Politecnico di Torino

Master's Degree in Engineering and Management

Deployment and Optimization of the Qualification Process for Initiatives in the Air Care Business: a Procter & Gamble Case Study.

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Abstract

Initiatives represent day to day business in plenty of companies, from manufacturing to service organizations: they provide continuous innovation to the business while always fulfilling consumer needs and quality requirements.

Even though initiatives are created to satisfy consumer expectations on a specific product or performance, they need to comply with a strict system of rules and regulations ensuring the fulfillment of the success criteria.

This paper addresses the Initiative deployment in one of the best companies in the laundry and cleaning supply sectors: Procter & Gamble.

Procter & Gamble has a rigorous quality system in place in order to provide branded products and services of superior quality and value that improve the lives of the world's consumers, now and for generations to come. The reputation of every product is based on the assurance that it is safe for humans and the environment. The initiative on which this paper is based was deployed by the External Supply Solutions department in cooperation with a Contract Manufacturer.

In particular, the qualification process for an initiative in the Air Care sector will be illustrated.

This initiative qualifies two new formulas for two products of the brand Ambi Pur/Febreze to mitigate the uneven formula runout which is the #1 consumer complaint at the Contract Manufacturer site.

It describes the journey and the multiple controls to be performed throughout the supply chain in order to ensure the correct deployment of the initiative.

In addition to this, on the basis of the thorough qualification process performed in case of initiatives, with the help of the Quality Assurance team we decided to optimize the procedure to be performed in case of qualification of seasonals for the Air Care business.

This optimization split in two waves will ensure the simplification of bureaucracy behind an initiative, needed to perform the qualification while consistently guaranteeing the compliance with the success criteria.

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Acronyms List

Acronym	Equivalent
ESS	External Supply Solutions
MPD	Material Process/Package Delivery
QA	Quality Assurance
SPOC	Single Point of Contact
CM	Contract Manufacturer
ISO	International Standard Organization
FDA	Food and Drug Administration
CFR	Code of Federal Regulations
P&G	Procter & Gamble
SL	Site Leader
SIL	Site Initiative Leader
IOL	Initiative Operational Leader
R&D	Research & Development
SDS	Safety Data Sheet
PDV	Product & Package Design Validation
LSL	Lower Specification Limit
TGT	Target
USL	Upper Specification Limit

DISCLAIMER

Data shown in this document is not real as per confidential purposes.

Introduction

At the basis of this study there is the analysis of the qualification process for external companies or Contract Manufacturers that produce Procter & Gamble's products in an international context: the External Supply Solutions department works with more than ten different Contract Manufacturers around the world with different business relationships that characterize each one of them.

In particular, this essay focuses on a qualification process that occurred between October and November 2022 focused on the qualification of two new formulations and the mitigation of the uneven formula runout which was considered as the #1 consumer complaint, in the Air Care business.

The motivation that led me to make a deep dive on this topic has a double nature: the interest for the Quality world has always been present and strongly influenced by my educational path with exams both in my bachelor's and master's degree that made me appreciate Statistics for process control or quality management which are great tools to have in your own cultural baggage. In addition to this, the other main reason is that I never understood before my experience at Procter & Gamble how quality strongly influences every step of Product or Package Design, Initiative Deployment, and many others.

The objective of this essay is to provide an insight into the steps required to deploy an initiative in a consumer goods company. Furthermore, this paper intends to cover the possible optimizations to the qualification process that were evaluated during my internship and applied in the future.

This paper is divided into five chapters: in the first chapter the company's introduction is given, illustrating the values that characterize Procter & Gamble and the internal structure of the External Supply Solutions team; moreover, it illustrates the stage-gate model used to approach the projects; in the second chapter, a deep dive in the Procter & Gamble quality system is provided illustrating the different regulations on which it is based; in addition to this, it focuses

on the difference between Quality Assurance and Quality Control and their role in the Quality System; the third part illustrates the qualification process for the initiative in detail going through all the steps and the mandatory documents for the qualification with the additional duration and possible unforeseen events that characterized this project; in the fourth chapter, the potential optimization proposals are illustrated considering as a starting point the qualification described in the third chapter; last but not least in the fifth chapter the final conclusion is drawn analyzing the most relevant data present in the previous chapters.

Thanks to this project and to the External Supply Solutions department who gave me the opportunity to look deeper into their processes, it was possible to analyze how a qualification process impacts the deployment of an initiative.

1. Company Description

1.1 Procter & Gamble

Procter and Gamble, also known as P&G, is one of the biggest consumer goods companies in the world. The P&G logo is shown down below in Figure 1.

Based in Cincinnati, Ohio (USA) the company operates in the laundry and cleaning supplies sectors, as well as the cosmetics and personal care sectors with more than 100000 employees. It was created in 1837 by William Procter, a British candlemaker, and James Gamble, an Irish soap maker, merging their businesses supplying soap and candles. Over the years, the product lines extended including oral hygiene products and beverages like coffee or tea.

By the beginning of the 21st century they spread over different markets such as house and home, personal beauty, health and wellness and others.

The company has always been in the lead for Advertisement, breaking through new markets with great innovations (The Editors of Encyclopaedia Britannica, 2023).

Figure 1: P&G logo

1.1.1 Brands

Procter and Gamble products are distributed along 5 different reportable segments with 36 major brands worldwide. As shown in Figure 2 the segments with more impact are the following:

- Fabric and Home Care with 35% of net sales and main brands as Ariel, Febreze or Swiffer;
- Baby, Feminine and Family Care reaching 25% of net sales and presenting as main exponents Pampers, Always or Tampax;
- Beauty Care which reaches 18% of net sales for 2022 and includes brands as Pantene, Head & Shoulders, or Olay.

