

1.2 Scope

The management of Quality applies to **ALL** areas within our **Business and Functional units**. This includes, but is not limited to, research, design and development, clinical, sourcing, supply, validation/ qualification, production, packaging, labelling, operations, laboratory and testing, product release, storage, transportation, distribution, installation, service, marketing, and post-market surveillance.

1.3

Quality Values

We build trust by focusing on Culture, Capabilities, Compliance and Customers.

Culture

Culture is the cornerstone of Quality. We drive quality in a positive and proactive way. At Johnson & Johnson, we have a customer-focused, Credo-centered mindset, and our leaders set the tone at every level.

Capabilities

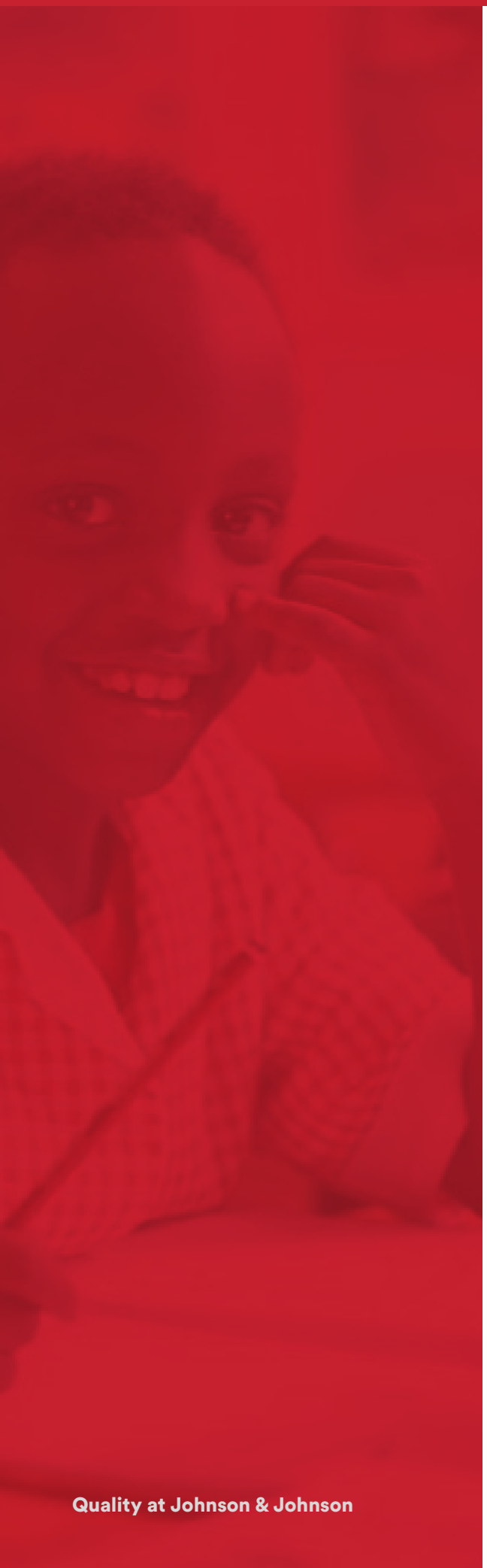
We empower our Research & Development, Supply Chain, and Commercial teams to design, make, and deliver the right product with the right performance, every time. The scale of Johnson & Johnson is leveraged to fuel innovation and designed to achieve more competitive products, technology, and process quality.

Compliance

Everyone must understand their role in ensuring quality at Johnson & Johnson and getting it right the first time is a priority. To assist with this goal, we have Johnson & Johnson Quality Standards to ensure compliance to regulation, drive consistency, and reduce risk. We focus on the continuous improvement of our products and services to set the benchmark.

Customers

All of our actions have a direct impact on our ability to help people around the world live longer, happier, and healthier lives. We listen to our customers to understand what's important and enable quality solutions to drive value and enhance the customer experience.



2. Commitment to Quality

Our Commitment to Quality starts with Our Credo, which is the foundation of the Johnson & Johnson QMF.

2.1 Our Commitment to Quality starts with Our Credo, which is the foundation of the Johnson & Johnson QMF. The values that guide our decision making are spelled out in Our Credo. Our Credo reminds us that “everything we do must be of high quality.” Our Credo represents the Values that are shared among all Johnson & Johnson businesses, functional units, and employees.

Our Credo.

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens — support good works and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Visit www.jnj.com/credo/ to learn more about Our Credo.

3. Johnson & Johnson Organization

Johnson & Johnson was founded in 1886. It has since grown to become one of the world's largest and most broadly-based healthcare companies.

- → Johnson & Johnson conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.
- → Over 140,000 employees across the globe work every day to help transform healthcare.
- → Over one billion lives are touched every day by a Johnson & Johnson product or service.

