RECKITT QUALITY MANUAL

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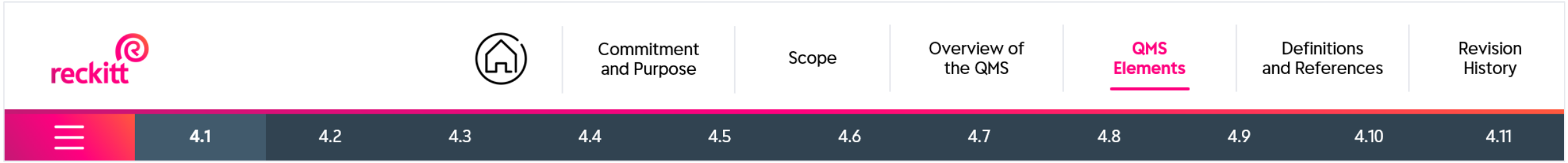
HOW TO USE THE RECKITT QUALITY MANUAL

Welcome to the Reckitt Quality Manual (RQM). This is your guide to quality management at Reckitt and shows you how to make sure you're delivering our organisation's objectives safely and to the highest quality standard.

We have created this manual to be interactive so you can navigate all the content seamlessly. You can also press "Ctrl+F" on your keyboard at any time to search for a relevant keyword.

Click the Home icon to return to the Contents page or select any of the top tabs on a page to jump to a specific section.



In the QMS Elements section, you can click on any of the numbered tabs to jump to a particular sub-section or click on the left button menu to go back to the QMS Elements overview page.

Within a section, you will see the following buttons beside the page number, which will allow you navigate to previous / next pages and sections.

EXAMPLES:

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WHAT'S INSIDE THE RECKITT QUALITY MANUAL

Click on the links below to navigate to the relevant page.

1.0 Commitment and Purpose

1.0 COMMITMENT AND PURPOSE

Our Commitment to Quality

We exist to protect, heal, and nurture in the relentless pursuit of a cleaner and healthier world.

Our brands have been loved for generations and creating products people trust is the foundation of our business.

We make it our personal responsibility to exceed the increasing and evolving expectations of our consumers and stakeholders, through our relentless pursuit of excellence.

We drive performance and deliver continuous improvement to enable innovation and build sustainable growth.

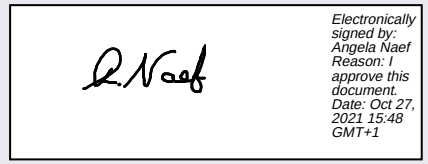
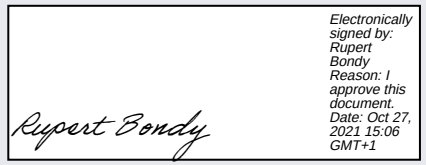
Together, we can deliver outstanding products and services, and meaningful value for our business.

Laxman Narasimhan

Electronically signed by: Laxman Narasimhan Reason: I approve this document. Date: Nov 19, 2021 12:11 GMT

1.0 COMMITMENT AND PURPOSE

Group Executive Committee (GEC) Commitment

Name	Kris Licht	Volker Kuhn	Patrick Sly	Sami Naffakh	Angela Naef
Title	President Health and Global Chief Customer Officer	President Hygiene	Chief Operating Officer, Nutrition	Chief Supply Officer	Chief Research and Development Officer
					
Name	Miguel Veiga Pestana	Filippo Catalano	Ranjay Radhakrishnan	Rupert Bondy	Jeff Carr
Title	Head of Corporate Affairs and Chief Sustainability Officer	Chief Information and Digitisation Officer	Chief Human Resources Officer	SVP General Counsel and Company Secretary	Chief Financial Officer
					

1.0 COMMITMENT AND PURPOSE

Our Purpose

To protect, heal and nurture in the relentless pursuit of a cleaner, healthier world.

Our Fight

Making access to the highest quality hygiene, wellness and nourishment a right, not a privilege.

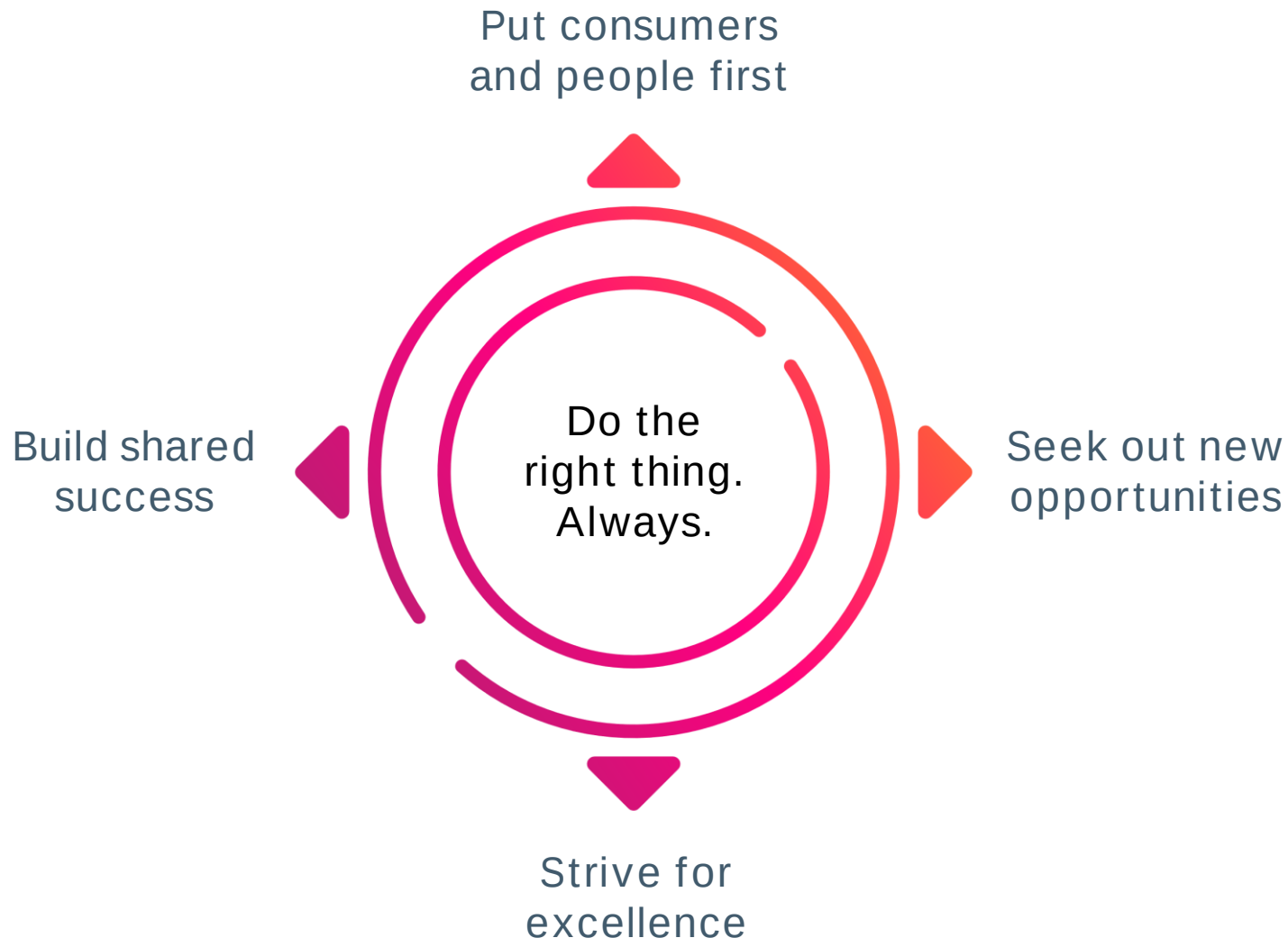


Figure 1: Reckitt Compass, Purpose and Fight

1.0 COMMITMENT AND PURPOSE

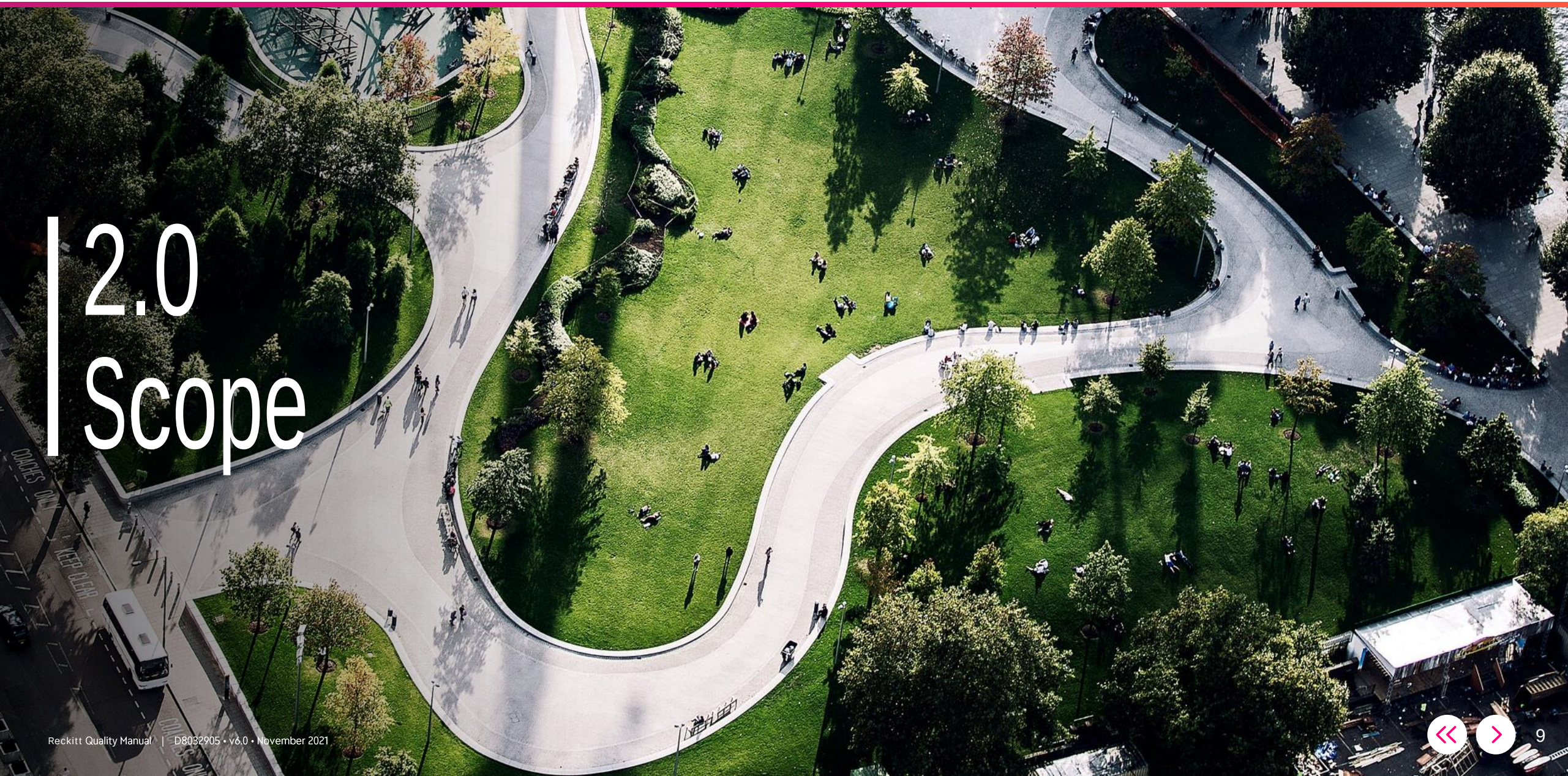
The purpose of the Reckitt Quality Manual (RQM) is to define how the quality management system (QMS) operates across the product lifecycle and to create an environment where all employees 'live' Quality in all their actions. This ensures that the Quality Commitment is delivered through our quality objectives, encompassing safety, quality and legislative compliance of Reckitt products to meet consumer, customer and external requirements.