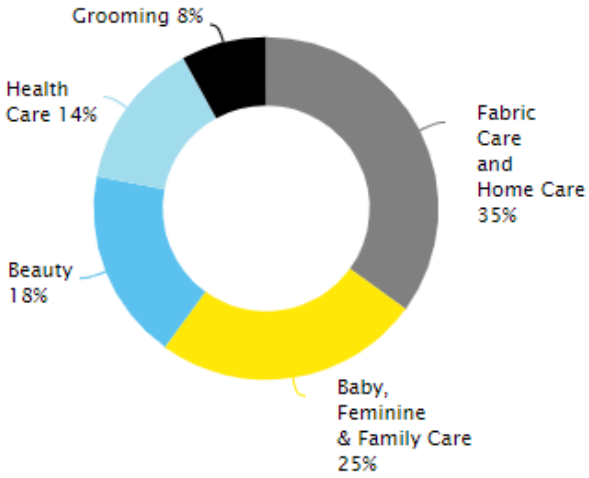


Figure 2:Net Sales per Business Unit 2022

This project includes all the products related to the Febreze and AmbiPur brand whose logos are shown in Figure 3, which are part of the Air Care segment and part of the

Home Care category (About P&G - P&G at a Glance | Procter & Gamble Investor Relations, s.d.).

Figure 3: Air Care logos

1.1.2 Purpose, Values and Principles

Procter and Gamble's Purpose, Values and Principles are the foundation of their unique culture. The company has evolved over the course of their history, but these principles have lasted and will continue to be passed down to the next generations of P&G employees.

The main purpose is to improve more consumers' lives in meaningful ways every day, by providing branded products and services of superior quality and value. By doing this, consumers will reward with leadership sales, profits, and value creation, allowing the communities and stakeholders to grow.

The Values of Procter & Gamble reflect and define how to collaborate with each other and with partners: Integrity, Ownership and Trust are some of the said values. Being 'data-based and intellectually honest in advocating proposals, including recognizing risks', acting like 'owners, treating the Company's assets as our own and behaving with the company's long-term success in mind' and 'respect our P&G colleagues, customers and consumers, and treat them as they want to be treated' are key of the Procter and Gamble's culture.

Procter and Gamble's Principles are eight, among them, 'Show Respect for All Individuals' and 'The Interests of the Company and the Individual Are Inseparable' (Procter & Gamble, s.d.).

1.1.3 External Supply Solutions

This study has been performed in the External Supply Solution department by the Material Process Delivery – Process Team in cooperation with the Quality Assurance Team. This department focuses on the Home and Fabric Care products produced by external parties. It works in collaboration with several Contract Manufacturers across Europe.

The goals of the department focus on the Product Supply division, part of the manufacturing team delivering projects on Quality, Cost and Time:

- Quality: focuses on delivering quality products that meet consumer expectations and specific standards;
- Cost: this is what ensures that the company is growing and sustainable. All projects pass under a cost check and some of them are focused on reducing the cost and maintaining up to standard the other two pillars: Quality and Time;

- Time: competitiveness is achieved by meeting the expectations for initiatives and time to market.

The organization of the department can be found in Table 1.

Team	Role & Responsibilities
Material Process Delivery – Process	Technical team working on the process going from raw materials to finished products
Material Process Delivery – Packaging	Technical team working on the packaging of products focusing on optimization of packing materials and equipment
Quality Assurance	Ensuring Quality Standards are met by all Contract Manufacturer products – P&G related
Operations	Managing daily operations and initiatives across Contract Manufacturers. Divided as follows: ● Site Leader (SL): responsible for operations related to one Contract Manufacturer like budget, tests, or materials. ● Site Initiative Leader (SIL): managing initiatives by different Contract Manufacturer, working

	closely with the Initiative Operation Leader (IOL)
Purchasing	In charge of negotiations with Contract Manufacturers and Contract Manufacturers relationship with P&G, managing contracts
Stewardship	In charge of topics divulgation and proper use of resources
Capability	In charge of activities related to organization and personnel.

Table 1: External Supply Solutions Organization

The whole team manages several Contract Manufacturers across Europe and not only. Teamwork is essential to move forward day-by-day delivering successful daily business and new initiatives to the market.

1.1.4 Material Process Delivery

The Material Process Delivery Team is divided into two branches: Process and Packaging. Each member of both teams works in both branches with more expertise in one or the other.

MPD Process ESS is the 'face of R&D' as the first representation of R&D into the ESS Organization and the 'First Making SPOC (Single Point of Contact)' for the Contract Manufacturers on Raw Materials, Process Equipment and Formulas.

It is responsible for:

- Qualifying Market Initiatives;

- Qualifying Technical Projects;
- Fixing daily issues related to Raw Materials/Formulas/Processes;
- Qualifying New Suppliers for Raw Materials.

It provides:

- Process Improvements (Improving Equipment, Process Reliability, and others);
- Process Savings (Scrap Reduction, Manufacturing Operating Expense Reduction);
- Agility to Business (End-to-End Synchronization, Reducing Line Bottlenecks, and Inventory).

Delivers:

- Initiatives Successfully (Lower Cost and Shortest Time);
- Propose Savings Initiatives.

MPD Packaging ESS provides packaging expertise to support new initiatives and manage any packing changes or materials for productions at Contract Manufacturers. It ensures a continuous improvement in cost performance and quality of products.

It is responsible for:

- Qualification of new packing lines at Contract Manufacturer sites;
- Transport Tests, PPCT (product pack compatibility test) Printer qualification support;
- Qualification of new local suppliers, new materials/designs.

Ensures:

- Suppliers and Contract Manufacturers' materials meet the specifications and run-on packing lines without any trouble.

Together they work to provide the right technical expertise to support the company and Contract Manufacturers in the deployment of new initiatives and daily business.

1.1.5 Quality Assurance

Quality Assurance (QA) is an independent function with end-to-end vision in order to preserve objectivity regarding internal assessments and product release decisions.

The main objective is to deliver the promised quality to consumers, regulators, and employees, leveraging Quality as a competitive advantage for business growth.

It is accountable for:

- Quality Results and compliance for several Contract Manufacturers;
- Concurrence and/or approval of technical standards or deviations;
- Delivery of initiative excellence: start of new lines, new equipment, or sites;
- Technical readiness to deliver intended consumer experience.

In addition to this, Quality Assurance is also responsible for the overall Micro program and development of capabilities across Contract Manufacturers, providing Micro risk assessments and recommendations in case of a new project or initiative.

It works closely with the other functions (MPD, Operations, Stewardship, Platform QA) to establish a Quality culture in the External Supply Solutions Organization and monitor the health of the quality system to ensure continuous improvements both internal and external.

1.1.6 Project Management

The stage-gate model is the primary strategy used for Project Management by Procter and Gamble. It is used to efficiently design and deliver initiatives to create value for the consumers, company, and shareholders.

