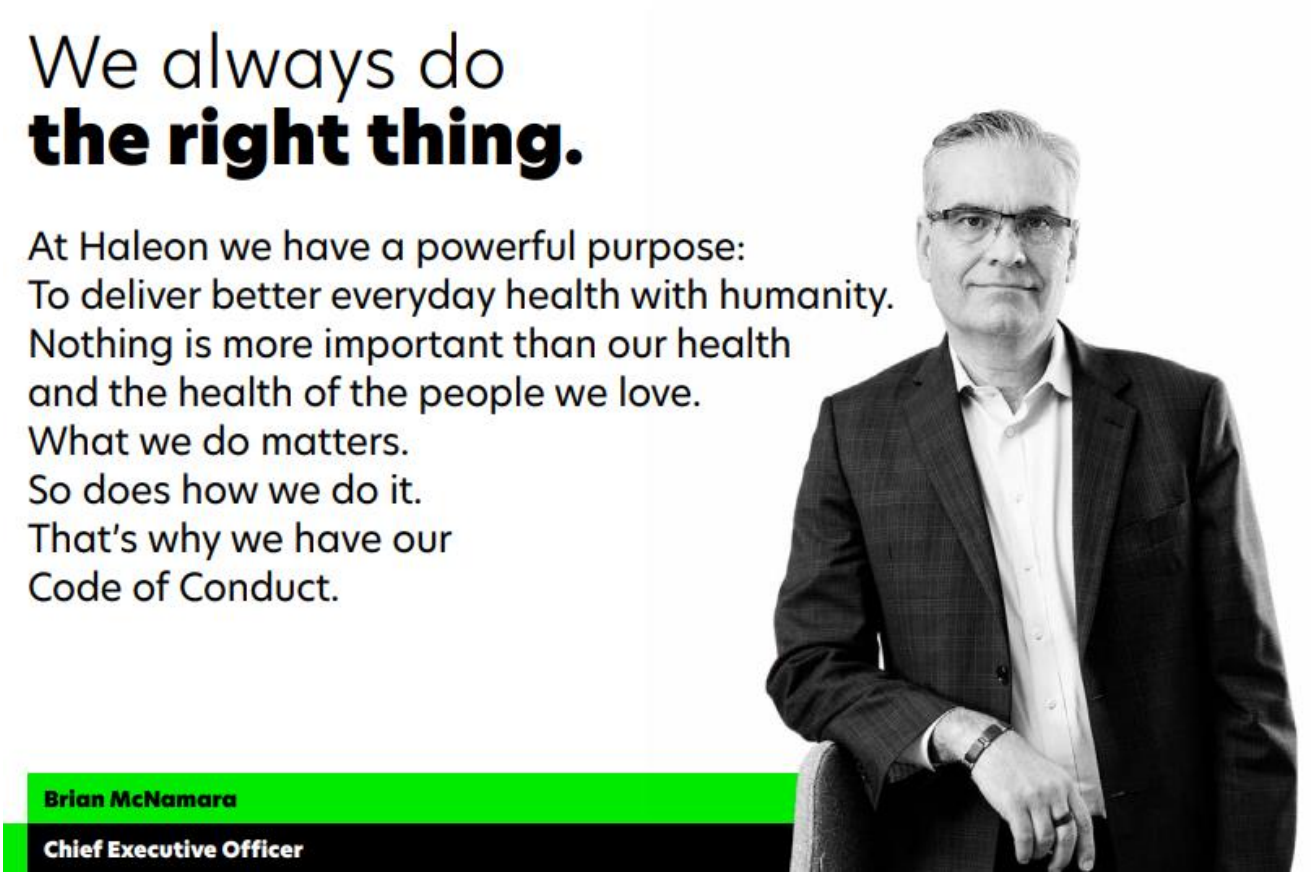
HALEON

Product quality and safety at Haleon

Delivering better everyday health with humanity

Content

1. Quality and safety at the forefront



1.1 Purpose of the Haleon quality and safety system

Fulfilling our purpose demands strict attention to every aspect of the design, production, and delivery of our products. Our Haleon Quality System (HQS) aims to govern these activities to ensure that our products are safe, perform as promised and with minimal impact on the environment.