The RQM provides the basis to drive Right First Time (RFT) and risk-based approaches in all processes to avoid serious quality and service issues, increase speed to market and reduce the cost of error.

The Reckitt Quality Commitment defines our organisational quality policy and is a key enabler of the Reckitt Compass, Purpose and Fight.

Role	Author	Approver	Approver
Name	Conall Burns	Valerie Sieurin	Martin Bardle
Title	Global QMS Senior Manager	SVP Head of Global Quality	Global Quality Compliance & Health & Safety Director
	Conall Burns Electronically signed by: Conall Burns Reason: I am the author of this document Date: Oct 27, 2021 14:21 GMT+1	Valerie Sieurin Electronically signed by: Valerie Sieurin Reason: I approve this document. Date: Nov 10, 2021 08:53 GMT	Martin Bardle Electronically signed by: Martin Bardle Reason: I approve this document. Date: Oct 28, 2021 12:10 GMT+1

2.0 Scope



2.0 SCOPE

The RQM is applicable to all functions across all Global Business Units (GBUs). The application of the RQM should be appropriate and proportionate to each of the product lifecycle stages in Figure 2 below and is based on the principles of risk management.

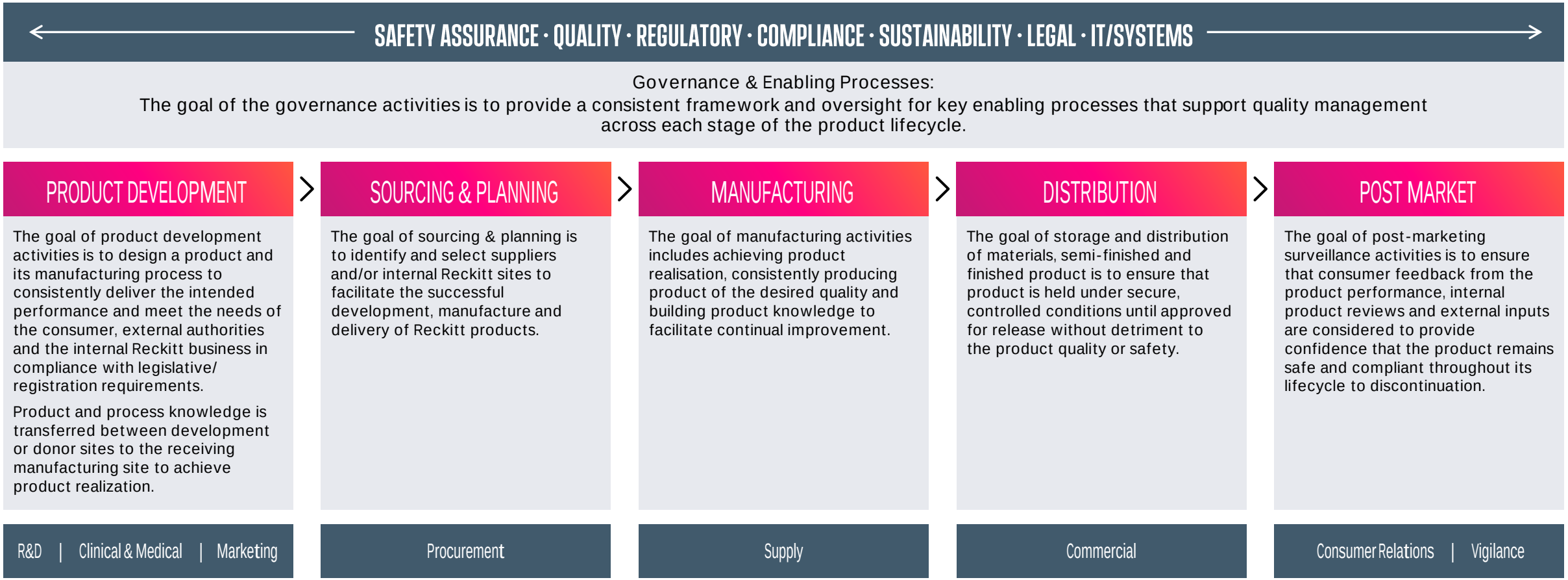
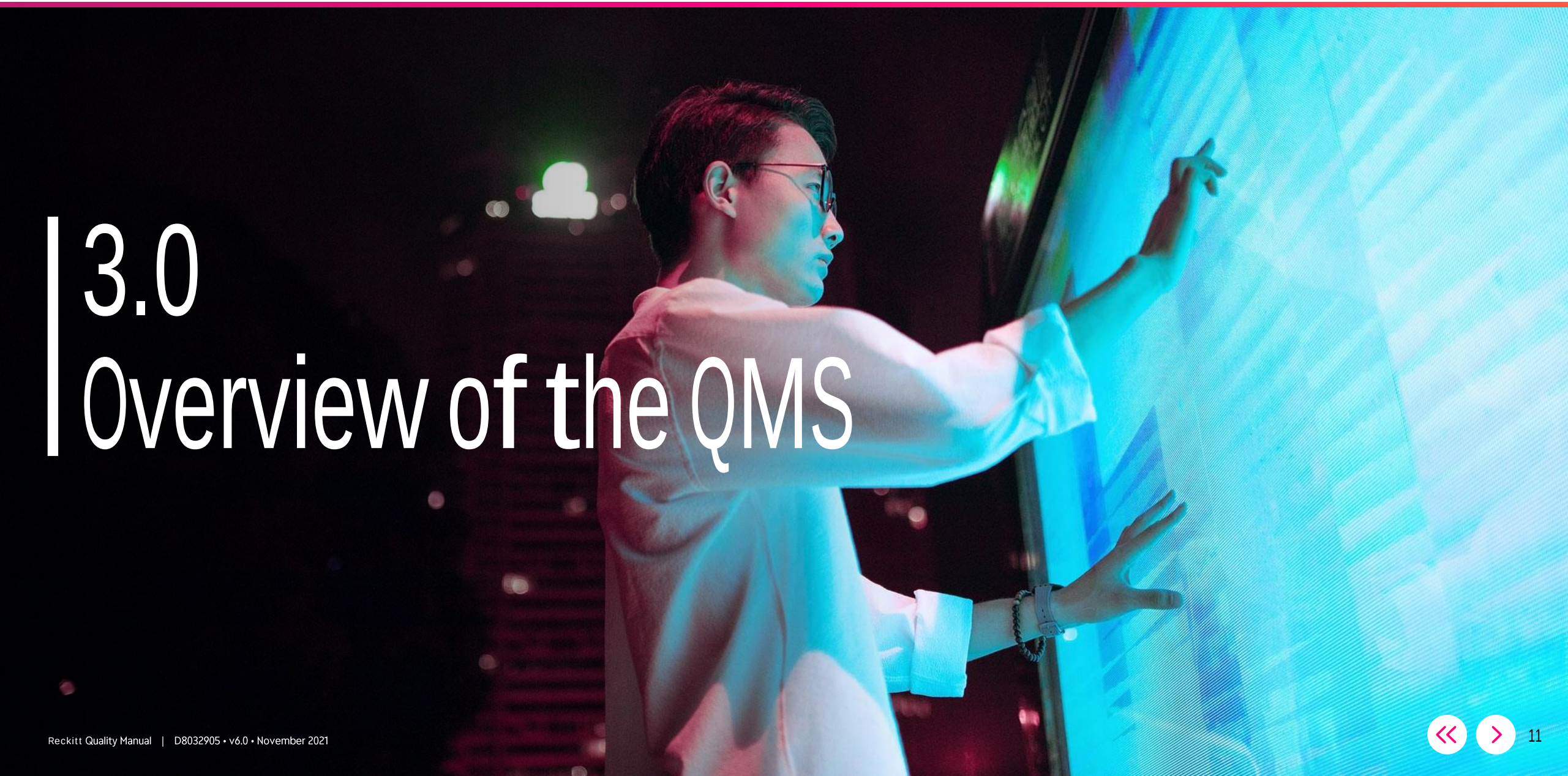


Figure 2: RQM across the Product Lifecycle



3.0 Overview of the QMS

3.0 OVERVIEW OF THE QUALITY MANAGEMENT SYSTEM (QMS)

A Quality Management System (QMS) is a clearly documented set of processes, requirements and responsibilities that ensure a systematic approach to embedding quality across the business. The QMS enables Reckitt to fulfil our Commitment to Quality, achieve our organisational objectives, and exceed the expectations of our consumers, customers and stakeholders.