It is a model built to minimize risk.

It is composed of 5 stages and 4 gates, each one characterized by a specific project status and priority level as shown in Figure 4 .

Stages are group of activities that can be performed either in series or in parallel based on the level of risk that a project can endure. They are managed by cross-functional teams.

- Stage 0 is ideation which coincides with the brainstorming phase to develop new ideas. It is followed by the first gate which is the Ideation Screen which will focus only on a few of the ideas brainstormed;
- Stage 1 is the Scope which consists of the determination of the project's viability. SWOT analyses are carried out to underline the strengths and weaknesses of the possible project;
- Stage 2 builds on top of the first stage creating a business case which will include the product or project definition and a hypothetical development plan;
- Stage 3 is the one including all major departments. Here the design and development are locked;
- Stage 4 includes the tests and trials of the products in the market with collection of feedback through focus groups. This stage will help to modify small bugs and apply final touches;
- Stage 5 is where the product is launched to the market, and everything is tested.

As mentioned before, between each stage there is a gate which functions as a decision-making checkpoint: the possible decisions are: go, kill, hold, or recycle. The major gate is the third one (Development Review) which coincides with the Project Commitment. Good process management processes never go beyond the six gates

as there would be too much attention on the preparation of the gate reviews rather than the actual management of the project.

Project Management is used to manage the stages between the gates and to reduce the time that passes in between two gates. It is of critical importance in cases such as the ones where it is used for the development and launch of new products (Kerzner, 2009).

Every project requires a Critical Path Schedule which gives specific indications on which tasks to prioritize depending on which stage we are in (Strahan, 2022).

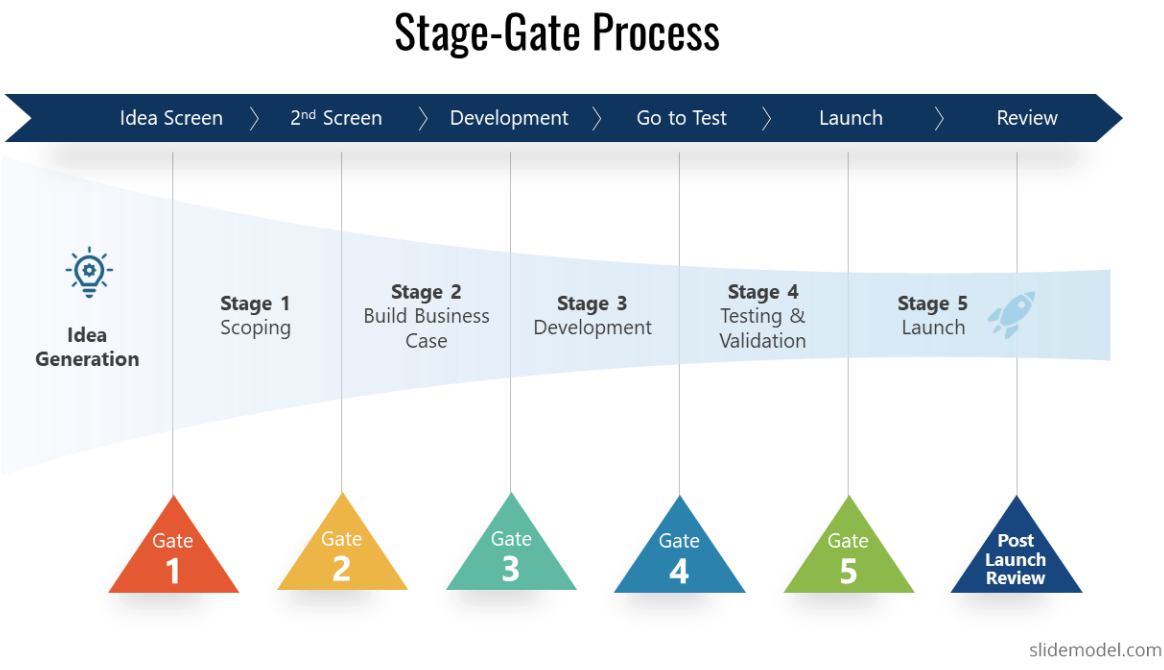


Figure 4:Stage-Gate Model

2. How Quality is perceived in Procter & Gamble

2.1 Safety & Compliance

Procter and Gamble consumer products enable better quality of life providing a range of benefits to society, such as improved health and personal hygiene or cleaner homes. In addition to this, one of the main expectations for all the consumer products under Procter and Gamble's brands is safety and respect for human health or environment. Since the beginning of Proctor and Gamble's history, safety has always been one of the prerequisites for business. As of today, this philosophy is reflected in the statement of purpose that was mentioned in the previous chapters.

Safety is considered as an intrinsic part of both the quality and value of the products.

Procter & Gamble assures the safety of products, packages, and operations for both employees, consumers, and the environment. It is a requirement for conducting business and one of the main elements to build and maintain trust in the company's products.

The safety of all products and materials is evaluated in detail before the market release, exploiting risk assessment methods to understand the potential exposures or other hazards. These evaluations are mandatory for the early stages of product design and for the product development process. Moreover, safety standards are used globally.

Procter and Gamble' Product Safety programs follow the policies and principles below:

- Products and packages if used as intended are safe for both consumers and environment;
- The company ensures that operations are safe for employees in the environment;
- Meeting all the regulatory and legislative requirements regarding Product Safety and labeling;

- Provide factual information about products and packaging safety to any interested parties.

The reputation of every product depends on the assurance that they are safe. Procter and Gamble's approach is based on scientific assessments of safety. The data gathered on the ingredients ensures that they are compliant with any regulatory standards and to the safety of humans and the environment.

The process to analyze every ingredient before it’s used in one of the products is illustrated in Figure 5 below (Procter & Gamble).