Quality at Haleon includes all the processes, people, and systems that we use to deliver on the promises we make to our consumers and customers.

We use our Haleon Quality System to control and govern quality at Haleon, and we use the feedback from our consumers, internal and external customers, to continuously improve.

1.2 Scope of the Haleon quality and safety system

The management of quality applies to all areas within our business. This includes, but is not limited to, design and product development, sourcing, production, storage, distribution, marketing, and post-market safety surveillance.

1.3 Architecture of the Haleon quality system

The Haleon quality system framework includes:

- Written quality standards and processes
- Data digital and technology
- People organisation, culture, and capabilities
- Haleon's expertise in strategic areas of excellence such as trusted science, operations, and customer excellence

2 Commitment to quality and safety

Our Commitment to product quality and safety stems from our purpose. To deliver better everyday health with humanity, we must ensure that quality and safety principles are embedded in everything we do. Our Haleon Quality System reflects the criticality of quality, making it incumbent upon leadership to create a culture that places quality and safety at the forefront of the mind of every colleague.

We are a health company that puts people first. We exist to deliver better everyday health with humanity. Billions of people have confidence in our world-class portfolio of brands designed to improve everyday health and wellbeing. We build our products on trusted science and understand how to operate in healthcare, and we comply with the diverse regulations that apply to our products around the world.

The values that guide our decision making are spelled out in our culture. Every improvement we make can have a positive impact on people's everyday health. As explained in our Code of Conduct, this is why we show up, every day, to endeavour to always do the right thing, with a restless energy to go beyond, to do what matters most, and to keep it human.

Our purpose and culture represent the values and behaviours that are shared among all Haleon businesses, functional units, and employees. The culture of Haleon is a culture of quality and safety.

3. Haleon's organisation

3.1 Overview

Our priority is to ensure we can safely deliver our products when, where and how our consumers want and need them. People trust our products, and our end-to-end teams work to ensure the right product is always available.

We've been on a 10-year journey to transform our Quality and Supply Chain (QSC) as we've greatly increased our product portfolio through acquisitions of the consumer healthcare portfolios of Novartis and Pfizer. We have simplified our network and moved from three distinct but predominantly pharmaceutical manufacturing mindsets to one that allows us to be best in class within FMCH – Fast Moving Consumer Healthcare.

Our organization is staffed with experts from a variety of disciplines (including pharmacovigilance[1], clinical development, and toxicology) that enable us to evaluate product safety from numerous perspectives. The Haleon Consumer Safety (CS) organisation includes Consumer Safety Science experts who provide proactive monitoring of product safety profiles based on scientific evidence for the entire life cycle of all Haleon products. The Consumer Safety organisation also includes Consumer

[1] Pharmacovigilance (PV, or PhV), also known as drug safety, is the pharmaceutical science relating to the "collection, detection, assessment, monitoring, and prevention" of adverse effects with pharmaceutical products

Safety Operations and Regions which supports safety activities including management of adverse event information, management of safety requirements in contracts and a centralised regional/country model covering 163 countries. Haleon has an EU QPPV (Qualified Person Responsible for Pharmacovigilance)[2] as well as local QPPVs where required by regulation.

3.2 Our focus areas

Our focus areas are oral health, respiratory, pain relief, vitamins minerals and supplements, digestive health and more, and our quality and safety principles are applied to all Haleon product types regardless of product registration. At Haleon we are committed to prioritising the safety of our consumers above all else.

For more information on our portfolio please refer to our website: https://www.haleon.com/our-brands.