The QMS does not only apply to the Quality function – the QMS supports all functions involved in the end-to-end lifecycle of creating and providing products and services for the business.

An effective QMS:

- Protects our consumers by providing products that are safe and compliant
- Drives a right-first-time culture to uphold confidence in our business and brands
- Ensures collaboration and consistency to improve speed to market
- Promotes risk-based thinking to empower effective decision making
- Supports continuous improvement across the organisation

Note: Business policies and procedures that do not relate to the QMS are outside the scope of the Reckitt Quality Manual.

3.1
QMS Documentation Hierarchy

Find out more

3.2
General Requirements

Find out more

3.3
Legislative Requirements & International Standards

Find out more

Click here to go back to overview

3.1 QMS DOCUMENTATION HIERARCHY

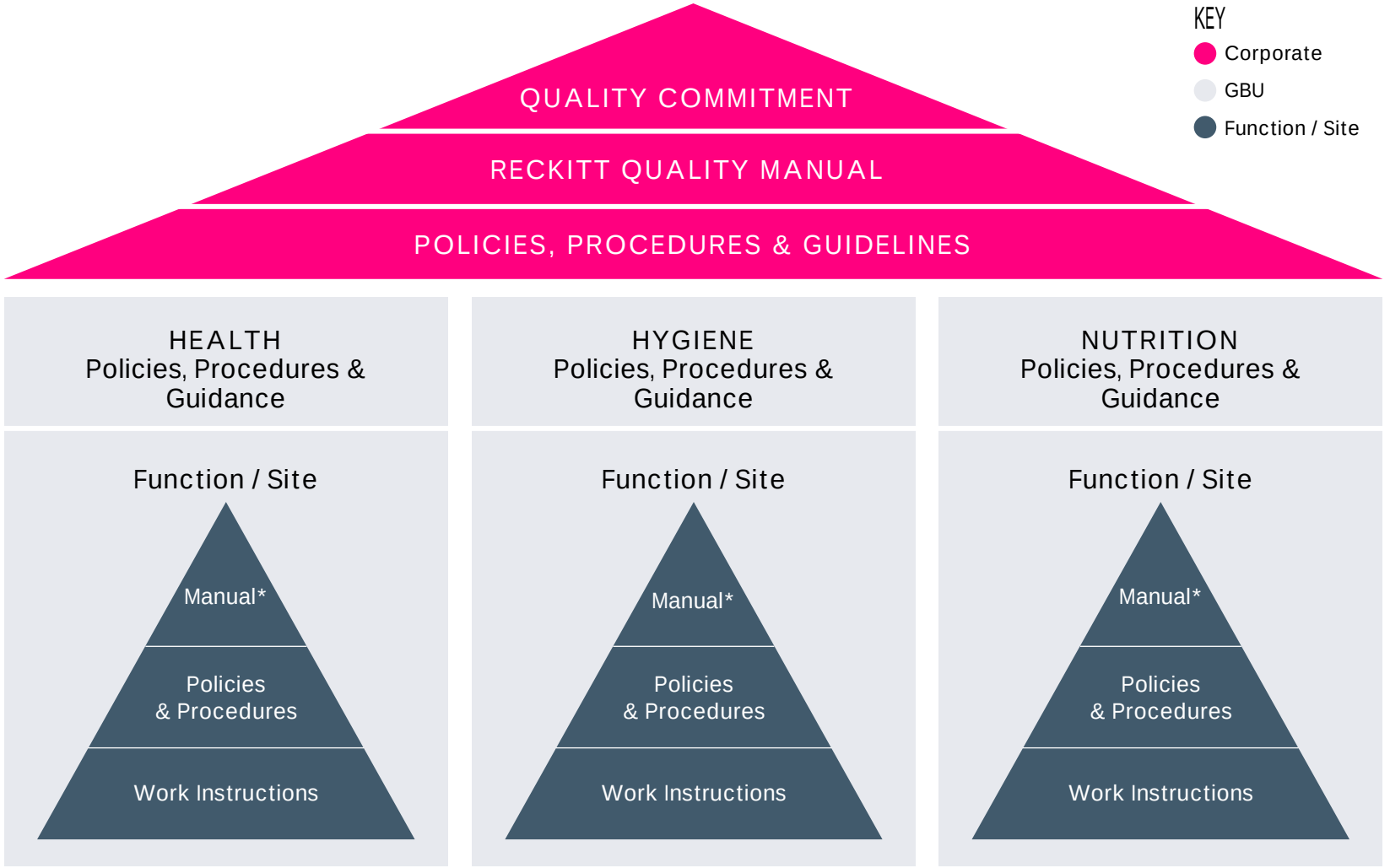
The QMS is comprised of different levels of scope across the business:

I. Corporate level documents apply to all functions and GBUs in Reckitt.
II. GBU level documents apply to all functions within a specific GBU.
III. Function / Site level documents apply to all activities / teams within a specific Function or Site.

All levels of the of the QMS support the Quality Commitment and help achieve its objectives.

For further context, refer to the Document Hierarchy Definitions.

Click here to see the Document Hierarchy Definitions



* As required; see Document Hierarchy Definitions

Figure 3: Reckitt QMS Document Hierarchy

Note: Function / Site QMS documents must comply with all relevant local legislation (see section 3.3)

3.1 QMS DOCUMENTATION HIERARCHY

Document	Purpose
Quality Commitment	Provides the strategic quality direction for Reckitt. Quality objectives are set to support the delivery of the Commitment
Reckitt (Corporate) Quality Manual	Describes the scope of the QMS and defines the 11 key elements that are the foundation to fulfilling the Quality Commitment. Where applicable it may be used as the Local Quality Manual at site or function level.
Corporate Quality Policies, Procedures, & Guidance (PP&G)	Builds on the 11 key elements of the Reckitt Quality Manual to provide requirements and guidance for the QMS applicable across all Reckitt Global Business Units, functions, and sites
Global Business Unit Quality Policies, Procedures & Guidance	Builds on the 11 key elements of the Reckitt Quality Manual to provide requirements and guidance for the QMS specific to each individual Reckitt Global Business Unit, in addition to fulfilling requirements of relevant Corporate PP&G
Functional / Site Quality Manual	Where required locally in addition to the RQM, each Reckitt site or function should have a high-level document describing the activities for that site or function, how these are controlled by the local QMS, and must fulfil the requirements of the applicable Corporate and GBU PP&G.
Functional / Site Quality Policies, Procedures & Guidance	Provides local requirements and guidance specific to the function or site and their activities. Incorporates Corporate and GBU PP&G relevant to the function or site, with additional information on application within the function or site as necessary
Work Instructions	Provide operational instruction for the local site or function to ensure the consistent performance of the specified task and provides a documented record of completion (For example, batch records, specifications & methods, training records, etc.)

Click here to go back to the Document Hierarchy diagram

Table 1. Reckitt QMS Document Hierarchy definitions

Click here to go back to overview

3.2 GENERAL REQUIREMENTS

All Reckitt sites and functions operating within the product lifecycle shall comply with the requirements of the RQM through compliance with the applicable Global Policies, Procedures, and Guidance and the implementation of supporting local procedures as necessary.

The design of the QMS should be structured to facilitate common understanding and consistent application.

Each site or function shall determine the scope and processes required for their local QMS, and provide sufficient resources to implement, maintain and check its effectiveness to meet the RQM and any local legislative requirements.

Supply sites exporting to other markets must ensure that they operate in compliance with the relevant legislative requirements of the receiving markets.

The local QMS must include appropriate processes, resources and responsibilities to provide assurance of contracted activities and purchased materials.

The RQM will be reviewed on an annual basis to ensure it remains suitable, adequate and effective.

Note: For Medical Devices, refer also to the Global Medical Device Quality Manual D0178006 for specific requirements.

Click here to go back to overview

3.3 LEGISLATIVE REQUIREMENTS & INTERNATIONAL STANDARDS

Reckitt Global Policies, Procedures and Guidance are written to comply with, or to provide guidance to the standards in Table 2.

However, it is expected that local country legislation will be followed to support products sold in those markets and will take precedence over internal Reckitt requirements in the event of any conflict.

Note: Where sites are expected to maintain accreditation to specific standards, these requirements must be defined and managed within the relevant local or GBU Quality Management Systems.

Legislation	Applicable Products
21 Code of Federal Regulations (CFR) Part 111	Vitamin, Mineral & Supplement products
21 Code of Federal Regulations (CFR) Parts 101, 106, 107, 110, 111, 113 & 117 Code of Practice General principles of Food Hygiene (CAC/RCP 1-1969) Code of Hygiene Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)	Infant Formulation products
Cosmetic Product Regulation (EC) No. 1223/ 2009 Food, Drug & Cosmetic Act ISO 22716:2007 GMPs for Cosmetics	Cosmetic products
Medical Device Directive 93/42/EEC Medical Device Regulation 2017/745 ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes 21 Code of Federal Regulations (CFR) Part 820	Medical Device products
Eudralex Volumes 1-10 EU Legislation & Guidelines for Medicinal products ICH Standards 21 Code of Federal Regulations (CFR) Parts 11, 210 & 211 WHO GMPs for Pharmaceutical products	Medicinal products and Investigational Medicinal products
ISO 9001:2015 - Quality Management System Requirements	Hygiene products

Table 2. Legislation and Guidance used to build the RQM

4.0 QMS Elements

4.0 QUALITY MANAGEMENT SYSTEM ELEMENTS

The RQM is divided into 11 key elements, each of which has general requirements to follow. The sections include references to relevant QMS documents that provide the global framework for the topic. Site / Product *etc*. specific document references are not included within the RQM.

Click on the relevant element to the right to find out more. You can also use the numbered tabs on a page to jump to each of the individual sections.