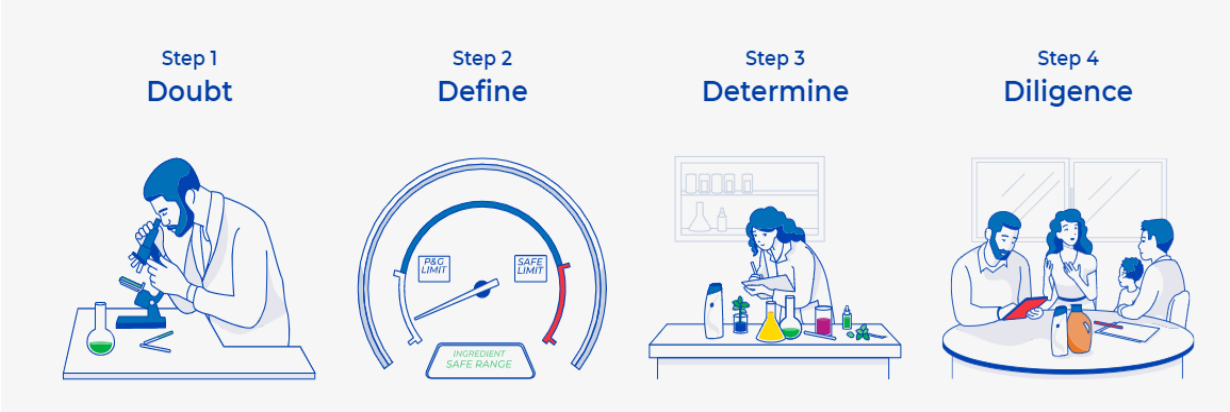


Figure 5: Procter & Gamble ingredient analysis process

2.2 Quality Assurance Definition

There are different definitions of Quality Assurance that cover historical, philosophical political and social aspects.

In particular, Quality Assurance is defined as:

"… systematic management and assessment procedures adopted by a higher education institution or system to monitor performance and to ensure the achievement of the quality outputs or improved quality."

The term assessment and evaluation are often used as synonyms to denote techniques, procedures, instruments and methods for measurement and analysis used to monitor the performance (Arun Patil, 2009).

It is a system that establishes a set of requirements for the development and production of reliable products. The main objective is to increase the company's credibility through the improvement of work processes and efficiency and the increase of customer confidence.

Quality assurance is of vital importance for a company to create both products and services that meet customers' requirements and expectations. It deploys high quality products which enable the creation of a loyalty bond with customers and consumers.

Moreover, the procedures and standards alongside support the prevention of product defects before they arise.

The main organization enforcing practices and process guidelines to implement Quality Assurance is the International Organization for Standardization (ISO) (Gillis, 2019).

2.3 Procter & Gamble's Quality Assurance

Procter and Gamble's Quality Assurance is part of the company's larger supply chain, alongside the Purchasing, Product Supply, and Supply Chain and Logistics teams. These teams, all together, contribute to the making and refinishing of the products to ensure that consumers will always receive the highest quality (Quality Assurance Jobs in P&G | P&G Careers, s.d.).

2.4 Quality Assurance vs Quality Control

Quality Assurance and Quality Control are two different concepts with many differences even though sometimes they are used interchangeably. Quality Assurance and Quality Control are two aspects of Quality Management: Quality Assurance activities cover all activities and responsibilities of the quality system while Quality Control is a subset of the Quality Assurance activities. There are also some elements that belong to the quality system that could not be specifically covered by either Quality Assurance or Quality Control activities but could involve both. This concept is summarized in Figure 6 below.

Quality Assurance provides confidence that goes in two directions: internally to management and externally to customers, third parties, government agencies and others. It can be defined also as all the activities implemented that provide the confidence that the product or service fulfils the quality requirements (Quality Assurance vs Quality Control: Definitions & Differences | ASQ, s.d.).

Auditing is a part of the quality assurance function which is important to ensure the actual quality level of a product by comparing the actual conditions with the quality requirements and reporting the results to the management. It examines all the aspects of a business, product or service. It may be conducted either by an internal auditor or by an external or independent auditor hired by the company. Audits are divided into three types: product, process and system.

An inspection evaluates something to assess whether it meets the specific requirements. It is usually conducted by regulatory agencies, for instance, the Food and Drug Administration or others. Inspections can be performed by internal members and an inspection report should be drafted including the details of the present state of the item being inspected and any issues found.

Both audit and inspection are processes evaluating a business or product, but key differences are present between the two.

1. **SOURCE**: an audit usually is focused on processes present at the company while an inspection focuses on the product or service provided;
2. **DEPTH OF REVIEW**: inspection is limited to specific requirements that ensure the suitability of the product. On the other hand, an audit is a deeper review of the product or process;
3. **FORMALITY**: an audit is more formal and documented than an inspection;
4. **PURPOSE**: the scope of the audit is to improve processes while the scope of the inspection is to determine whether a product or service meets the specifications;
5. **TIMELINE**: audit focuses on identifying the weaknesses in the system and improvement opportunities for the future. Inspection is focused on the past performance of the process.

Quality Control, on the other hand, can be defined as the part of quality management which is focused on the fulfillment of the quality requirements. It refers more to the technical part of quality management (The Difference Between Inspection And Audit, 2022).

Figure 6: Quality System

2.5 Procter & Gamble's Quality Program

Through all the steps of the product life, Procter and Gamble's Quality Program ensures the compliance of the products to the quality standards.

Quality Program includes the Quality System and the associated activities like Quality Assurance and Quality Control activities which are associated with the Quality Control plan which ensures that the materials and execution present in the project are conforming to the Contract requirements, design documents and project specifications.

Procter & Gamble's Quality Program is a very strict program based on multiple Quality standards on top of the usual ISO standards used for companies that produce goods. This enables the delivery of better-quality open products to satisfy both customers and consumers.

The reference ISO standards which are the basis of Procter & Gamble's Quality System are the following:

- 21 CFR 210/211;
- 21 CFR 820;
- ISO 13485;
- ISO 22716.

Each one of them will be described in detail below.

ISO or International Organization for Standardization is a worldwide federation of national standards bodies. The International Standards are created by technical committees which are then sent to member bodies for voting. Governmental and non-governmental organizations, some in collaboration with the ISO, also take part in the work.

ISO 22716 (Guidelines on Good Manufacturing Practices)

These guidelines whose logo is shown in Figure 7, are intended to provide guidance regarding the good manufacturing practices for cosmetic products. In specific they have been prepared according to the cosmetic industry to meet the specific needs of this sector: They offer advice both organizational and practical for the management of the factors affecting the product quality like you mean technical or administrative factors. They consider the flow of products from the reception to the shipment. These guidelines are the practical development of the quality assurance concept through the description of activities that are based on scientific judgment and risk assessments. The objective is to define all the activities that ensure the creation of a product that meets the success criteria.