The Johnson & Johnson Family of Companies is organized into Segments (Pharmaceutical, MedTech and Consumer Health). These Segments have decentralized businesses, including individual Operating Companies or Franchise management structures that may execute or support functions such as Research and Development, Sales and Marketing, Regulatory Affairs, or other activities regulated by health authorities. Certain functional expertise may be managed at the Johnson & Johnson Enterprise level, such as Information Technology (IT) and Human Resources. These Enterprise-level functions are managed through a combination of centralized capabilities and business-facing support. Collectively the Segments with all supporting Enterprise-wide and Functional units comprise the Johnson & Johnson Enterprise.

3.1

Decentralized Businesses:

Pharmaceutical Products

The Pharmaceutical segment is actively developing treatments for our patients in six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases.

MedTech

The MedTech segment includes a broad range of patient-centric products and solutions used in surgery, orthopaedics, vision, and interventional solutions used principally in the professional fields by physicians, nurses, hospitals, eye care professionals, and clinics.

As pioneers in med tech, we continually focus on elevating the standard of care—working to expand patient access, improve outcomes, reduce health system costs, and drive value. We create smart, people-centered healthcare to help the patients we serve recover faster and live longer and more vibrantly.

Consumer Health

The Johnson & Johnson Family of Consumer Companies offers one of the world's largest range of consumer healthcare products. Our baby care, skincare, oral care, wound care, over-the-counter, and women's health products feature brands trusted by consumers and healthcare professionals worldwide. By anticipating needs and creating solutions and experiences, we help people live healthy, vibrant lives.

3.2

Major Enterprise-Level Functions

Johnson & Johnson Supply Chain (JJSC)

Johnson & Johnson Supply Chain includes three business sector supply chains—Pharmaceuticals, MedTech and Consumer Health—that cover planning, sourcing, internal and external manufacturing, as well as the Supply Chain Strategy, Innovation & Deployment organization, and the Deliver organization, which manages distribution and customer service. Additional enterprise-wide functions that are part of the Johnson & Johnson Supply Chain include Environmental Health, Safety & Sustainability, and Engineering & Property Services.

Medical Safety Office and Regulatory Affairs

The Johnson & Johnson Office of the Chief Medical Officer is a global group of medical and scientific professionals focused on advancing evidence- and science-based decision-making that is driven by bioethical principles and values.

The Regulatory Affairs organization provides regulatory expertise to all J&J businesses on the development requirements, regulatory submission requirements, and approval process for J&J products. This group is responsible for ensuring all product registrations and approvals are accurate and current. Regulatory Affairs also ensures that all product labeling meets the regulatory requirements for each market that a product is distributed.

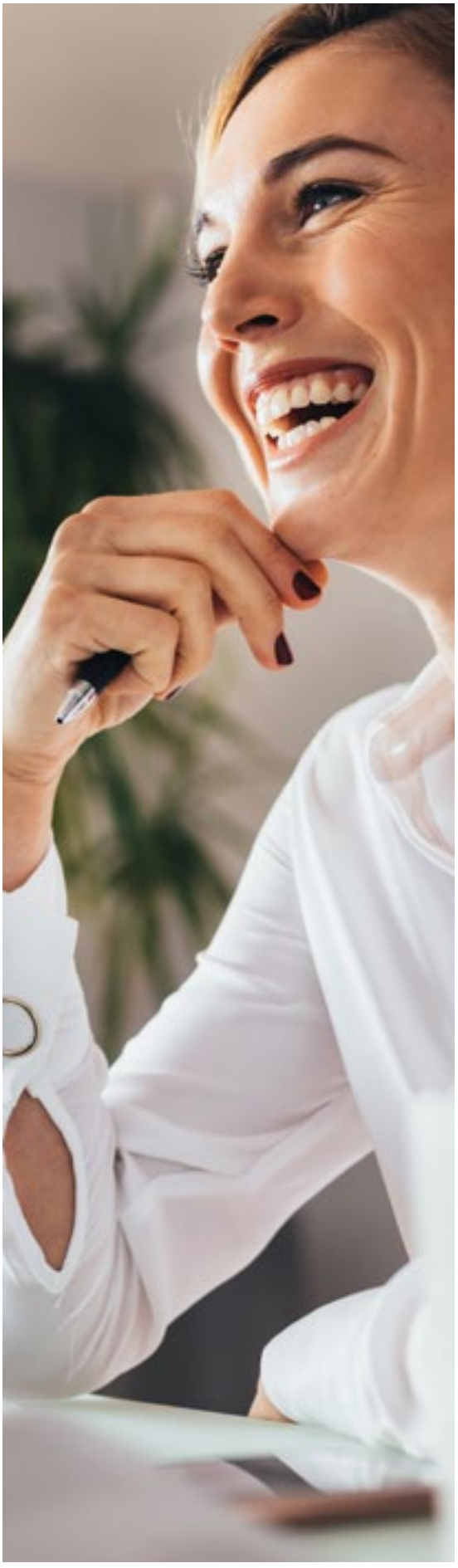
Quality and Compliance

The Quality and Compliance function provides end-to-end support to all Business and Functional units to ensure that product is designed, manufactured, and delivered with high quality and in compliance with regulations.