Note: Unless stated otherwise within a document's scope section, Global QMS documents published for the "Health" business unit prior to March 2020 were inclusive of the 'Infant and Child Nutrition (IFCN)' cluster, which was part of the "Health" business unit up to this point. Following business restructuring, the IFCN cluster now forms part of the Global Nutrition business unit. New or updated Global QMS documents from March 2020 that apply to both Health and Nutrition shall state so for clarity.

4.1 LEADERSHIP AND TRAINING

PAGE 1 OF 2

4.1.1 GENERAL

- Reckitt Leadership are accountable for the establishment of the Quality Commitment that describes the overall intentions and direction of the company related to quality, and the effectiveness of the RQM to achieve the quality objectives.
- Oversight of the effectiveness of the RQM is performed through Management Review (refer to section 4.11.2)

Reference Documents:
Global Training Procedure D0117487
Global Management Review Policy D8036468

4.1.2 QUALITY OBJECTIVES

- Reckitt Leadership ensure that all employees operating within the RQM scope are made aware of:
  - The RQM
  - Applicable quality objectives
  - How they contribute towards the effectiveness of the QMS

4.1.3 ORGANISATION

- All Reckitt employees must have documented roles and responsibilities

4.1.4 RESOURCES

- Reckitt Leadership shall determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS to meet the quality objectives and the regulatory and customer requirements
- Resources shall include, as appropriate:
  - People (including training)
  - Buildings and associated utilities
  - Equipment
  - Distribution
  - Information technology
  - Working environment

4.1.5 COMMUNICATION

- Reckitt Leaders will regularly communicate to employees the progress against the quality objectives
- The QMS facilitates the rapid escalation process of non-conformances to the Reckitt Leadership team

4.1 LEADERSHIP AND TRAINING

PAGE 2 OF 2

4.1.6 PERSONNEL

4.1.6.1 Qualifications

- All Reckitt employees have a role profile that describes their role and responsibilities, and which will support their training and development
- Reckitt employees must be competent on the basis of appropriate education, training or experience which must be assessed, documented and retained to fulfil the requirements of their role

4.1.6.2 Training & Development

- Individuals obtain the necessary competencies as part of their personal development. Specific training shall be provided for all employees whose responsibilities have a direct impact on the safety and/or quality of Reckitt product, and Personal Hygiene training where they may come into direct contact with product
- Personnel responsible for training shall possess the appropriate level of knowledge and experience to effectively present the subject material

4.2 RISK MANAGEMENT

PAGE 1 OF 1

4.2.1 RISK MANAGEMENT PRINCIPLES

- Risk management is integral to the QMS and is a systematic process for the identification, assessment, control, communication and review of risks to product and the consumer / user. It can be applied both proactively and retrospectively and facilitates continual improvements of both process and product performance throughout the product lifecycle
- A documented Hazard Analysis Critical Control Points (HACCP) programme covering the operational processes (product development, manufacturing, testing and storage / distribution) must be in place for facilities producing Infant Nutrition or Food Supplement products
- The evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the consumer / user
- The level of effort, formality and documentation of the risk management process is appropriate with the level of risk
- Risk plans shall be reviewed on a periodic basis in accordance to local procedures

Reference Documents:
Global Product Compliance Risk Management Procedure D8333720

4.3 WRITTEN INSTRUCTIONS

PAGE 1 OF 1

4.3.1 GENERAL

- Documents (electronic and paper-based) required by the QMS will be appropriately controlled to ensure:
  - they are reviewed and approved for adequacy prior to issue
  - updated and re-approved as necessary
  - only the current version is available for use when and where it is needed
  - changes are version controlled

Reference Documents:
Global Document Management Procedure D8296637

4.3.2 BATCH RECORDS

- Master Batch Manufacturing or Packaging Records are created for each semi-finished and finished product produced by Reckitt. Master records will be created and approved by individuals who have the appropriate level of training, experience and knowledge of the product and process
- Batch Manufacturing or Packaging Records are controlled documents that are traceable to the Master Record. They are completed by personnel at the time of the production process

4.3.3 DATA GOVERNANCE AND INTEGRITY AND GOOD DOCUMENTATION PRACTICE

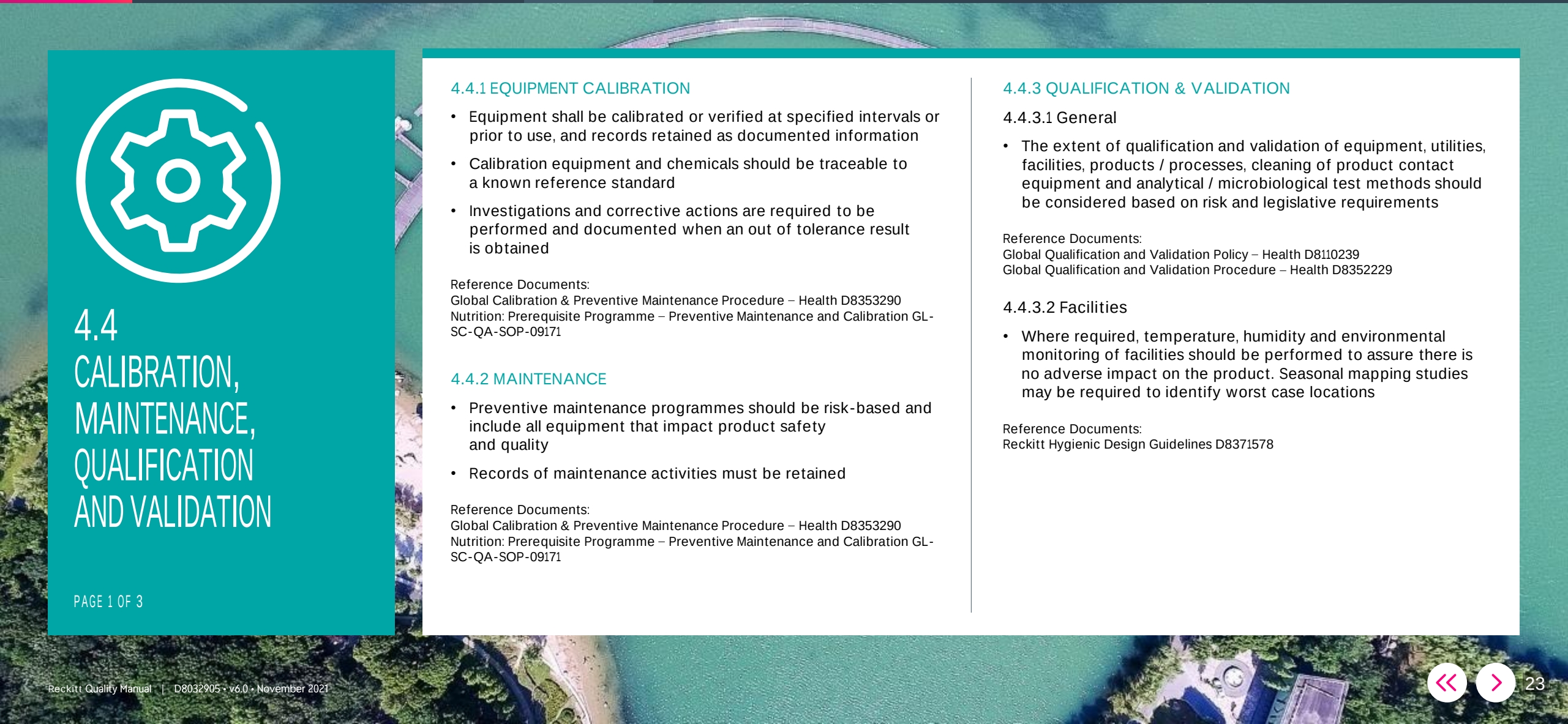
- Reckitt shall implement a systematic approach to provide a high level of assurance that across the product / data life cycle all records and data are accurate, consistent, trustworthy and reliable following Good Documentation Practices

Reference Documents:
Global Data Governance and Integrity Policy – Health D8217466
Global Data Governance and Integrity Procedure – Health D8320141
Global Data Governance and Integrity Procedure – Hygiene D8341438

4.3.4 DOCUMENT RETENTION

- Documents must be retained in accordance with the Reckitt Corporate Record Retention Policy (Legal) and any local or international legislative requirements
- Following the retention period, documents must be destroyed unless required to support the product (for example claims or validation records, records pertaining to a serious adverse customer complaint, etc.)

Reference Documents:
Reckitt Corporate Document Retention Policy



4.4 CALIBRATION, MAINTENANCE, QUALIFICATION AND VALIDATION

4.4.1 EQUIPMENT CALIBRATION

- Equipment shall be calibrated or verified at specified intervals or prior to use, and records retained as documented information
- Calibration equipment and chemicals should be traceable to a known reference standard
- Investigations and corrective actions are required to be performed and documented when an out of tolerance result is obtained

Reference Documents:
Global Calibration & Preventive Maintenance Procedure – Health D8353290
Nutrition: Prerequisite Programme – Preventive Maintenance and Calibration GL-SC-QA-SOP-09171

4.4.2 MAINTENANCE

- Preventive maintenance programmes should be risk-based and include all equipment that impact product safety and quality
- Records of maintenance activities must be retained

Reference Documents:
Global Calibration & Preventive Maintenance Procedure – Health D8353290
Nutrition: Prerequisite Programme – Preventive Maintenance and Calibration GL-SC-QA-SOP-09171

4.4.3 QUALIFICATION & VALIDATION

4.4.3.1 General

- The extent of qualification and validation of equipment, utilities, facilities, products / processes, cleaning of product contact equipment and analytical / microbiological test methods should be considered based on risk and legislative requirements

Reference Documents:
Global Qualification and Validation Policy – Health D8110239
Global Qualification and Validation Procedure – Health D8352229

4.4.3.2 Facilities

- Where required, temperature, humidity and environmental monitoring of facilities should be performed to assure there is no adverse impact on the product. Seasonal mapping studies may be required to identify worst case locations

Reference Documents:
Reckitt Hygienic Design Guidelines D8371578

4.4 CALIBRATION, MAINTENANCE, QUALIFICATION AND VALIDATION

4.4.3.3 Equipment

- Equipment shall be qualified and verified as clean in accordance with local procedures to prevent contamination of product