These guidelines cover the quality aspects of the product but not the safety aspects for the personnel engaged in the plant or the aspects related to the protection of the environment.

The safety and environmental aspects of the company could be influenced by local legislation and regulation. Moreover, they are not applicable in the case of research and development activities and distribution of the finished products.

Figure 7: ISO 22716 logo

To summarize we will illustrate the steps correlated to production, control, storage and shipment for cosmetic products.

For production, the principle is that at each stage of the **manufacturing** and the **packaging** operations, measures should be taken in order to produce products that meet the defined success criteria. Specifically, from manufacturing operations point of view, relevant documentation should be available at each stage and my walk through operations should be carried out according to the documentation which includes: suitable equipment, formula for the product, list of all the raw materials that have been identified and used in the production according to the documents, indicating batch numbers and quantities, and the detailed manufacturing operations for each stage which will include the addition of raw materials,

speeds, mixing times, sampling cleaning and if necessary also sanitization and cleaning information.

In addition to this, before starting the manufacturing operations it should be confirmed that the documentation relevant to the manufacturing operations is available, call mom that's available and released, suitable equipment is ready for use, working, cleaned and in case it's necessary sanitized. Clearance of the area should be performed to avoid mixing the materials of the current operation with materials from previous manufacturing operations.

Batch numbers should be assigned for each manufactured bulk product. Call mom but this number does not need to be identical to the number that appears on the label of the finished product.

As for the in-process operations, all the raw materials should be measured, weighted, and labeled to ensure identification with name or identification code, batch number and the storage conditions in case this information is critical to ensure the quality of the product.

In addition to this, improved process controls and acceptance criteria should be defined and that should be performed according to specific programs with the investigation of any result outside the success criteria defined.

As for manufacturing operations, relevant documentation should be present for each stage of the packaging operations.

Moreover, all the packaging operations should be performed according to the documentation which includes suitable equipment, a list of the packaging materials previously defined for the finished product and the detailed list of the packaging operations to be performed like labelling and coding.

The same criteria present for the startup checks during the manufacturing operations are applied also to the packaging operations.

In addition to this, the identification of the packaging line should always be possible through name, identification code or the identification code of the finished product. In case used, control equipment on-line should be checked regularly.

For the in-process controls the same criteria of the manufacturing operations apply to the packaging operations. Filling and labeling are continuous processes. In case this is not the case, specific measures should be applied for mix ups or mislabeling to occur.

Finished products should meet the defined acceptance criteria. **Storage**, **shipment** and **returns** should be managed to maintain the quality level of the finished product. Prior to the market all finished products should be checked through the established test methods and should comply with the success criteria. Moreover, product release should be carried out only by the quality authorized personnel. In addition to this, finished products should be stored in specific areas and under appropriate conditions. In case needed, finished products should be monitored while stored. When the finished products are released, in a physical location that provides the same level of assurance. Moreover, all the finished product containers should contain information like name, identification code, batch number or storage condition when they are Critical for the quality of the product. Periodic inventory checks should be performed in order to assess that the acceptance criteria are met and to ensure inventory accuracy. measures should be taken to ensure the shipment of the defined product.

Quality Control is responsible for ensuring that the necessary control is performed for sampling and testing so that the material released for use and the products Release the first shipment quality success criteria. Test methods should be defined to confirm that the products comply with the chosen criteria. Moreover, controls should be performed based on the defined test methods. Acceptance criteria should be established to specify the requirements to be met by raw materials, packaging materials, finished products. All results should be reviewed and later a decision should be made in terms of approval, rejection or pending. In addition to this, out of specification results should be investigated by the authorized personnel which will define

whether there is a sufficient justification for re-testing to be performed to assess whether it's a deviation, rejection or pending.

Equipment, sample quantity and sampling method are a few of the terms that should be defined for the sampling preparation performed by the authorized personnel (International Organization for Standardization, 2007).

ISO 13485 (Medical devices — Quality management systems — Requirements for regulatory purposes)

This international standard in Figure 8 below, illustrates the requirements for a quality management system that can be used in case the company is involved in one or more stages of the life cycle of a medical device like design and development, production, storage and distribution and others.

Figure 8: ISO 13485 logo

The requirements of this International Standard can also be extended to suppliers or external parties providing the product or any component of the product. Multiple jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this International Standard expects that the organization identifies its role(s) under applicable regulatory requirements, then it denotes the regulatory requirements that apply to its activities under these roles and at the end it incorporates these applicable requirements within its quality management system. These requirements differ even from region to region. The organization needs to understand how the definitions in this International Standard will be interpreted in light of regulatory definitions in the jurisdictions in which medical devices are made available. This International Standard can also be used by internal and external parties to estimate the organization's ability to meet customer and standards applicable to the quality management system and the organization's own requirements. It is highlighted that the quality management system requirements specified in this International Standard are complementary to the technical rules for products that are necessary to meet customer and applicable standards for safety and performance. The adoption of a quality management system is a strategic decision of an organization. The design and realization of this type of system is influenced by the organizational environment, the related changes and the influence that it has on the conformity of the medical devices; the organization's needs and objectives; the products that are provided and the processes involved; the company's size and organizational structure and regulatory requirements applicable to the organization's activities.

This International Standard is based on a process approach (the application of a system of processes within an organization, together with the identification and interactions of these processes and their management to produce the desired outcome) to quality management. Such an approach emphasizes the importance of understanding and meeting requirements; considering processes in terms of added value; obtaining results of process performance and effectiveness; improving processes based on objective measurement. This ISO does not include

requirements specific to other management systems but enables an organization to align or integrate its quality management system with related management system standards. Requirements of this International Standard apply to organizations regardless of their size and no matter their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the guidelines apply equally to associated services as supplied by the company. The processes required by this ISO that apply to the organization, but are not performed by itself, are the company's responsibility and are accounted for in the organization's quality management system by supervising the processes. If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These guidelines can provide alternative approaches that are to be addressed in the quality management system. If any requirement in resource management, product realization or measurement, analysis and improvement of this ISO is not applicable due to the activities performed by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system (Cooper, 2017).