4. How Johnson & Johnson Manages Quality

Johnson & Johnson manages Quality through its Quality organizational roles and responsibilities, policies, standards, processes, and procedures. This is referred to collectively as the Quality Management Framework. There are individual Quality Management Systems throughout the Business and Functional Units that are supported by Senior Management. Senior Management within Johnson & Johnson is the highest level of management with the responsibility, authority, and control of resources to define, implement, and/or modify the structure, policies, procedures, processes, and practices of the organization(s).

Senior Management ensures the Quality and Compliance function has key decision-making and oversight responsibilities for all Quality Management Systems across the Enterprise. However, responsibilities from Management down to the employee level are applied so that every employee has a responsibility to Quality.



5. The Role of Management

5.1 Management Responsibilities

Management at all levels and in all functions have a significant role in building the culture at Johnson & Johnson by demonstrating leadership and a commitment to quality. Management has oversight to ensure that Business and Functional units are operating within the individual Quality Management Systems and that the QMS aligns with the Quality Policies, Quality Standards, and applicable regulations.

Key processes under management responsibilities include the following:

Plan

- **Quality Planning** – Management establishes the organization's Quality plan, goals, and objectives and cascades these expectations throughout the organization to ensure all employees are engaged in the quality priorities. Management at all levels of the organization ensures Business and Functional unit quality plans and objectives align with business strategies and the Quality Policies.

- **Resource Management** – Management of each Business and Functional unit identifies resource requirements and provide resources, infrastructure, and qualified personnel to establish, maintain, and improve the elements of the quality system. This includes Quality Planning through implementation.

- **Management of Outsourced Activities** – Management ensures there are processes in place at each Business and Functional unit to control, review, and ensure all outsourced services (including external manufacturing and suppliers that are executing GxP activities) are in compliance to applicable regulations.

- **Acquisitions and Divestitures** – Management of each Business and Functional unit will ensure that appropriate resources and processes are established to assess and manage the quality and compliance responsibilities for Acquisition and Divestiture of products, services, and companies.

Monitor

- **Management Review** –The performance of the individual business units within Johnson & Johnson is reviewed and monitored by Management. Management Reviews are documented and include monitoring of key metrics, adequacy of the QMS, the potential impact identified risks, and actions taken to mitigate risks. The output of Management Reviews is used to define corrective and preventive actions for continuous improvement and annual Quality Planning.

- **Quality Monitoring** –Quality oversight and on-going monitoring are performed by Business and Functional units to identify and mitigate risks. Feedback is provided to appropriate Management throughout product lifecycle to ensure continuous improvement of the individual Quality Management Systems.

Communicate

- **Escalation and Internal Communication** – Management of each Business and Functional unit implements effective communication processes at all levels. A formal escalation process is established to notify Quality Management and, if required, applicable Health Authority and Regulatory Agencies of significant product quality, regulatory compliance, and quality system issues throughout product lifecycle.