Reference Documents:
Reckitt Hygienic Design Guidelines D8371578

4.4.3.4 Processes (Product)

- Reckitt shall determine the knowledge necessary for the operation of processes to achieve consistent conformity of the products

Reference Documents:
Global Qualification and Validation Policy – Health D8110239
Global Qualification and Validation Procedure – Health D8352229

4.4.3.5 Cleaning and Sanitisation

- Reckitt shall establish cleaning and sanitisation procedures for product-contact equipment that define requirements and frequencies, including between products and sequencing of products

Reference Documents:
Global Qualification and Validation Policy – Health D8110239
Global Qualification and Validation Procedure – Health D8352229
Reckitt Hygienic Design Guidelines D8371578

4.4.3.6 Utilities

- Water
  - Water systems must be suitably qualified and meet the Global Hygienic Design and any legislative requirements
  - All process water and water used for final cleaning / sanitisation shall originate from potable sources or be treated to meet potable standards prior to use
  - The specification of water used for final rinsing / sanitisation shall be at least equivalent to that used in the product formulation
  - The type and frequency of controls and monitoring of water shall be performed in accordance with established procedures and records maintained
- Gases
  - Gases that come into direct contact with product or product-contact parts shall be of acceptable quality to prevent contamination
  - Appropriate filters must be used to remove particulates and potential contaminants
  - The quality of the gas should be monitored in accordance with an approved schedule

4.4 CALIBRATION, MAINTENANCE, QUALIFICATION AND VALIDATION

4.4.3.6 Utilities (cont.)

- Steam
  - Steam generation systems must be appropriately qualified and maintained. Steam must be of a defined quality to prevent contamination of the product, equipment or facility and meet any legislative requirements
  - The quality of the steam should be monitored in accordance with an approved schedule

Reference Documents:
Reckitt Hygienic Design Guidelines D8371578

4.4.3.7 Computer Systems

- Computer Systems shall be suitably validated / qualified before use, and maintained in a qualified state after use in accordance with risk-based principles

Reference Documents:
Global Computer System Validation Policy D0294486
Global Standalone Computer Systems Validation Procedure D8386698

4.4.3.8 Analytical / Microbiological Test Methods

- R&D are responsible for the development and validation of semi-finished and finished product test methods
- The extent of method development required depends on the nature of the test method and semi-finished or finished product
- Where reference standards are used, these should be suitably qualified and traceable back to a primary standard
- Where applicable, test methods transferred between sites should follow a written agreement

Reference Documents:
Microbiological Laboratory Guidance D8107842
Analytical Laboratory Guidelines – Health D8356798
Nutrition: Analytical Test Method Transfer GL-SC-QA-SOP-03052

4.5 PRODUCT DEVELOPMENT

4.5.1 RESPONSIBILITIES

- The QMS for the development of products is the responsibility of the Chief R&D Officer
- The QMS for ensuring the Regulatory Compliance of Reckitt products is the responsibility of the GBU Heads of Regulatory

4.5.2 GENERAL

- Each site developing product or providing data for legislative compliance shall implement a local QMS based on the RQM, associated Global Policies, Procedures and Guidance and any local market requirements
- Product Realisation is achieved by designing, planning, implementing, maintaining and continuously improving the QMS to promote the consistent delivery of products to meet internal and external customer needs
- R&D are responsible for provision of the following documents:
  - Product Formulation
  - Method of Manufacture
  - Product Specification
  - Quality Control test methods
  - Raw Material Specifications
  - Primary Packaging Specifications
  - Method Development Validation, Stability Testing and Product Shelf Life
  - Claim Support (including Clinical Trials)

Reference Documents:
Global Product Development Procedure – Health D8339069
Global Product Development Procedure – Hygiene D8339070

4.5.3 PRODUCT DEVELOPMENT RISK MANAGEMENT

- Products are developed and tested to ensure that they meet the appropriate safety, quality and regulatory compliance standards for the product type and markets where they are sold

4.5.4 CLINICAL TRIALS

- The Chief R&D Officer is responsible for authorizing and conducting clinical trials and ensuring that they meet the necessary internal and external requirements

Reference Documents:
Reckitt Clinical Trial Policy D8324233
Nutrition: Clinical Study Management GL-RD-CLIN-SOP-05222

4.5 PRODUCT DEVELOPMENT

4.5.5 MINIMUM REQUIREMENTS

- R&D Centre of Excellence Health sites are required to complete self-assessments against the minimum QMS requirements as defined in Global R&D Quality Self-Assessment D8314832
- All R&D Hygiene sites are required to complete self-assessments against the minimum QMS requirements as defined in R&D Quality Standards Hygiene Self-Assessment D8362980

Reference Documents:
Health: Global R&D Quality Self-Assessment D8314832
Research & Development Quality Standards Hygiene Self-Assessment D8362980

4.5.6 STABILITY

- Stability testing will be performed to ensure that Reckitt products will meet their finished product specifications throughout their determined shelf-life according to the packaging to be used and intended markets for sale
- The parameters selected for evaluation during stability testing should be stability-indicating and based upon product knowledge and risk management

Reference Documents:
Global Stability Policy – Health D0111875
Stability Management and Shelf Life Assessment – Hygiene D8350604

4.5.7 TECHNOLOGY TRANSFER / DESIGN CONTROL

- The transfer of product and process knowledge between R&D to Reckitt site, R&D to EMO site, or between any sites is essential to achieve product realisation

Reference Documents:
Global Technology Transfer Policy – Health D0339777
Technology Transfer Procedure – Hygiene D8355808
Nutrition Technology Transfer Procedure GL-RD-INV-SOP 09259
Health: Design Control for Medical Devices Procedure – D8265186
Health: Medical Device Post Launch Review Procedure D8267716

4.5 PRODUCT DEVELOPMENT

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4.5.8 REGULATORY

- Reckitt projects requiring regulatory support shall have a Regulatory Project Lead (RPL) as the primary contact. They are responsible and accountable for strategic inputs and delivery of regulatory activities. They may be a part of either the Global Regulatory or Local Regulatory function and responsibility will depend on the type of activity and if a category brand is impacted.
- Global Regulatory Affairs (GRA) develop and maintain the core regulatory dossier required to support product registration and launch, and maintenance of category brands (or multi-region non-category brands) in accordance with local requirements
- Local Regulatory Affairs (LRA) are responsible for compiling and submitting product registration and launch in accordance with local requirements and consistent with the core regulatory dossier provided by GRA
- LRA are responsible for developing and maintaining the core regulatory dossier for non-category brands marketed in a single region
- For all licensed medicines and monographed products, LRA and GRA are responsible for ensuring that a current and accurate Product Compliance Summary (PCS) or equivalent is approved and issued. The purpose of the PCS is to:
  - Provide a summary of all approved documentation relating to the manufacture, assembly and testing/release of a product for a specific market to facilitate product release for sale
  - Facilitate the maintenance of regulatory compliance within Reckitt and any EMOs via Change Management
- Reckitt complies with the requirements of all regional / national chemical (substance) inventories (e.g. REACh)

Reference Documents:
Regulatory Health Operating Model Manual D8360299
Hygiene Regulatory Global QMS Manual D8369202

4.5 PRODUCT DEVELOPMENT

4.5.9 APPLICABLE NEW OR REVISED LEGISLATIVE REQUIREMENTS

- The Reckitt Regulatory Intelligence (RI) framework is used to assess and communicate the impact of any regulatory changes that have the potential to impact the compliance of any Reckitt product that is marketed, registered or under development
- The scope of the RI process includes announced, draft and finalized: Legislation Changes, Technical Guidelines, Standards and Associated FAQs, and Substance Restrictions

Reference Documents:
Regulatory Health & Nutrition Intelligence Procedure D8338678
Regulatory Hygiene Intelligence Procedure D8338726

4.5.10 ARTWORK

- Marketing are the artwork process owners and lead the artwork generation, approval and change process in accordance with the reference documents

Reference Documents:
Global Artwork Process Procedure D8340610

4.5.11 ADVERTISING

- Advertising of Reckitt products will be approved by persons qualified to do so within each country and by Reckitt regulatory

Reference Documents:
Global Health and Nutrition Off-Pack Advertising Promotional and Other Communication Materials Procedure D0117480
Global Hygiene Off-Pack Advertising and Promotional Materials D8384510
Reckitt Corporate Breast-Milk Substitute Marketing Policy

4.5.12 SUSTAINABILITY

- Sustainability is the responsibility of every employee
- Reckitt maintains a Restricted Substances List (RSL) Policy to ensure a consistent, global approach to safeguarding our consumers, employees and the environment from exposure to specific ingredients of concern, beyond regulatory requirements
- Reckitt are committed to the responsible sourcing of natural raw materials
- Reckitt are committed to upholding Human Rights and comply with all applicable laws and regulations

Reference Documents:
Restricted Substances List (RSL) Policy D8240073
Reckitt Policy on Human Rights and Responsible Business
Reckitt Policy on the Responsible Sourcing of Natural Raw Materials

4.5 PRODUCT DEVELOPMENT

4.5.13 CONSUMER SAFETY

- Reckitt are committed to the development, marketing and monitoring of products that can be manufactured and used safely as directed in our Reckitt Corporate Product Safety Policy
- Reckitt are committed to supplying safe products to our consumers and to understanding all the issues involving safety associated with our products. It is the policy of Reckitt to:
  - Ensure a Product Safety Evaluation Report (PSER) must be available for every Reckitt product before it can be commercially launched
  - Comply with regulatory requirements for product safety testing, labelling and vigilance
  - Ensure a Product Safety Data Sheet (PSDS) must be available covering the safe supply, handling and use for all Reckitt products
  - Continually assess products, packaging, labelling, ingredients, adverse events and complaints to ensure the health and safety of consumers, customers and employees
  - Apply consistent consumer safety standards globally
  - Actively seek scientific, regulatory and consumer information regarding potential consumer safety issues either directly or through responsible trade associations, professional societies, regulatory authorities and consumer groups
  - Freely disclose consumer safety information on Reckitt products through the release of accurate, up-to-date and relevant information to appropriate governmental, professional and business organisations, and to the public
- In accordance with the Reckitt Corporate Animal Testing Policy, it is our policy not to conduct or commission animal tests unless required by government agencies or where Reckitt is ethically obligated to do so to ensure the safety and efficacy of its products
- In accordance with product and market requirements, Reckitt shall implement safety features to enable:
  - Identification of individual packs
  - Verification of a product's authenticity
  - Verification of whether the product has been tampered with