21 CFR 210/211 (CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL)

The regulations outlined in both paragraphs 210 and 211 of Title 21 whose logo is present in Figure 9, are the minimum current good manufacturing practices for methods used, facilities or controls used for the manufacturing, processing, packaging or holding of a drug to assure that said drug meets the safety requirements and has Identity and strength to meet the quality and purity requirements that need to possess.

The failure to comply with any regulations present in this Title will render such drug adulterated and the drug and the person who is responsible for the failure to comply will be subject to regulatory action. Owners and operators of establishments which are engaged in the testing, processing, storage, labeling, packaging or distribution of products that are drugs (related to human cells and tissues) are subject to regulatory action in case of non-compliance of the success criteria (21 CFR Part 210 -- Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, s.d.).

Figure 9: 21 CFR 210/211

In many cases, the various regulation pertaining to drugs and biological products for human use should supplement each other and not supersede each other unless the regulations specify otherwise.

If a person engages in operations which are subject to regulations present in Title 21 section 210, 211, 225 or 226 and not others then, said person needs only to comply with those regulations applicable to the operations that were engaged.

In addition to this, a quality control unit should be defined with the responsibility and authority to approve or reject the various components such as drug product containers, packaging

materials, labeling and others and to review production records to ensure no errors occurred or in case they were present, fully investigated. Moreover, products manufactured, processed, or packed by another company under contract should also be under the authority of the quality control unit.

Adequate facilities should be available to the quality control unit for test or approval/rejection of components, packaging material or in-process materials and the quality control unit as the responsibility to approve or reject the all the specifications or procedures impacting the quality or identity of a product. All the responsibilities and procedures that the quality control unit should follow, should be written.

As for the qualifications of the personnel, all the people engaged in the manufacturing, processing, packing or holding over product should have education or training to perform the assigned function with the use additionally of the protective gear for safety reasons and protection from contamination of the drug products.

Any personnel who present illnesses or open lesions that could affect the safety or quality of the products should be excluded from direct contact with components until this condition is solved in order not to jeopardize the safety or the quality of the products.

Moreover, the equipment used should be constructed so that contact components, and in-process materials should not be active, additive or absorptive to ensure the safety and quality of the product meets the success criteria.

Additional information is mentioned regarding the regulations related to control of components: general requirements mention that written procedures should be present and followed, describing the identification, sampling, storage or approval/rejection of the products. Components and finished products should always be handled and stored in order to prevent contamination.

Apart from all the information mentioned in this paragraph, Title 21 of the CFR part 211, presents detailed explanations of all the manufacturing practices to be followed for finished

pharmaceuticals (21 CFR Part 211 -- Current Good Manufacturing Practice for Finished Pharmaceuticals, s.d.).

21 CFR Part 820 – QUALITY SYSTEM REGULATION

The good manufacturing practices requirements are illustrated in the quality system in Figure 10 below.

Quality System regulations in this specific part specify the methods, facilities and controls used for the design, packaging, labeling, storage of finished products for human use. The aim of the requirements is to ensure that finished products are in compliance with the Federal Food, Drug and Cosmetic Act.

If the manufacturer engages in activities only subject to requirements in this part and not in others, then he needs to comply only with the regulations applicable to the operations performed.

The quality system regulation specific to part 820 supplements the regulations present in Title 21, except when stated otherwise.

Each manufacturer should establish and maintain a quality system that is appropriate for the specific product designed and meets all the criteria mentioned in this part.

Management with executive responsibility should establish the policy and its objectives and ensure the implementation of said policy at all levels of the organization. The responsibilities of all the personnel should be established as well as the authority and independence needed to perform the assigned tasks. Adequate resources should be provided to meet the requirements: this includes trained personnel, activities assessments and internal quality audits.

Figure 10: 21 CFR Part 820

Management should review the suitability of the quality system with sufficient frequency according to established procedures in order to evaluate and ensure the effectiveness and satisfaction of the requirements of this part (820) and the manufacturer's quality policy and objectives. Each manufacturer may set out a quality plan that outlines quality practices, resources and activities relevant to the devices produced. Moreover, procedures and instructions should be defined to create documentation necessary for the quality system.

Each manufacturer should also establish the procedures for quality audits and define when to conduct the audits in order to ensure that the quality system is following the requirements defined and to determine the effectiveness of said quality system.

All quality audits should be conducted by individuals who do not present a direct link to the matters that are being audited. In case necessary, corrective actions including reaudits should be considered. Reports of each quality audit, including the dates and results should be reviewed by the management having the responsibility for the matter audited.

Moreover, all manufacturers should establish and keep plans that describe the design and the development activities of the product followed by the definition of responsibility for implementation. These plans will identify and describe the various interfaces with different groups or activities that provide or are part of any input to the design and development process of the product. As for the design output, procedures and documents should be defined in order to assess the conformity of the design output with the design inputs requirements. In the design

output procedures, success criteria should be explicated in order to ensure that the design outputs are essential for the correct functioning of the device identified. In addition to this, formal documented reviews of the design should be planned and conducted at the appropriate stages of the product's design development. Procedures include that representatives for each key stage of the design development should be present followed by one or more individuals that do not have direct responsibility for the design reviewed. Design Verification should be provided in order to ensure that the design output meets the design input requirements. One of the last steps in the Design Controls paragraph present in part 820 is Design Validation. Each manufacturer should introduce procedures for validating the product design. Design Validation should be performed under specific operating conditions on initial production units, lots or batches or equivalents. Moreover, it should verify that the device produced conforms to user needs and intended users and should include testing of the production units under use conditions. It should include risk analysis and software validation in cases needed.

Detailed information may be found in Part 820 of Title 21 about Document Controls, Purchasing Controls, Identification and Traceability, Production and Process Controls, Acceptance Activities and so on (21 CFR Part 820 -- Quality System Regulation, s.d.).

3. Initiative

3.1 Project Scope

The initiative consists of the qualification of two new formulations for plugs (3Volution and GP2) to pursue perfume craveability and to mitigate the uneven formula run out specifically for 3Volution.