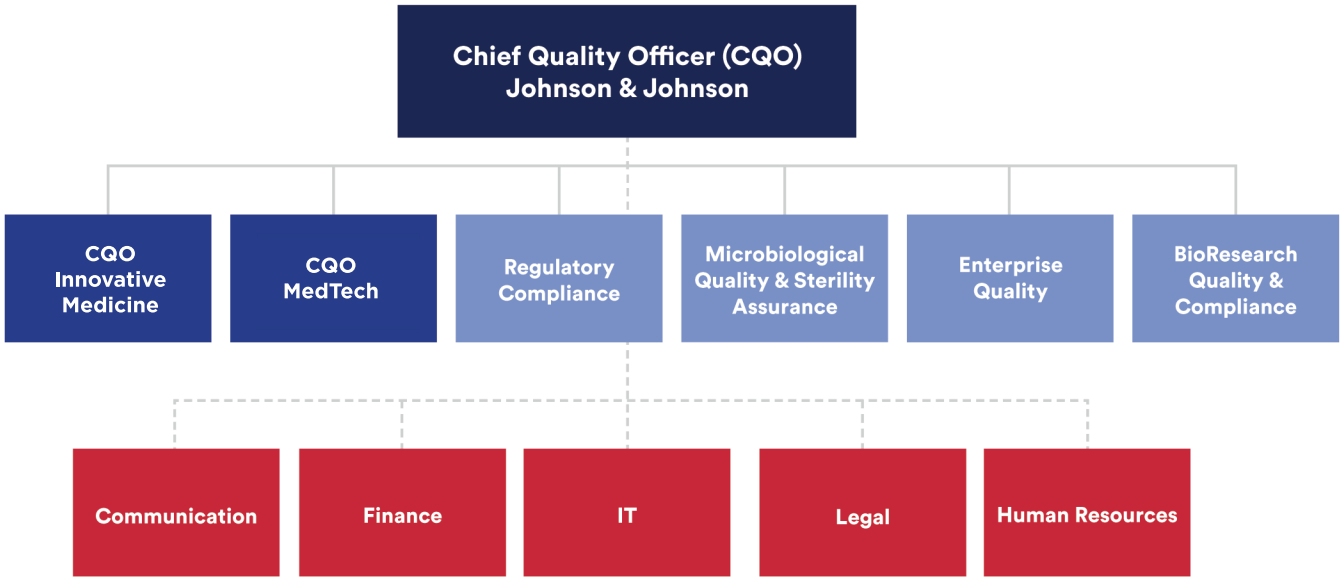
6. Quality Organization & Governance

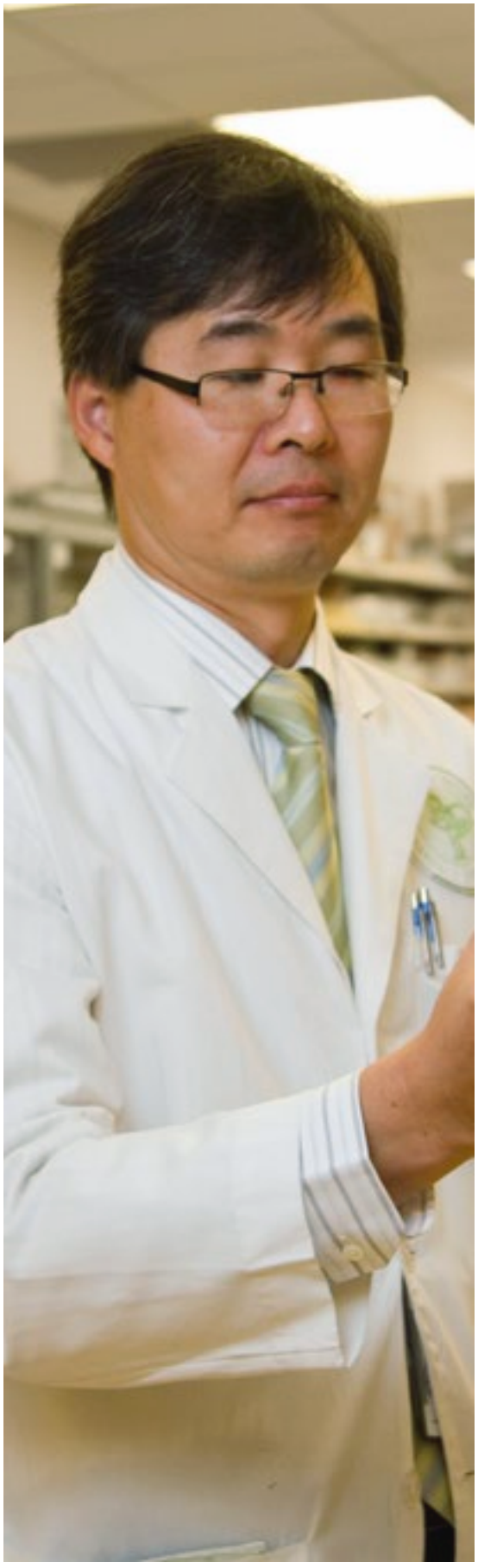
6.1

Quality Organization

The Johnson & Johnson Quality & Compliance (J&J Q&C) organization has a worldwide presence in pharmaceuticals, medtech and consumer health, ensuring that products are designed, manufactured, and delivered effectively. Quality management has a significant role within Johnson & Johnson and is represented on each Company Global Operating Committee 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.

Quality and regulatory compliance issues are escalated, and the performance of the quality management system is reported to the Johnson & Johnson Chief Quality Officer. The Quality & Compliance organization is independent of all other business functions and is the ultimate decision-maker for the applicable Market Authorization Holder in all matters of quality and regulatory compliance. An independent audit function within Quality provides compliance oversight to deliver early detection and mitigate quality and compliance risks throughout the entire organization.





6.2 Johnson & Johnson Chief Quality Officer & Segment Chief Quality Officers

Johnson & Johnson Chief Quality Officer

The Johnson & Johnson CQO leads the Johnson & Johnson Quality & Compliance organization and is responsible for:

- → Providing strategic direction and oversight of quality and regulatory compliance for the Johnson & Johnson companies end-to-end across all our business and functions;
- → Establishing the Quality and Compliance (Q&C) Vision, and Strategic Priorities, and communicating these to employees;
- → Establishing Johnson & Johnson Quality Policies and Standards that will promote consistency in quality requirements across all Business and Functional units;
- → 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
- → Reporting quality and regulatory compliance metrics and issues to executive management.