3.3 Our principles underpinning product safety and quality

Product quality and consumer safety:

What we do matters. So does how we do it. Our aim is to ensure we are a trusted company with high standards of business conduct. We are committed to consumer satisfaction, safety, and compliance with good practice regulations. These assure the quality, safety, and efficacy of our products. We have product safety and quality company positions, internal policies and processes established to manage this and have portals for consumers to access product information and report a possible adverse reaction.

Our code of conduct outlines our expectations on quality and safety standards and on product promotion and scientific engagement, you can find out more here. Our Product and Ingredient Safety position is here.

We promote our products in line with the applicable laws and regulations of the countries in which we do business. We engage responsibly with the scientific community to understand and communicate scientific information about our products. We have internal guidance for employees on engaging with external experts and the code of scientific engagement.

3.4 New product development principles

Each product we create is developed with the utmost care to meet consumer needs and preferences, and always within the parameters of local and regional regulatory frameworks. We have extensive controls in place, designed to evaluate benefits and risks, and to identify potential concerns about ingredients in every product we develop. Our Haleon Safety Board also plays a vital role: comprised of Haleon Chief R&D Officer, Chief Medical Officer, Chief Scientific Officer and senior Haleon physicians and scientists this committee defines the Product Safety Strategy for Haleon products and key ingredients and ensures compliance with company policies, applicable laws and regulations.

Among our team of more than 1,400 research and development scientists, the safety of our products is non-negotiable. We apply best practice standards throughout research and development, product design, manufacture, and release, as well as providing after-sale consumer support and in-market safety monitoring, in accordance with all applicable regulations.

[2] The appointment of an EU QPPV is a mandatory requirement for all medicinal products authorised within the EU and they are responsible for ensuring that the Marketing Authorisation Holder's pharmacovigilance system is compliant with EU requirements.

We conduct clinical trials on development and marketed products, where deemed necessary, to understand their safety and efficacy. Our Clinical Development professionals ensure that the clinical trials we conduct are designed to produce valuable safety and efficacy data, and we have robust controls in place to adequately protect all participants in accordance with applicable regulations and guidelines, including ICH's Good Clinical Practice Guidelines (GCP). We provide publicly accessible information on Haleon-sponsored clinical trials via external clinical trial registries, irrespective of whether the results are likely to be perceived as positive or negative. Our approach to Clinical Trials is here. Our Toxicology group is comprised of toxicologists who provide a toxicological perspective on ingredients and formulations.

4. The role of management

Haleon manages quality through its organisational roles and responsibilities, standards, and processes. This is referred to collectively as the Haleon Quality System (HQS), which is supported by senior management. Safety is also managed with a quality system that applies to all Haleon products, processes, and the organisational structure.

The Haleon executive team is the highest level of management with the accountability, authority, and control of resources to define, implement, and/or modify the structure, policies, procedures, processes, and practices of the organisation. Senior management has key decision-making and oversight responsibilities for all the Haleon Quality System(s) across the Enterprise.

Senior management roles across quality and safety functions include the Chief Research and Development Officer and Chief Supply Chain Officer (both roles are members of Haleon Executive Team), Head of Quality, Chief Medical Officer and Chief Scientific Officer.

Management at all levels and in all functions have a significant role in building the culture at Haleon by demonstrating leadership and a commitment to quality. Management has oversight to ensure that business and functional units are operating within the Haleon Quality System. Responsibilities from management down to the employee level are applied so that every employee has a responsibility for quality.

Management of each business and functional unit identifies resource requirements and provides resources, infrastructure, and qualified personnel to establish, maintain, and improve the elements of the Haleon Quality System.

For more information on Haleon management approaches see here.

5.Quality and safety organisation and governance

5.1 Quality and safety organisation

Everyone at Haleon is responsible for product quality and safety. We have dedicated quality and safety organisations with a worldwide presence that provide end-to-end support to all business and functional units to ensure that products are designed, manufactured, marketed, and distributed effectively with product safety as priority.