3.1.1 3Volution

The 3Volution is the product in scope for this project.
In this section, a description in detail of the Primary Packaging will be provided.
Primary Packaging or Consumer Unit Part is the one that directly affects the First Moment of Truth: for this reason, many aspects have to be taken into account before applying any change to the product.
The 3Volution Starter Kit follows the bill of materials below as shown in Figure 11:

- Device: thanks to the use of electric power acts as a warmer, enabling the diffusion of the three different fragrances;
- Three bottles: crystal bottles containing the formulations (one each);

- Three caps: plastic caps used to hold the formula inside the bottle;
- Three sticks: sticks made of fibers to spread the perfume in the warmer;
- Back Card: contains information about the brand, variant, usage instructions, bar code, symbols for recyclability and other as per legal requirements;
- Blister: protects the product from any possible damage during transportation and allows the consumer to see the product without opening the packaging;
- Scratch and Sniff Sticker: as the blister shows the consumer the product, this sticker allows the consumer to smell the fragrance of that specific variant.

Figure 11: 3Volution Starter Kit

Thanks to the rotation of the three different formulations, 3Volution is able to renew freshness and fight against bad odors, always keeping a uniform and balanced scent.

In addition to this, refills for 3Volution are also sold separately: they present the same Primary Packing as the Starter Kit which includes the same components of the Starter Kit except for the Warmer. Here as well, the following components of the Primary Packaging can be found as shown in Figure 12:

- Back card;
- Blister;
- Scratch and Sniff sticker.

Figure 12: 3Volution Refill

3.1.2 PLUG

The GP2 or PLUG is another product that was impacted by this initiative illustrated in Figure 13 below.

It is composed by the following parts:

- Device: thanks to the use of electric power acts as a warmer, enabling the diffusion of the two different fragrances;
- Two bottles: crystal bottles containing the formulations (one each);
- Two caps: plastic caps used to hold the formula inside the bottle:
- Two sticks: sticks made of fibers to spread the perfume in the warmer;
- Back Card: contains information about the brand, variant, usage instructions, bar code, symbols for recyclability and other as per legal requirements;
- Blister: protects the product from any possible damage during transportation and allows the consumer to see the product without opening the packaging.

Figure 13: PLUG

For the correct usage, it is needed to unscrew the caps of the crystal bottles containing the refill and insert them into the warmer until a click is heard. Then, insert the warmer into the outlet, adjust the intensity level and enjoy up to 50 days of freshness.
It is recommended to use it in high traffic rooms that are in need of continuous freshness.
Moreover, it is important to not use the PLUG in an unsafe outlet or on its side.

3.2 Background

The bulk of 3Volution perfumes has been screened during consumer tests for the degree of craveability which is a mixed measure of various key aspects like Conscious Liking, Emotional Response, Non-Chemical Perception and Context Fit.
This consumer data resulted in the identification of the most uncravable perfumes which enabled several changes to the current 3Volution combos for more craveable alternatives.
This has been denoted as the beginning of the craveability journey which will continue and evolve with other initiatives in the years 2023-2024.
As mentioned in 4.1, uneven formula runout has been defined as the #1 consumer complaint for 3Volution in Europe. This has been emphasized by the new Warmer device introduced in July 2021 which presents a signal that highlights the bottle run out near the EOL (End of Life).
Part of the initiative has been to improve the two perfume formulations that present the too long run-out across the Top 7 Variants in the Europe Region.

3.3 Contributors

Multiple parties took part in this project, each with specific roles and responsibilities.
Every contribution was essential to accomplish the successful delivery of the initiative, complying with the quality targets and ensuring the respect of time constraints.

3.3.1 Site Initiative Execution Leader (SIEL)

Site Initiative Execution Leader is part of the External Supply Solutions organization. He/she leads the Initiative Execution Process through the Contract Manufacturer's site resources. He/she works closely with the Site Leader for the operational matters and with the Value Stream single point of contact for the portfolio overview. Moreover, the SIEL is the Contract Manufacturer site's single point of contact for the Initiative Operations Leader and for the Technical Readiness Leader. In addition to this, he/she is responsible for the Contract Manufacturer readiness prior to launch.

3.3.2 MPD Process

My role as Material Process Delivery Process single point of contact in this initiative was to follow up the creation of the two new formulations which was deployed by two different suppliers, follow up the delivery of the perfume fragrances to our Research and Development single point of contact and ensure the correct delivery of the finished formulation samples to our Contract Manufacturer and our Research & Development central site for the performance of ulterior tests.

Moreover, my main objective was to develop the Performance Qualification protocol and report, two documents essential for the delivery of the initiative. The collaboration among the various single points of contact was essential for the correct deployment of these two documents.

3.3.3 Quality Assurance (QA)

Quality Assurance is present during all the steps of the initiative.
Specifically, it follows with the Material Process Delivery single point of contact during the draft and approval of both the Performance Qualification protocol and Performance Qualification report which is drafted after the Performance Qualification run at the Contract Manufacturer's site.

3.3.4 Contract Manufacturer (CM)

Contract Manufacturer is the third party who produces Procter & Gamble products. Every Contract Manufacturer presents a different business model that represents their relationship with the company. They are the ones in charge of the production and shipment of the product after the qualification has been approved by Quality Assurance. They coordinate with the External Supply Solutions team on a variety of topics: starting from the amount of raw materials to order for the Performance Qualification Run to the release of the pallets produced after the run with the Quality Assurance single point of contact.

3.3.5 Research & Development (R&D)

The role of Research & Development is essential for the deployment of the initiative to market. Research & Development is present during all the steps of the initiative, from the early stages considering the Product & Package Design Validation to the final stages of the qualification process including the creation of the samples to be shipped at the Contract Manufacturer site. Besides the active contribution to the qualification process, the Research and Development team meaningfully works on transforming the consumer's lives through scientific and technological discovery. The Research & Development team is a

diverse group of multi-skilled individuals from dermatologists, toxicologists to mechanical, chemical and data science engineers, working on product development that will improve consumers' lives. The Research & Development roles at Procter & Gamble cover four main areas:

- Research: including roles in Packaging Research focusing on learning new core packaging technologies, executing procedures for packaging development and developing films or foils for consumer products; roles in Product Research focusing on consumer research studies, converting ideas or concepts into commercial processes; and roles in Analytical Laboratory, Pilot Research Lab, Product or Process;
- Science: includes roles such as Associate Scientist which focuses on the understanding of science to deliver innovation and driving technical understanding to solve technical problems; roles as Scientist which guides and influences technical projects direction, creates advances in science, technology or engineering creating results for new projects or processes;
- Engineering: includes roles such as Formulation Engineer which focuses on the development of formulas that deliver improved performance, chemical and biological technology that drives technical advantages; Product Engineer which connects with consumers to understand and meet their needs; and roles such as Process Engineer or Packaging Engineer;
- Data: includes functions such as Data Scientist which focuses on leading projects using machine learning tools, using tools like Tensorflow and others to identify and solve business problems; Data Engineer which develops and maintains data pipelines, supports Data Scientists that are developing machine learning or Statistical Models (Procter & Gamble, s.d.).