Segment Chief Quality Officer

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:

- → Assuring Segment procedures are in place that align with Johnson & Johnson Quality Policies and Standards;
- → Establishing quality plans and goals/objectives for the Segment;
- → Managing resources to effectively execute and monitor the quality plan and goals/objectives for effectiveness throughout the Segment; and
- → Communicating quality needs, performance, and risks to the relevant Segment Group Operating Committees and to the Johnson & Johnson CQO.

6.3

Enterprise-wide Quality Functions

Enterprise-wide Quality Functions provide quality governance and services to support Business and Functional units throughout the Enterprise. These functions consist of Regulatory Compliance and Enterprise Quality.

Regulatory Compliance

The Regulatory Compliance function provides independent oversight and guidance across the Enterprise. This function supports regulatory compliance activities, performs internal/external audits, supports monitoring/verification of Corrective and Preventive Action (CAPA), and remediation activities. This team also includes Enterprise-wide Standards Management, which provides effective regulatory outreach and communicates compliance risks to executive management.

Enterprise Quality

There are several teams that provide enterprise quality support and services to our businesses. These include: Enterprise Quality, Commercial Quality, Supplier Quality Reliability, Technology Quality and Emerging Technologies.

- → Enterprise Quality continuously improves Quality processes across Enterprise to advance Customer Experience.
- → Commercial Quality Shared Services provides quality operations support for global transportation and finished goods temperature control.
- → Supplier Quality Reliability delivers improved processes, digital solutions and data analytics in the supplier lifecycle management.
- → Technology Quality accelerates and enables technology solutions and ensures the overall strategy for validation/qualification of applications and infrastructure.
- → Emerging Technologies acts as a catalyst across the segments to accelerate our quality strategy through digital enablement.

6.4

Functional Quality Management

Functional units are specialized units that provide a specific service to one or more businesses throughout the Enterprise. Support includes but is not limited to pre-clinical/clinical quality management, commercial product quality, and delivery quality.

Bio Research Quality & Compliance (BRQC)

BioResearch Quality & Compliance supports the business product portfolio and works in close partnership with R&D and Medical Safety (OCMO), as well as with segment CQOs. BRQC provides quality and compliance oversight for Pharmacovigilance (PV), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Animal Welfare, in addition to segment-specific activities (e.g., Cosmetovigilance) across Pharmaceutical, MedTech and Consumer Health.

Commercial Quality (CQ)

Commercial Quality provides oversight and support to local operating companies in the areas of strategy and planning, quality system oversight, compliance reporting, portfolio and product lifecycle management, product supply, and external manufacturing. Commercial Quality also provides quality oversight to distribution and customer service to protect the company compliance profile, reduce risk, and focus on customer needs through ensuring Supply Reliability.

Deliver Quality & Compliance (Deliver Q&C)

Deliver Quality & Compliance provides quality oversight to distribution and customer service to protect the compliance profile, reduce risk, and focus on customer needs through ensuring Supply Reliability.

6.5

Responsibilities for Key Processes

Each Johnson & Johnson Business and Functional unit is responsible for ensuring that all procedures and processes related to monitoring and improvements for products comply with the Johnson & Johnson Quality Standards and applicable regulations. Key systems with defined requirements are in place to monitor quality processes within the Business and Functional units.

Key Processes:

Regulatory Notification and Monitoring

Current, new, and proposed regulatory agency requirements and industry standards are monitored for impact to Johnson & Johnson Quality Standards, filings, registrations, clinical protocols, submissions, business operations/activities, and products. Health authority and regulatory changes, requirements, and trends are communicated to Management.

Field Action & Recall Management

Patient and consumer safety are a top priority for everyone at Johnson & Johnson. As a result, Johnson & Johnson has a system in place to assess alleged product issues. If required, product recalls, product withdrawals, product corrections, or any other product specific actions affecting product quality or regulatory compliance are taken in accordance with all regulatory requirements. All decisions on field actions are taken independent of commercial/business influence by a Quality Review Board (QRB), which is composed of Quality, Medical Safety, Medical Affairs, and Regulatory Affairs leadership. These actions are documented and communicated to Health Authorities in a timely manner.

Complaint Handling

Product complaints are documented, managed, investigated, and reported. Product complaints are promptly evaluated for possible reportability to health or regulatory authorities, and appropriate notifications are initiated. Trends are monitored, and triggers are established to allow escalation of Significant Quality Issues.

Vigilance and Post-Marketing Surveillance

Johnson & Johnson has a program in place to identify, assess, document, and report Adverse Events and undesirable effects during all phases of the product lifecycle, including clinical trials, as required by applicable regulation. This includes the monitoring of trends and the establishment of triggers to allow escalation of Significant Quality and Safety Issues.