Reference Documents:
Reckitt Corporate Product Safety Policy
Reckitt Corporate Animal Testing Policy
Consumer Safety Assessments D8291823
Raw Materials Questionnaire Procedure D8293152

4.6 PRODUCTION

4.6.1 GENERAL

- All manufacturing processes will be approved, clearly defined and be capable of consistently producing product complying with the approved specification

4.6.2 RESPONSIBILITIES

- The QMS for the production of products is the responsibility of the Chief Supply Officer
- Site Directors (or equivalent) are responsible for ensuring that their sites operate in accordance with the requirements of the RQM, including any outsourced operations under their responsibility

4.6.3 SITE REGISTRATIONS / CERTIFICATION

- The site leadership team are responsible for obtaining and maintaining the necessary approvals to manufacture and supply their products to the required markets, supported by Regulatory

4.6.4 COMMERCIAL TRANSFER FROM MANUFACTURE TO MARKET

- There shall be approved Statements of Compliance or Technical Agreements in place between Reckitt Supply sites, EMOs, Distribution Centres and the markets they supply that clearly define roles and responsibilities for the supply chain from manufacture to market

Reference Documents:
Global Company Technical Agreements Procedure D8158883
Intra-Company Forward Selling of Health Products D8064550

4.6.5 PRODUCT RELEASE REQUIREMENTS

- The Quality function are responsible for the release of finished product
- The first time a new product is released for sale by a Supply site, a Good For Sale (GFS) certificate shall be provided by that site to the first market supplied. Refer to D0117199 Launch Stock Good For Sale
- The Release for Sale Procedure is followed for subsequent batch release

Reference Documents:
Release For Sale Procedure – Health D0381438
Release for Sale Procedure – Hygiene D8340716
Launch Stock Good For Sale (GFS) D0117199

4.6 PRODUCTION

4.6.6 IDENTIFICATION

- All raw materials, packaging components, semi-finished and finished products shall be suitably identified (by manual or electronic means) so that their identity and status is clear
- All major equipment will be identified by a unique identification number or code
- Any products that are returned to Reckitt sites should be suitably identified and distinguished from conforming product

4.6.7 TRACEABILITY

- Records will be made demonstrating that all the necessary steps during receipt, manufacture, packing, testing and distribution have been adequately completed and enable the complete history of a batch to be traced, including quantities, storage locations and status
- Batch numbers (Lot numbers) including where applicable expiry or use by dates must meet regulatory requirements for the markets in which they are produced and distributed

Reference Documents:
Health: Medical Device UDI (Unique Device Identifier) Policy D8375783
Serialisation and Aggregation Procedure - Health D8387248
Health: Global On-Line Verification (OLV) Procedure D8352415

4.6.8 EQUIPMENT

- Equipment should meet Hygienic Design requirements to facilitate effective cleaning and sanitization and prevent contamination of product

Reference Documents:
Reckitt Hygienic Design Guidelines D8371578

4.6.9 MANUFACTURING STANDARDS

- Supply sites will meet the manufacturing standards for the products supplied

Reference Documents:
Minimum Manufacturing Standards – Health D8323092
Global Manufacturing Quality Standards – Hygiene D8323091
Nutrition: Minimum Standards GL-SC-QA-SOP-09046

4.6 PRODUCTION

4.6.10 CONTROL OF NON-CONFORMING PRODUCT

- Appropriate risk-based action must be taken based on the nature of the non-conformity and its effect on the conformity of the product, as per section 4.10.1. This will include:
  - Correcting the non-conformity
  - Investigation and root cause analysis
  - Corrective and Preventative actions to prevent recurrence of the root cause(s) and occurrence of similar issues
  - Review of the effectiveness of the actions taken
- Rejected stock shall be identified and controls will be in place to prevent failed or quarantined stock from being used
- The Quality function are responsible for its use, release, acceptance under concession or the rejection of raw materials, packaging components, semi-finished and finished products

Reference Documents:
Global Deviation and CAPA Procedure D8323632
Nutrition: Deviation Management GL-SC-QA-SOP-03042
Global Guidance for Product Quality Acceptance D8374541

4.6.11 MANUFACTURING CONTROLS

- Critical steps of manufacturing and packing processes will be clearly defined and suitably validated / qualified and shown to be capable of consistently manufacturing products of the required quality and conforming to their specifications
- Reconciliation of product must be performed in accordance with local procedures

Reference Documents:
Yield and Reconciliation – Policy and Guidance for Health Products D8293730

4.6.12 PACKAGING & LABELLING CONTROLS

- There will be written procedures designed to assure that the correct labels and other packaging materials are used
- Reconciliation of finished packed product (and where required, Printed Packaging components) must be performed in accordance with local procedures

Reference Documents:
Yield and Reconciliation – Policy and Guidance for Health Products D8293730

4.6 PRODUCTION

4.6.13 CROSS CONTAMINATION CONTROL

4.6.13.1 Microbiological Control

- There will be local procedures in place to prevent objectionable microorganisms in semi-finished or finished products

Reference Documents:
Microbiological Guidance for the Development and Manufacture of Reckitt Products D8341599

4.6.13.2 Cleaning

- There shall be a general cleaning and sanitisation programme in place for the facility that includes all manufacturing, packaging, testing and storage areas
- The methods and frequency of cleaning shall be determined on the risk profile the specific area has with respect to product safety and quality

4.6.13.3 Environmental/HVAC

- Where environmental controls are required to be in place, these must be adequate to protect the product from contamination and/or degradation and achieve conformity to specification
- Where required through risk assessment, monitoring of the environment should be performed. This may be continuous or periodic based upon the level of risk and any legislative requirements and may include:
  - Temperature / Humidity
  - Pressure differentials
  - Viable particulates (microbiological monitoring)
  - Non-viable particulates (physical particle monitoring)

Reference Documents:
Guidance and Best Practice for Establishing a Microbiological Environmental Program (EMP) D8381794
Reckitt Global Engineering Guidelines – HVAC Systems D8360457

4.6 PRODUCTION

4.6.13.4 Facility Design

- Facilities will be designed to facilitate people and product flow and minimise risk of cross-contamination of product occurring
- Manufacturing facilities shall implement production zoning where risk assessment identifies potential for contamination of product. Areas of different zoning must be physically identified, and the following controls should be considered:
  - Movement of personnel and materials
  - Personal hygiene and workwear requirements
  - Equipment and facility (e.g. walls, floors, etc.) design
  - HVAC systems (e.g. air flow, air filtration, etc.)
  - Cleaning and sanitisation
  - Security access

Reference Documents:
Reckitt Hygienic Design Guidelines D8371578

4.7 TESTING AND RELEASE OF PRODUCT

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4.7.1 LABORATORY FACILITIES

- Laboratory facilities should be equipped to perform routine material, components, semi-finished and finished product analysis
- Facility design should ensure process and people flow, personnel safety and protection of the environment
- Microbiological Laboratory design should prevent cross-contamination of the production environment
- Where specific tests are outsourced to a specialist provider, written agreements must be in place defining roles and responsibilities between Reckitt and the provider

Reference Documents:
Microbiological Laboratory Guidance – D8107842
Analytical Laboratory Guidelines – Health D8356798
Minimum Manufacturing Standards – Health D8323092
Global Manufacturing Quality Standards – Hygiene D8323091

4.7.2 LABORATORY CONTROLS

- Sampling of raw materials, packaging components, semi-finished and finished products are taken in accordance with approved risk-based procedures
- Test methods must be appropriately qualified / validated
- Testing is performed against the approved specification and test methods and results are documented and retained
- When an out of specification / out of trend result is obtained, the Reckitt QMS requires that:
  - the incident is investigated to confirm if the result is valid
  - the root cause(s) is/are identified, and the risk presented by the incident evaluated
  - where justified, retesting is performed in accordance with local procedures
  - where appropriate and commensurate with the level of risk, take corrective and preventative actions to prevent the incident recurring / occurring
  - invalidation of a test result should be scientifically justified
  - final review and the decision on any affected product is made by Quality

Reference Documents:
Microbiological Laboratory Guidance – D8107842
Analytical Laboratory Guidelines – Health D8356798
Nutrition Food Safety Standards – Microbiological Standards for Finished Goods and Raw Materials GL-SC-QA-SOP-09194
Nutrition: Global Microbiological Testing Procedure for Nutritional Powders and Select ingredients GL-SC-QA-SOP-02598

4.7 TESTING AND RELEASE OF PRODUCT

4.7.3 PRODUCT RELEASE

4.7.3.1 General

- Release of product for sale shall not proceed until all required checks have been completed and documented in accordance with local procedure requirements approved by Quality
- Where positive release of product is required this must be performed by Quality
- Products may be shipped under quarantine prior to full Quality release when there is an approved local procedure and the receiving market have confirmed they have suitable controls in place to prevent distribution of the product before full release is provided by Quality at the manufacturing site

Reference Documents:
Release for Sale Procedure – Health D0381438
Release for Sale Procedure – Hygiene D8340716
Global Guidance for Product Quality Acceptance D8374541

4.7.3.2 Good For Sale

- For all Reckitt products that fall into the categories below a Good For Sale (GFS) is issued prior to the first commercial supply:
  - New product development (NPD) manufactured either in-house and/ or at an External Manufacturer Organisation (EMO)
  - Technology transfer i.e. products that are transferred to Reckitt or an EMO site from another Reckitt or EMO site
  - Existing product development (EPD) that includes changes to formula or primary packaging and raw material suppliers unless decided otherwise by the relevant Quality Manager based on assessment of risk

Reference Documents:
Launch Stock Good For Sale (GFS) Procedure D0117199

4.7.3.3 Medicinal / New Drug Applications (NDA) / Monographed Products

- For all licensed medicines and NDA / monographed products it is the responsibility of the LRA to ensure that a current Product Compliance Summary (PCS) is approved and available to the site of manufacture to ensure that all the information required to manufacture and supply the product in accordance with registered requirements is available to the site