Quality management has the responsibility and authority to ensure that quality system requirements are effectively established and maintained within the respective organisations. Quality, safety, and compliance issues are escalated, and the performance of the quality management system is reported to senior management.

Haleon quality and safety leadership are responsible for:

- Providing strategic direction and oversight of quality, safety, and compliance for Haleon end-to-end across all our business and functions
- Establishing the Quality and Compliance Vision, and strategic priorities, and communicating these to employees
- Establishing Haleon policies and standards that will promote consistency in quality and safety requirements across all business and functional units
- Establishing a global quality plan/manual to ensure continuous improvement
- Assuring transparency of risk and decision-making with executive management
- Reporting quality, safety and regulatory compliance metrics and issues to executive management

The global quality function also provides expert support to the business and functional units when and where required.

Consumer Safety (CS) is a central function, independent to Business Units, and is responsible for vigilance activities including product risk management for the Haleon product portfolio.

5.2 Business units' quality organisation

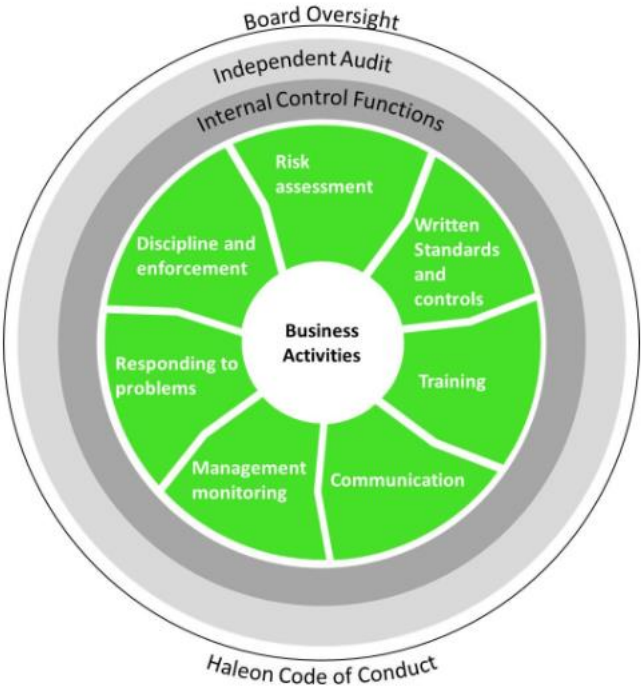
The Business units' quality organisations provide end-to-end support to the operations to ensure that product is designed, manufactured, marketed, and distributed with good quality and in compliance with Haleon quality standards and local regulations.

5.3 Responsibilities for key quality- and safety activities

The following diagram (to the right) show's Haleon's internal control framework.

In alignment with Haleon Internal Control Framework (ICF), Quality and Safety is organised in a multi-layered structure for monitoring key activities to ensure compliance with relevant standards and policies. This includes different levels of:

- Internal verification: corporate audits, global internal business monitoring, local management monitoring (5.3.1)
- Written standards: Quality standards, procedures, work instructions and tools (5.3.2)
- Training: GxP (Good Practices) training and Quality capabilities (5.3.3)
- Communication and governance (5.3.4)
- Responding to problems: Quality incident management (5.3.5)
- Product quality risk management (5.3.6)



5.3.1 Internal verification – audit management:

Independent audit - An independent corporate audit function outside of the quality organisation performs yearly assessments to provide risk & assurance assessment oversight of Haleon product quality risk to deliver early detection and mitigate product quality risks throughout the entire organisation. They assess the organisation against Haleon's ICF and to detect any potential risks to the organisation. The last independent corporate assessment of the quality organisation was in Q1 2023, and no risks were identified.