A post-market surveillance system is in place to collect, record, and analyze relevant data on the quality, performance, and safety of a product throughout its entire lifecycle.

Change Control/Change Management

Change Management is important for GxP activities and is applied throughout product lifecycle (research through discontinuation). A documented systematic process is in place to propose, evaluate, approve, implement, and review changes in a controlled manner. The process provides a consistent mechanism for documentation and evaluation of changes and defining requirements that must be satisfied prior to the implementation of changes.

Nonconformances and Corrective/ Preventive Action

Investigations to determine the root cause or assignable cause of each nonconformance related to product, processes, and the quality system are conducted using root cause analysis methodologies. These investigations are documented, tracked, and trended.

Corrective and Preventive Actions (CAPA) are established to manage and document the correction of a nonconformance (corrections), eliminating the root cause of a nonconformance (corrective action) and preventing the occurrence of a nonconformance (preventive action) with an evaluation of effectivity.

Periodic Product Review

Product reviews are conducted and documented per Johnson & Johnson Quality Standards and as specified by Health Authorities to assess process performance and suitability of product specifications, evaluate manufacturing or process controls, detect trends, and identify steps for corrective action and/ or continuous improvement. The elements specified in the Product Review are analyzed and compared to the results of previous reports and all regulatory requirements.

Audit Management

The Johnson & Johnson Audit program (applicable to internal companies and external suppliers) monitors the effectiveness of the quality system and ensure compliance to the Johnson & Johnson global standards and worldwide Health Authority requirements. Audits are performed per a defined audit schedule utilizing a risk-based approach.

Document and Data Management Controls

Johnson & Johnson has a documentation system to ensure control of quality procedures and records. The documentation system includes processes for the identification, creation, review, approval, distribution, implementation, storage, retention, and control of all quality systems and product requirement documents.

Data and quality records and information considered fundamental and necessary to continue operations follow GxP requirements and are protected and controlled throughout the data lifecycle, from initial generation through processing, use, data retention, archive, retrieval, and destruction.

6.6

Key Quality System Enablers

Risk Management

Risk management requirements are part of the Johnson & Johnson Quality Policies. Risk management principles are applied throughout Johnson & Johnson to identify risks based on scientific evidence throughout the product lifecycle (Research and Development through Product Discontinuation). Risk management principles must meet applicable regulatory requirements.

Measures are taken to minimize and control the quality and compliance risks throughout the various Quality Management Systems, to advise Management of each Business and Functional unit of remaining risks, and to communicate risks effectively to customers, healthcare professionals, and regulatory agencies wherever appropriate.

Knowledge Management

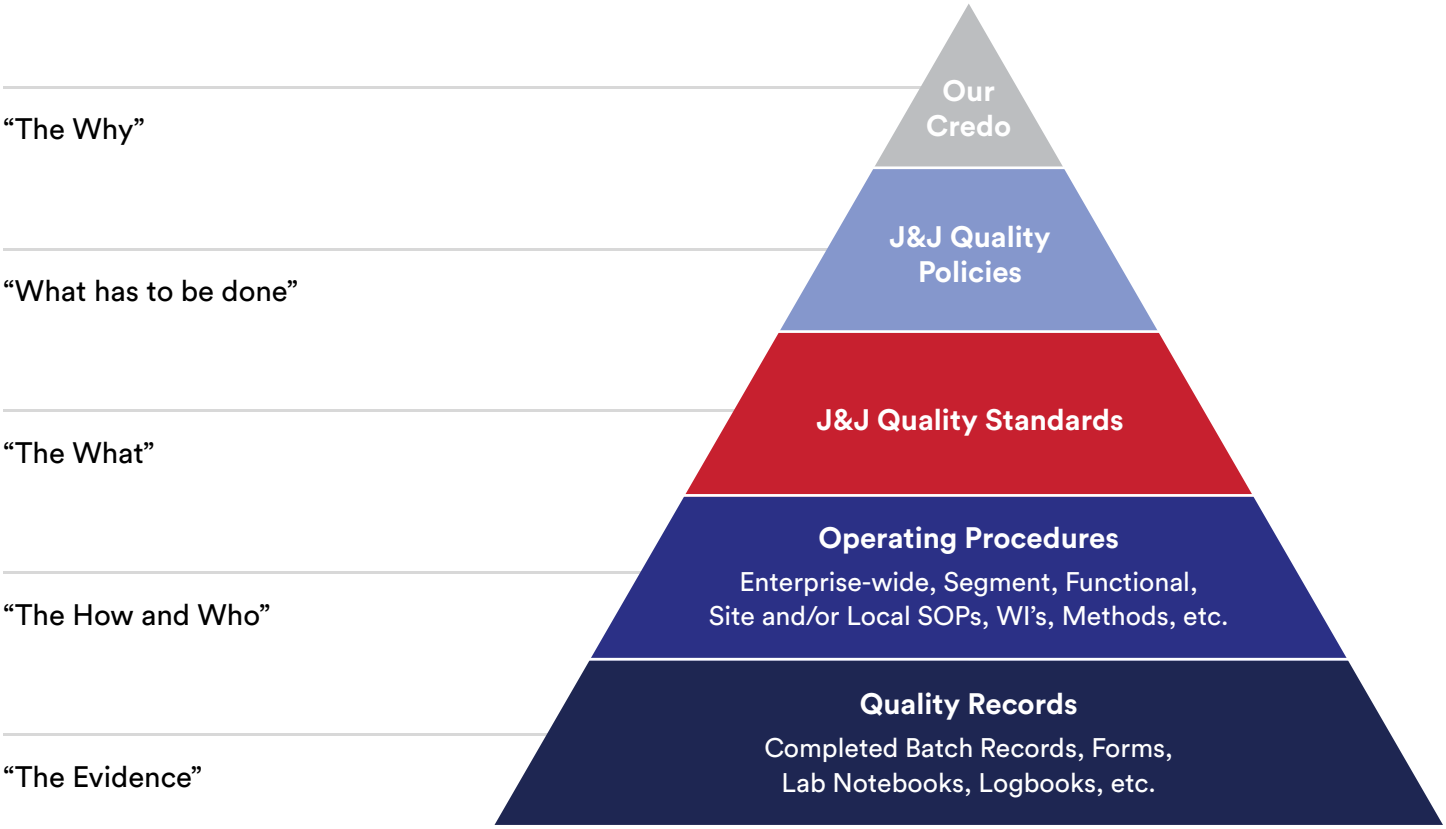
Knowledge management encompasses the sharing of best practices to promote a culture of cross-segment discussions designed to raise the level of quality performance across the company. Knowledge Management connects to the Quality Management Framework by providing Learning Solutions that are designed using a fit-for-purpose approach. This approach focuses on providing value to our customers by delivering the right training content to the right audience at the right time.