Reference Documents:
Regulatory Health Operating Model Manual D8360299

4.7 TESTING AND RELEASE OF PRODUCT

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4.7.4 RETENTION SAMPLES

- Representative samples from each delivery of raw materials, packaging components should be stored for the finished product shelf life plus one year
- Representative samples from the finished product should be stored for the shelf life plus one year, or in accordance with local or market requirements if longer. There should be sufficient samples to conduct the full analysis to specification in duplicate
- At the end of the retention period, samples must be destroyed in accordance with approved procedures
- Retention samples must be stored in an appropriate secure location with environmental controls suitable for their long-term storage in the original consumer packaging

4.7.5 ON-GOING STABILITY

- Where required, on-going stability studies shall be conducted by Reckitt Supply (or contracted by Reckitt Supply to an approved EMO) to support product maintenance activities

Reference Documents:
Ongoing Stability Policy – Health D0069482

4.7.6 SPECIFICATIONS

- R&D are responsible for specification generation (excluding in-house specifications which are generated by Supply)
- Approved specifications for materials, packaging components, semi-finished and finished goods should be available prior to placing orders
- Specifications must comply with registered details and meet any legislative requirements
- In-process control specifications may be included as part of the method of manufacture as process knowledge is developed

Reference Documents:
Health: Preparation, Review, Approval & Revision of Raw Material & Formulation Documents D8299498
Hygiene: Preparation, Review, Approval & Revision of Raw Material & Formulation Documents D8356837

4.8 SUPPLIER AND MATERIAL MANAGEMENT

4.8.1 MANAGEMENT OF OUTSOURCED ACTIVITIES

- Reckitt shall ensure that externally provided processes, products and services conform to Reckitt requirements
- Reckitt shall develop a risk-based process for the selection, evaluation, approval, monitoring of performance and periodic re-evaluations for outsourced activities

Reference Documents:
Global Supplier Management Procedure D8333716
Nutrition: Prerequisite Programme – Supplier Quality Management GL-SC-QA-SOP-09416
Nutrition: Third Party Manufacturer Quality Expectations Manual GL-SC-QA-SOP-05051

4.8.2 PROCUREMENT

- Procurement are responsible for the sourcing and procuring of direct spend materials
- Materials and services may only be sourced from Reckitt-approved suppliers
- Purchased goods or services must conform to agreed specifications and meet Reckitt requirements
- Where there is a change in supplier or in the materials / services they provide then the change management process as described in section 4.10.2 will be followed
- There shall be a process for the pre-selection, development, approval, ongoing assurance and delisting/exit of suppliers to Reckitt

Reference Documents:
Global Supplier Management Procedure D8333716
Nutrition Supplier Quality Expectations Manual GL-SC-QA-SOP-05043

4.8.3 AUDITING & REPORTING

- Where requirement is identified through risk assessment, Reckitt shall perform the following types of audits either internally or externally of suppliers to ensure conformance with Reckitt requirements
  - Quality audits
  - Health & Safety audits
  - Human Rights and Responsible Business audits

Reference Documents:
Global Audit Policy D0117484
Reckitt Policy on Human Rights and Responsible Business

4.8 SUPPLIER AND MATERIAL MANAGEMENT

4.8.4 STORAGE AND DISTRIBUTION

- Reckitt shall ensure that arrangements are made to ensure that materials, components and products are stored, distributed and handled so that quality is maintained throughout their shelf life. Reckitt shall take a pro-active approach to ensure that defective or falsified (counterfeit) products are prevented from entering or are removed from the supply chain
- Any specific storage and protection requirements for Reckitt products shall be defined by R&D and documented in the Product Safety Data Sheet (PSDS). Where storage condition ranges are exceeded, an investigation and documented assessment must be made to understand the risk to product and actions required
- Products stored under quarantine status are prevented from release to market until Quality approval is given
- Storage facilities must be secure and hygienic to prevent their possible adulteration or contamination
- Rejected materials and product should be stored in a separate location to good stock
- All Distribution Centres (DCs) where Reckitt products are stored must hold appropriate authorisations to do so.
  A Responsible Person (RP) or equivalent should be assigned to each DC, where applicable, to ensure the authorisations are maintained

Reference Documents:
Global Distribution Policy D8333717
Global Distribution Procedure D8333718
Distribution Minimum Standards – Health and Nutrition D8376034
Distribution Quality Standards Hygiene Self-Assessment D8362978
Global List of Blocked Batches Procedure D8368280

4.8.5 FORWARD SELLING OF RECKITT PRODUCT

- There shall be an agreed process for the forward sale of health products between Reckitt commercial units ensuring the safety, quality and legality of the product in the receiving market

Reference Documents:
Intra-Company Forward Selling of Health Products D8064550

4.8 SUPPLIER AND MATERIAL MANAGEMENT

4.8.6 EMBELLISHMENT

- The embellishment of a product includes any activity that adds to the previously released consumer unit. Such activities must be permitted by local regulations and may only be performed by EMOs approved by Reckitt or at approved Reckitt sites
- Rework or reconditioning of Reckitt products includes any activities where changes take place after the completion of manufacture to address either a quality defect or market requirement. This may take place at the Reckitt Supply site where it was originally manufactured or be performed by EMOs approved by Reckitt

Reference Documents:
Global Embellishment Procedure – Health & Nutrition D0117481
Embellishment Management Procedure – Hygiene D8286315
Global Rework & Repackaging Procedure – Health & Nutrition D8366841

4.8.7 E-COMMERCE

- Products sold through e-Commerce channels shall follow agreed processes with defined responsibilities to ensure products comply with all safety, legal and quality requirements in the source and destination markets

Reference Documents:
Global eRB Quality Policy - D8384915

4.8.8 RECEIPT & DESPATCH

- Incoming raw materials, packaging components, semi-finished and finished products shall be inspected in accordance with local procedures prior to formal receipt by verifying the identity, lot number, quantity and supplier against purchase order or shipping documentation

Reference Documents:
Global Distribution Policy D8333717
Global Distribution Procedure D8333718
Minimum Manufacturing Standards – Health D8323092
Global Manufacturing Quality Standards – Hygiene D8323091
Nutrition: Minimum Standards GL-SC-QA-SOP-09046

4.8.9 PRODUCT RETURNS

- Each site shall have procedures for managing product returns. Returned products should be identified as such and a documented assessment made before any decision to re-release can be made. This should include knowledge of the storage and distribution conditions and locations, stock inspection and the remaining shelf life of the product

Reference Documents:
Global List of Blocked Batches Procedure D8368280
Global Product Recall Procedure D8196500

4.8 SUPPLIER AND MATERIAL MANAGEMENT

4.8.10 SAMPLING & TESTING

- Where sampling and verification checks or testing of supplier goods or services is required, local procedures will use risk-based principles to describe the level of sampling and testing performed
- For intra-company transfer of semi-finished products, raw materials or packaging components, shipments shall be accompanied by an appropriate Certificate of Analysis. Receiving plants do not need to repeat analytical/microbiological testing if the goods have remained within Reckitt control and in sealed containers unless required by local legislation. Identity testing may be required.

4.8.11 TECHNICAL / QUALITY AGREEMENTS

- Responsibilities for outsourced activities shall be clearly described and documented in a Quality / Technical Agreement signed and agreed between Reckitt and the outsource provider

Reference Documents:
Global Company Technical Agreement Procedure D8158883

4.8.12 DUE DILIGENCE

- Reckitt will perform cross-functional due diligence checks before approval of external manufacturers to produce product exhibiting the Reckitt label is given. The approach will incorporate risk-based principles and applies to both products wholly owned by the EMO, or co-developed with Reckitt

Reference Documents:
Global Technical Due Diligence Review Procedure D8347218

4.8.13 SALES

4.8.13.1 General

- Sales personnel must be adequately trained to give precise information about Reckitt products and ensure they have Vigilance knowledge
- Products should be stored in accordance with the Product Safety Data Sheet (PSDS) and labelling requirements
- Medicinal product samples must have been released in accordance with the Reckitt Release For Sale requirements and may only be provided to Healthcare professionals in accordance with the national law

4.8 SUPPLIER AND MATERIAL MANAGEMENT

- Sample packaging and accompanying invoices shall be clearly labelled indicating that the samples may not be sold and shall be kept secure at all times and be within the product expiration date (where applicable) when distributed. Records must be kept of trade samples issued including batch numbers, quantities and where/who issued to. Product may only be supplied to customers with the appropriate authorization

Reference Documents:
Reckitt Corporate Interactions with Healthcare Professionals and Healthcare Entities Policy
Reckitt Corporate Breast-Milk Substitute Marketing Policy
Nutrition: Samples and Product for Professional Evaluation to Healthcare Professions and Entities GL-COMPL-SOP-07638

4.8.13.2 Products with Limited Remaining Shelf Life / Use By date

- Local procedures should be available to define the process to be followed for the sale of finished products with limited remaining shelf life / use by date.
- Acceptable limits to remaining shelf life / use by date must be determined in agreement with the Customer on a risk-basis for each product, considering the nature of the product, overall shelf life, typical product usage, supply chain duration and routes, and the Customer's commercial requirements, etc.
- The sale of any products with limited remaining shelf life / use by date must clearly be communicated to and agreed with the Customer prior to sale. Consideration should include:
  - Adequate Customer controls for the management of limited remaining shelf life / use by date stock
  - Sufficient demand for sale of the limited remaining shelf / use by date stock prior to expiry
  - Prioritisation of limited remaining shelf life / use by date stock to ensure sale prior to expiry
- In the event that it is permissible to extend a product's shelf life / use by date, local procedures / change control must define and control the process, considering:
  - Alignment with the market General Manager
  - Cross functional team to assess the impact, including at a minimum Regulatory, relevant Stability / Shelf Life management team, and Commercial Quality. Other functional teams may be involved as required.
  - The period of extension must be based on appropriate rationale and data
  - If applicable to licensed products, approval from relevant Regulatory Authority(s) for new/extended shelf life must be obtained prior to sale
  - Upon extension approval, products which display the shelf life / use by date on their packaging must be amended (e.g. overlabelling, etc.) to display the change to shelf life / use by date, with documented processes to capture and control completion of this activity.