Independent business monitoring – Every year, multiple internal audits are undertaken as part of our internal governance. Global internal Good Manufacturing Practices (GMP) audits are performed at Haleon manufacturing sites, including pilot plants, analytical labs, contract manufacturers and suppliers. These audits ensure that quality systems are in place and in use to effectively manage the production of materials and products manufactured. Haleon legal entities are audited against the Haleon quality management system and other applicable standards, including GVPs (Good Pharmacovigilance Practices) cGMPs (current Good Manufacturing Practices) and cGDPs (current Good Distribution Practices) for the markets supplied. Third parties are audited against the Quality Agreement with Haleon, and the standards used are dependent on the scope of the audit.

Independent pharmacovigilance and clinical audit functions provide quality assurance for pharmacovigilance/safety and clinical research processes in accordance with legislative requirements. The pharmacovigilance and clinical independent audits may cover core safety and clinical processes, markets, and regions, third parties and clinical investigation sites and they are performed according to an agreed audit plan that is risk based.

Local self-assessment - management monitoring is performed and managed directly by the local entities and business units.

5.3.2 Written standards and controls

Document and data management controls & hierarchy – Quality and Safety management is incorporated into Haleon's Code of Conduct. The Haleon Quality and Safety System Framework documentation hierarchy provides a foundation that sets forth the requirements for the organisation. The Quality and Safety 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. It covers a broad range of product types such as cosmetics, vitamins and mineral supplements, medical devices, medicinal products, and active pharmaceutical ingredients, as well as a broad range of country-specific and international organisational guidelines and standards documents.

Regulatory notification and monitoring - Current, new, and proposed regulatory agency requirements and industry standards are monitored for impact to Haleon Quality and Safety Standards, filings, registrations, clinical protocols, submissions, business operations/activities, and products. Health authority and regulatory changes, requirements, and trends are communicated to management.

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 that are executing GxP activities follow applicable regulations.

Quality control product testing – Quality control product testing throughout the supply chain is one of the quality controls to assure product quality. The control strategy is defined before the product is launched and verified throughout the product lifecycle. Every batch of raw materials, active pharmaceutical ingredients and packaging components are assessed by the suppliers and assessed by Haleon on a set basis upon acceptance of the supplier certificate of analysis. Finished products and intermediates are assessed via manufacturing and packaging in-process control checks, finished product testing, as well as ongoing stability testing conducted throughout the shelf life of the product.

Product quality control testing is conducted in-house by our internal manufacturing network, and in some incidences, we use external qualified laboratories where necessary. Our third-party manufacturers conduct product testing as part of their overall service.

Acquisitions and divestitures - Management of each business and functional unit ensures that appropriate resources and processes are established to assess and manage the quality, safety and compliance responsibilities for acquisition and divestments of products, services, and companies.

5.3.3 Training for the Organisation

All Haleon employees are provided with a mandatory induction training and an annual mandatory refresher on Haleon Code of Conduct which includes Haleon Global Quality Policy and Haleon Policy for Collecting information from Consumers (reporting of Human Safety Information including adverse events, medical information, and product quality complaints).

Quality training on Good Practices (GxP) topics is provided to all new Quality and Supply Chain (QSC) employees via the global QSC Induction Programme. This includes an introduction to GxP, data integrity, and fundamentals of compliance training in a regulated environment.

Annual GxP refresher training is selected and provided for employees based on industry trends; topics presented include data integrity, human performance, and corrective action plans (CAPA), Good Distribution Practices.

Safety training topics are provided depending on role and responsibility and includes new starter induction training and ongoing training related to processes, regulations (including GVP) or systems as they become effective.

Training on specific manufacturing and safety topics at Haleon manufacturing sites is provided by each site in accordance with our Personnel and Training Management standard, implemented by each site. Non-site workers also receive training relevant to their role, which includes GxP topics, including specific Quality and Safety topics such as investigation excellence, quality incident management skills and reporting adverse events.