Quality Culture

There is a reason that quality is the first responsibility in Our Credo: “Everything we do must be of high quality.” The high-quality products and services we deliver at Johnson & Johnson help billions of people live longer, healthier, and happier lives. In addition, delivering the right product with the right performance drives increased investments for innovation, extraordinary customer experiences, a stronger company reputation, higher levels of employee pride, and more overall success for Johnson & Johnson. No matter where an employee works—manufacturing plant, lab, distribution center, office, in the field—the goal is to inspire everyone to understand their role in delivering high quality in all that they do each and every day.

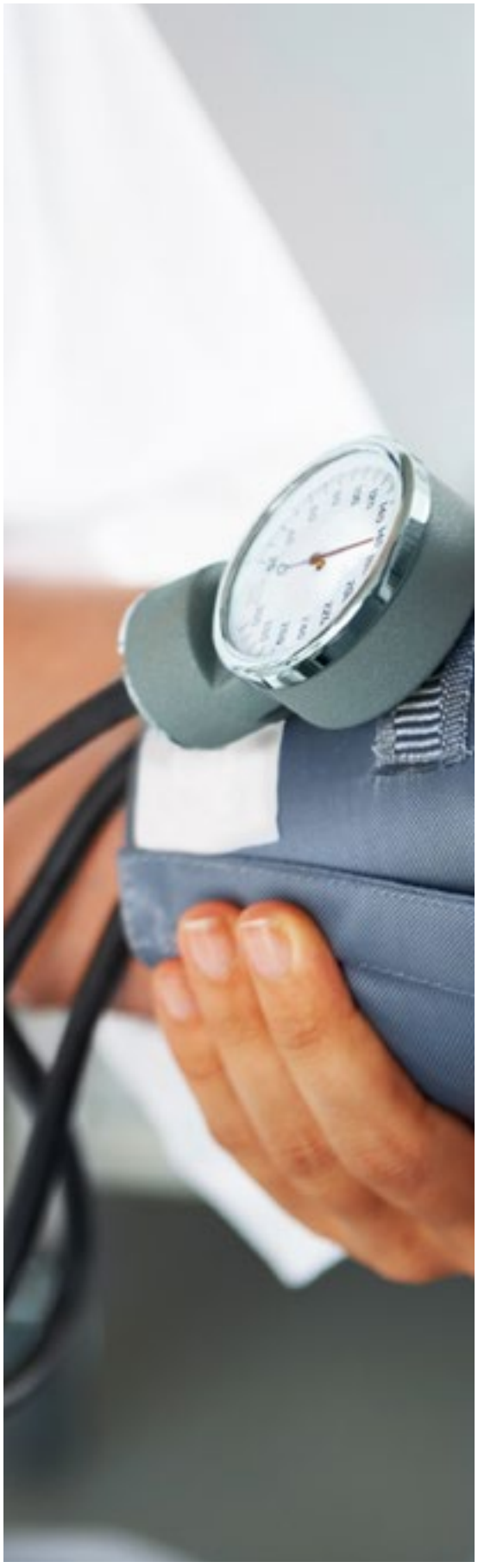
6.7

Quality Management Documentation Hierarchy



The Johnson & Johnson Quality Management Framework Documentation hierarchy provides a foundation that sets forth the requirements for all Johnson & Johnson companies. The Quality Policies and Standards are the highest-level documents and are based on core regulations that ensure compliance with good practice (GxP) requirements from global regulators. The "Core" covers:

- → A broad range of product types such as cosmetics, nutritional supplements, medical devices, drugs, biologics, and active pharmaceutical ingredients (APIs);
- → A broad range of country-specific and international organizational guidelines and standards documents;
- → And emerging markets and/or regulations.



Level 0 Credo

Johnson & Johnson's Commitment to Quality

Level 1 Quality Policies

These are top-level documents within the Johnson & Johnson Quality Management documentation hierarchy. These documents define the intentions of the organization and key Quality and Compliance processes throughout the Enterprise. The Quality Policies describe the Quality management approach, organizational structure, management responsibilities, and principles of operation that applied throughout the product lifecycle.

Level 2 Quality Standards

These documents provide the minimum requirements to ensure that materials, products, processes, and services are safe, effective, compliant to specification and meet applicable regulatory requirements. Quality Standards set forth the expectations of Johnson & Johnson. Elements of the Quality Standards are transcribed into Segment and/or local site documents.

Level 3 Standard Operating Procedures

These documents provide clearly defined instructions and specific details on how a process must be executed and responsibilities required to support operational processes. This level includes Procedural Documents that are Enterprise-wide SOPs, Segment, Functional, Site, and/or locally specific. Operational procedures must incorporate elements of the Quality Standards to ensure alignment with Johnson & Johnson's overall quality position.

Level 4 Quality Records

These are Local Documents that state the results achieved or provide evidence of Quality Management System activities performed. Examples of these documents are completed batch records, Forms, Lab Notebooks, and Logbooks. Quality Records must comply with Segment, Functional, Site, and/or locally specific procedures.

7. Johnson & Johnson Global Quality Audits & Regulatory Inspections

Johnson & Johnson Operational Units, Sites, and Functions are periodically audited to verify compliance with Johnson & Johnson Quality Policies, Quality Standards, local operating procedures, and regulations. Audits are performed at various levels of Johnson & Johnson, including Self-Assessments at the site level and at the corporate level. These audits are intended to proactively identify any risks to Johnson & Johnson and to ensure Johnson & Johnson units are meeting all regulatory obligations and commitments. When deviations from internal or external requirements are identified during audits or regulatory inspections, corrective and preventive action plans are put in place and monitored until resolution.

A key aspect of the Quality Management System is to ensure that all relevant Johnson & Johnson entities are prepared at all times to receive Regulatory Authorities' inspections. To ensure on-going inspection readiness, the following tools and support are provided:

- → Inspection Readiness evaluation tools are available to self-assess state of inspection readiness.
- → Inspection Preparation can be provided from Johnson & Johnson Regulatory Compliance (JJRC) and/or Operational Quality Units. This support can be provided both prior to and during inspections.
- → Mock Audits can be performed as well. The mock audits are also used as part of the Pre-Approval Inspection Management process.

External manufacturers and suppliers of Johnson & Johnson are also audited to ensure compliance with regulations under which they operate.

In addition, prior to the decision to enter a partnership or purchase of a product, a company, or process, Global Quality Audit is involved in the evaluation and selection through a due diligence process to assess the state of compliance and associated risks to Johnson & Johnson.

8. Quality Enabling the Future

Johnson & Johnson is embracing disruptive technology and digitization to deliver advanced pharmaceuticals, medtech, and consumer products of the highest Quality for our customers/patients/consumers around the globe. Manufacturing for the Future Technology focus areas include:

- → Robotics & High-Tech Process Automation
- → Predictive & Adaptive Control (Process & Equipment)
- → Autonomous Vehicles, Smart Transportation & Tracking
- → Digital Worker
- → Digital Recipe Management & Performance Management
- → 3D printing
- → Material Sciences and Surface Engineering
- → Digital Process Design Simulation & Optimization

Where the new world of healthcare intersects with the new world of technology, Johnson & Johnson is proactively uncovering where enhancements to Quality strategy or new Quality capabilities are needed early in the innovation funnel to simultaneously minimize risk and enable the future. We are preparing our Fit-for-Future Quality Management Framework to meet increasingly changing marketplace needs.

Document Revision History

V-1.0 – June 2020

V-2.0 – June 2022