4.9 POST-MARKET SURVEILLANCE

4.9.1 GENERAL

- Post Market Surveillance requires the coordination of trained and competent resources in consumer relations, quality, technical, safety, regulatory and medical functions to enable support and maintenance of Reckitt products post-launch

4.9.2 CUSTOMER AND CONSUMER FEEDBACK

- Customer and consumer feedback provides input to support new and/or existing product development and innovation activities
- Upon receipt of a customer or consumer complaint, the QMS requires that:
  - Customer Service personnel are suitably trained in receiving and responding to complaints
  - Complaints about products are examined and documented in a timely manner
  - The root cause(s) of quality defects investigated, and the risk evaluated
  - Where appropriate measures are taken in respect of defective products to prevent reoccurrence
  - The need to report the information to appropriate authorities is considered
  - Refer to 4.11.4 for Continuous Improvement from consumer feedback
  - Batch numbers (Lot numbers) including where applicable expiry or use by dates must meet regulatory requirements for the markets in which they are produced and distributed

Reference Documents:
Global Consumer Relations Policy D8301461
Global Consumer Relations Procedure – Hygiene D8378187

4.9.3 STORE CHECKS

- Where required store checks will be conducted by qualified Reckitt employees and the output supports product development improvement activities

Reference Documents:
Store Check Management Procedure for Hygiene D8367903

4.9 POST-MARKET SURVEILLANCE

4.9.4 VIGILANCE

- Reckitt shall appoint a Global Qualified Person for Pharmacovigilance (QPPV) who is responsible for ensuring that there is an effective QMS to collect, assess and collate all suspected adverse events / reactions potentially associated with Reckitt products (including Pharmacovigilance, Materiovigilance, Cosmetovigilance, Nutrivigilance and other relevant products)
- Upon receipt of a suspected adverse event, it is the responsibility of all Reckitt employees to notify the Global Vigilance Group so that the event is investigated and where appropriate reported to Competent Authorities / Notified Bodies
- A Drug Safety Officer (DSO) is required in each country marketing medicinal products who is responsible for ensuring that the local vigilance system is documented, implemented and followed

Reference Documents:
Global Vigilance Policy D0117477
Drug Safety Officer Responsibilities at each National Business Unit D0076979

4.9.5 RECALL MANAGEMENT

- A system will be in place to recall any batch of product, from sale or supply. The extent of recall action should be agreed and communicated internally within Reckitt before notification to the applicable external authorities or notified bodies as required by local legislation
- In the absence of any recall, the system will be challenged on a periodic basis

Reference Documents:
Global Critical Events Procedure D8068970
Global Product Recall Procedure D8196500

4.9.6 POST-MARKETING COMMITMENTS

- LRA and R&D Operations are responsible for the ongoing compliance of products sold in the local market. This includes ensuring any commitments made during initial product registration are completed post-launch

4.9 POST-MARKET SURVEILLANCE

4.9.7 MEDICAL DEVICES

- For Reckitt Medical Device products, Post Market Surveillance and Medical Devices Post Launch Reviews are performed

Reference Documents:
Health: Global Procedure Post Market Surveillance for Medical Devices D0370287
Health: Medical Device Post Launch Review Procedure D8267716

4.9.8 PRODUCT DISCONTINUATION

- Local procedures for the discontinuation of products shall be in place to manage completion of the terminal stage of the product lifecycle effectively. The process shall be managed via change management (refer to section 4.10.2) and will include:
  - Customer notification
  - Where appropriate, notification to Competent Authorities or other bodies with whom the product has been registered
  - Updating all internal Reckitt systems that the product has been discontinued
- The following activities must continue to be performed following product discontinuation:
  - Continued Vigilance throughout the product shelf life
  - Batch record, sample retention, product validation documents, change management and deviation record retention for at least 1 year after product expiration, or 5 years after release, whichever is longer
  - Where applicable, Technical Agreements shall be maintained with EMOs for the same period

Reference Documents:
Global Change Management Procedure D8298052

4.10 DEVIATIONS AND CHANGE MANAGEMENT

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4.10.1 DEVIATIONS (NON-CONFORMANCES)

- When a deviation (Non-conformity) occurs, including unplanned change from procedure, process, audit observation or consumer/customer complaints, the QMS requires that:
  - Local procedures are in place to describe and document the activities required to be completed in line with the Global Policy and any required legislative requirements
  - Take action to correct and return to a state of control
  - Identify the root cause(s) and evaluate the risk presented by the incident
  - Where appropriate and in accordance with the risk, take corrective and preventative actions to prevent the incident recurring / occurring
  - Evaluate the effectiveness of the CAPA
  - For critical deviations consideration should be given for escalation to a possible Critical Event

Reference Documents:
Global Deviation and CAPA Procedure D8323632
Global Critical Events Procedure D8068970
Nutrition: Deviation Management GL-SC-QA-SOP-03042

4.10.2 CHANGE MANAGEMENT

- When there is a requirement for a planned change to occur, the QMS requires that:
  - The system shall prospectively evaluate, prior approve and implement changes to products and processes using quality risk management principles
  - After implementation, an evaluation of the change should be made to ensure that there are no unintended consequences of the change

Reference Documents:
Global Change Management Procedure D8298052
Nutrition Global Change Control Management GL-SC-QA-SOP-03023

4.11 MEASUREMENT AND CONTINUOUS IMPROVEMENT

4.11.1 GENERAL

- Reckitt monitors, measures, analyses and improves processes needed to demonstrate conformity of product and of the QMS using risk-based principles

4.11.2 MANAGEMENT REVIEW

- Reckitt shall conduct Management Reviews in accordance with an agreed schedule to ensure the QMS continues to be suitable, adequate and effective. Oversight of the QMS across Reckitt is achieved and used to drive continuous improvement whilst ensuring compliance with all applicable external regulations, legislation, standards and internal Reckitt standards

Reference Documents:
Global Management Review Policy D8036468

4.11.3 KEY PERFORMANCE INDICATORS

- Reckitt will determine the Global KPI metrics that will be monitored and the frequency of reporting
- KPI Metrics will be analysed and evaluated during management review

Reference Documents:
Global Quality Reporting (Metrics) D8045802
Health Quality Metrics Reporting D8341451
Hygiene Quality Metrics Reporting D8341291

4.11.4 FEEDBACK

- Reckitt shall monitor feedback from customers and consumers relating to whether their requirements have been met. Feedback from customers shall serve as a potential input for product improvement. Refer also to section 4.9.2

4.11.5 SELF-INSPECTION, INTERNAL AUDIT AND EXTERNAL AUDIT FINDINGS

- Reckitt sites and functions shall conduct self-inspection / internal audits in accordance to an approved risk-based schedule to ensure that the QMS continues to meet both internal and external requirements
- Local procedures shall be in place to facilitate external audit management from Customers, Authorised Bodies and Competent Authorities
- Reckitt quality auditors shall be qualified and independent of the area to be audited
- Records of the audits and any resulting actions and responsibilities shall be maintained

Reference Documents:
Global Audit Policy D0117484
Lead Auditor Qualification and Competency Assessment Procedure D8082890
Global Auditing Process D0365356
Global Self Inspection Procedure D8362336
Global Audit Management Procedure D8355006
Guidance for Planning and Conducting Virtual Audits D8380401

4.11 MEASUREMENT AND CONTINUOUS IMPROVEMENT

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4.11.6 CONTINUOUS IMPROVEMENT

- All Reckitt sites and functions shall establish, implement, maintain and continuously improve a QMS that will analyse and evaluate appropriate data arising from monitoring and measurement and implement necessary actions including:
  - correcting, preventing or reducing non-conformances
  - improving processes and product performance

4.11.7 PRODUCT QUALITY REVIEW

- Where required, periodic quality reviews should be conducted with the objective of verifying the consistency of the existing process, appropriateness of specifications, highlight trends and identify areas for improvement

Reference Documents:
Health: Global Product Quality Review Procedure D0294730
Nutrition: Annual Product Quality and Conformance Review GL-SC-QA-SOP-05057

5.0 Definitions and references

5.0 DEFINITIONS AND REFERENCES

Definitions and abbreviations
EMO - External Manufacturing Organisation
GBU – Global Business Unit
GDP – Good Distribution Practice
GFS – Good For Sale
GMP – Good Manufacturing Practice
GRA – Global Regulatory Affairs
LRA – Local Regulatory Affairs
QMS – Quality Management System
PP&G - Policies, Procedures, & Guidance
R&D – Research and Development function
RQM - Reckitt Quality Manual

References
ISO9001: 2015 Quality Management Systems Requirements
ISO13485: 2016 Medical Devices – Quality Management Systems
EudraLex Volume 4 – EU Guidance for GMP Chapter 1 – Pharmaceutical Quality System
FDA Code of Federal Regulations
Guidance for Industry – Quality Systems Approach to Pharmaceutical cGMP Regulations
ICH Q10 – Pharmaceutical Quality System
WHO – GMPs for Pharmaceutical Products: Main Principles
EU Medical Device Regulations (MDR) 2017/745
D0178006 – Global Medical Device Quality Manual

6.0 Revision history

6.0 REVISION HISTORY

Version number	Revision reason
6.0	Revision of formatting to include interactive features. Quality Vision updated to Quality Commitment and added links to Reckitt's Compass, Purpose & Fight within section 1.0 (Commitment & Purpose). QMS overview clarification added to section 3.0. QMS Elements in section 4.0 re-ordered for more logical sequence. Addition of new section 4.7.7 to cover e-Commerce and associated references. Addition of new sub-section 4.7.13.2 within the 'Sales' section, to cover sale of Products with Limited Remaining Shelf Life / Use By date.

For previous version history, please refer to the Document History on TDS – document code D8032905

THANK YOU VERY MUCH FOR READING THE RECKITT QUALITY MANUAL.

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RECKITT QUALITY MANUAL

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