As part of our management of outsourced activities, we expect all GxP third parties to proactively reinforce and refresh their knowledge of industry best practice, and to have the appropriate GxP training standards in place. Every year, we provide additional training for targeted third parties in the form of guidance and improvement plans on topics such as contamination controls, data integrity or process capability for example. In 2022 we worked with our suppliers on 90 different improvement activities.

5.3.4 Communication and governance

Management review and quality monitoring - The performance of the individual business units within Haleon is reviewed and monitored by Management. Tiered monthly and quarterly management review of quality and safety systems, metrics and risks via a governance process encourages a factual approach to decision making, and ensures quality and safety systems are suitable, adequate, and effective. The output of management reviews is used to define corrective and preventive actions for continuous improvement and annual planning.

Continuous improvement - Management establishes the organisation's plan, goals, and objectives and cascades these expectations throughout the organisation to ensure all employees are engaged in the Quality and Safety priorities. Haleon uses the feedback from our consumers and customers, and from the activities in scope of our Haleon Quality System to continuously learn and improve.

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 management and, if required, applicable Health Authority and Regulatory Agencies of significant product quality, safety, efficacy, regulatory compliance, and quality system issues throughout product lifecycle.

Product lifecycle management - We use the process and product knowledge generated, and monitoring conducted throughout development, to establish a control strategy for manufacturing and have a well-defined system for process performance and product quality and safety monitoring in place that we apply to assure performance. It includes but is not limited to product and process design, pack design and security, periodic product review for quality and safety, process validation and change management.

5.3.5 Quality and safety incident management

Vigilance and post-marketing surveillance - Haleon has a process in place to identify, assess, document, and report product quality incidents and Adverse Events during all phases of the product lifecycle, including clinical trials, as required by applicable regulations. This includes the monitoring of trends and the establishment of triggers to allow escalation of significant Quality and Safety incidents. A post-market surveillance system is in place to collect, record, and analyse relevant data on the quality, performance, and safety of a product throughout its entire lifecycle.

Anyone can report an adverse event using our online form.

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 incidents.

Market action & recall management - Consumer and colleague safety are a top priority for everyone at Haleon. As a result, Haleon has a system in place to assess product incidents. If required, product recalls, product withdrawals, product corrections, or any other product specific actions affecting product quality or safety are taken in accordance with all regulatory requirements. All decisions on market actions are taken independent of commercial/business influence by a Product Quality Incident & recall Committee (PIRC), which is chaired by Quality. These actions are documented and when required communicated to Health Authorities in a timely manner.

You can find our annual reporting on recalls in our ESG Reporting hub and data book here.

5.3.6 Product quality and product user safety risk management

Quality and safety risk management - The Haleon Internal Control Framework (ICF) defines the essential elements expected of our compliance and risk management programmes at Haleon. A fit-for-purpose ICF, combined with embedding the Haleon culture and our Speak-Up campaign, ensures that the Haleon principal risks are actively and effectively controlled.

The product quality & product user safety risks are considered as enterprise risks and are being pro-actively managed by the quality and safety functions as well as the business via the Haleon risk management system, which includes for example crisis management, emergency response procedures and business continuity management plans (e.g., dual sourcing) being in place and tested every year with different scenarios.

Failure to ensure the quality and safety of our products throughout the entire supply chain can lead to physical harm of consumers, fines, withdrawal of licenses and interruption of operations, or reputational damages.

5.3.7 Trusted Ingredient risk management

Trusted Ingredient risk is the risk of not pursuing best-in-class science or not monitoring and responding to emerging ingredient data and changes in consumer perception of product ingredients which has the potential to negatively impact our brands and reputation.

Trusted ingredients risk is managed through an established Trusted Ingredients Framework, enabling us to collect intelligence from multiple external sources, anticipating and detecting early signals to inform our approach and action plans to tackle ingredient risk. We have cross-functional dedicated resources across Haleon that provide expertise in informing our choices of active ingredients and excipients/additives. We actively participate in industry associations to gain insights and to impact the environment we operate in for the benefit of consumers. Our position on Trusted ingredients, sustainably sourced is **here.** Further information on Trusted ingredients is located in the **Haleon Annual Report.**

6. External certifications and audits

Governments and industry regulators set the legal and regulatory environment in which we operate. We work with them to advance everyday health and manage risks.

100% of our manufacturing sites receive regular external inspections from their local health authorities to obtain their GxP certifications and maintain their license to operate. Our Quality and Safety organisations are subject to multiple regulatory inspections and certifications every year by national regulatory bodies and external certification bodies for different product registration status across our entire network. Some of these external certifications include the US FDA (United States Food and drug Administration), MHRA (Medicines and Healthcare products Regulatory Agency) and ISO (International Organisation for Standardisation) certifications such as ISO 13485 medical devices, ISO 22716:2007 Cosmetics, ISO 9001:2015 Quality Management System, ISO 45001:2018 Occupational health and safety management system, etc…. We continuously invest to sustain our strong quality, safety and compliance record and keep ahead of evolving regulatory requirements. We ensure that all relevant Haleon entities are always prepared to receive Regulatory Authorities' inspections. In 2022, all the 79 health authority inspections received across the network were successful.

Haleon's first pharmacovigilance inspection by Health Canada concluded in January 2023 with Haleon being awarded a compliant rating.

7. External network quality and safety management

Maintaining healthy long-term relationships with external third parties (e.g., external manufacturers, logistic service providers, suppliers of raw materials, components, or services) helps us protect business continuity and achieve our quality, safety, and environmental ambitions.

Prior to the decision to enter a partnership or purchase of a product, a company, or process, quality and safety are involved in the evaluation and selection through a due diligence process to assess the state of compliance and associated risks to Haleon. Quality agreements are in place to set forth our quality and safety expectations and responsibilities, and they are regularly assessed to ensure

compliance with regulations under which they operate. Haleon conducts quality audits on its external suppliers and re-assesses whether suppliers are meeting quality standards on a set frequency based on risk (e.g., active pharmaceutical ingredient suppliers are assessed every three years). In addition, they are also subject to inspections by regulatory agencies and notified bodies, according to local regulations and requirements. We work closely with targeted external third parties on common continuous improvement programs and training such as for example physical contamination risk management.

8. Objectives - Quality and safety enabling the future

Haleon is embracing disruptive technology and digitisation to deliver over the counter medicinal products, medical devices, and consumer products of the highest quality and safety for our customers, and consumers around the globe.

The following areas are some of the actions we are taking to enable the future of our product quality and safety functions:

- People: moving to a fast-moving consumer health business environment increases the need to attract and retain a balance of key leadership, quality, safety, and technical talents. The digitally native workforce and the virtualisation of work means that employees expect the flexibility and autonomy at work that they are used to getting in their digital lives, so we need to adapt the way we monitor, train, and incentivise quality and safety.

- Processes and systems: we need our internal processes and systems, and a culture that can quickly adapt to rapidly changing customer expectations and regulations for quality and safety.

- Data and technology: The technological and digital environment are evolving rapidly, increasing the expectation to have digital facilities, optimised processes, and relevant capabilities to support data management and data integrity. Quality and safety excellence is now determined by how quickly data can be captured, analysed, shared, and applied.

- Industry engagement: We also seek to learn from best practice and engage with others, we are a member of the Global Self-Care Federation which works with members and stakeholder groups to 'ensure evidence-based self-care products and solutions are recognised as key contributors to health for individuals and systems worldwide,'[3] and to advocate for legislation and regulations that best reflect relevant scientific data.

9. Document revision history

Version 2.0 – Sep 2023
Version 1.0 – Jun 2023

[3] Who we are vision, mission and work focus | Global Self-Care Federation (selfcarefederation.org)

10. Signatures

Chief Research and Development Officer

Chief Supply Chain Officer