3.3.6 Initiative Operational Leader (IOL)

The Initiative Operational Leader (IOL) is the Supply Network Organization Single Point of Contact (SPOC) for initiatives and changes of the supply network for both SIMPL and non-SIMP processes.

The objective of this role is to lead the SNO scope of an initiative and deliver the Supply Network Operations readiness which translates in securing to meet targets regarding Cash, SNO Quality and Schedule (SOS) for new and transitioning materials and products.

The Initiative Operational Leader is the key contact on behalf of the PSC (Planning Service Center) for all the parties illustrated above and not only.

The Initiative Operational Leader oversaw the overall coordination of the initiative, with weekly meetings with the various single point of contact of the various sectors (both Procter & Gamble and Contract Manufacturer), assuring that the CPS (Critical Path Schedule) would be observed by all parties and managing the PIPO (Phase In – Phase Out) of the necessary materials in order to ensure the successful deployment of the initiative.

3.4 Qualification Process

The fundamental purpose of the process validation is to ensure that the process inputs support the relative outputs in order to create a repeatable process.

Moreover, the process validation is a dynamic process which is subject to change based on the collection of data part of the day-to-day manufacturing activities performed (Mark Allen Durivage, 2016).

In the following paragraphs a detailed description of the steps performed for the qualification process will be found.

3.4.1 Product & Package Design Validation

One of the first steps in the Qualification process after the Project Commitment phase is the definition of Product and Package Design followed by Change Management.

This document is created by the Research & Development Team, and it refers to Product and Package design validation through a process of continuous testing to check whether the product that has been modified still meets the consumers' expectations. In addition to this, this document also refers to Change Management.

Change Management can be defined as "the application of a structured process and set of tools for leading the people's side of change to achieve a desired outcome".

It is a complete definition of the process related to the change itself and the project management (Prosci, 2022).

The change in this case is related to the initiative to mitigate the uneven formula runout across multiple Variants in Europe, in order to optimize the consumer experience.

In particular, for the Product Design Change, several different functions are examined to document the change and to state the new product compliance with the success criteria.

A few examples can be found in the list below, these include a series of

- **Stability of the product**: which documents the product shelf life and supply chain, including the consumer usage and warehouse;
- **Technical Performance:** which includes the work needed to confirm that the product design is still compliant with the success criteria;
- **Claims/Artwork:** possible change in any certifications;
- Product Safety & Regulatory: PASS Clearance, Global Product Stewardship compliance, product registrations and safety data sheets including child safety testing;
- Process design: Learning plan up to relevant scale, operating window study;

- **Stability for Package:** includes the ship test, compatibility and robustness through the supply chain including e-commerce and finished product packages at the contract manufacturer. It confirms that the product meets the weight and dimensions expectations;
- **Micro:** confirmation of the micro risk class for the formula and materials;
- Device: it documents the technical consumer performance reliability of the device followed by the environmental and transport conditions;

3.4.2 Samples Creation

In order to perform the qualification, samples of the two new formulas were created in the Research and Development Department in Brussels Innovation Centre (BIC).

Each formula consists of multiple parts: a fragrance which leaves the scent, perfumes which act as stink blockers and odor fighters capturing ammonia and sulfur-based compounds (Ingredients in Febreze , s.d.). All these components mixed together, creating the formula contained in the crystal bottles mentioned in Chapter 3.1.

The perfumes were produced by different companies: one was created by a Procter and Gamble plant and the other was supplied by an external supplier with whom Procter and Gamble already had previous business relationships.

I worked closely with the Initiative Organization Leader and the Site Initiative Leader single point of contact to ensure the safe arrival of the perfumes to the Brussels Innovation Center. In addition to this, thanks to the availability of the Research and Development single point of contact, I was able to assist in the creation of the samples which allowed me to learn significant insights on the making procedures related to the Air Care business.

As the new formulations created were a reformulation of already existing formulas, as mentioned in the previous chapters, multiple modifications were made in ENOVIA

(Enterprise InnoVation Interactive Application) which is a platform that enables the creation, revision, and archive of technical standards in addition to the storage of bill of materials of the products.

With the introduction of the two new formulations, multiple Bill of Materials were modified with the new information and identification codes.

Moreover, the formula card which is the document summarizing the specifications of the formula and to provide the success criteria defined to ensure that the performance of the formula meets the Quality Standards. It needs to be updated by the Research and Development Team with the new formula densities before the release of the Run by the External Supply Solutions Quality Assurance single point of contact in collaboration with the Contract Manufacturer.

The formula densities are measured multiple times at different temperatures by the Contract Manufacturer at the arrival of the formula samples and during the Run: both times the density measures need to be compliant with the measurements performed by the Research and Development team during the creation of the samples. If not, a document can be created to state the deviation of the density value of the formulation samples from the centerlines and modified accordingly.

3.4.3 Legal Requirements

Following the formula samples creation at the Research & Development department in the Brussels Innovation Center, in order to start the qualification and ship the mentioned samples to both the Contract Manufacturer and the Procter & Gamble site in the United States of America, multiple documents should be provided.

I was in constant contact with both the Global Product Stewardship team and the shipment team to ensure that the correct paperwork (Safety Data Sheet and Import Papers) would be

produced and enable the correct shipment of the samples to the Procter & Gamble site and the Contract Manufacturer time in compliance with the critical path defined for the initiative by the Site Initiative Leader.

Safety Data Sheet (SDS) or Material Safety Data Sheet (MSDS) as showed in Figure 14 is a document required by law from the chemical manufacturer, distributor or importer for every hazardous chemical to downstream users in order to share information regarding the hazards. It is the upgraded version of the Material Safety Data Sheet, as it is now more user friendly.

The Safety Data Sheet includes information regarding the properties of each chemical, environmental health and physical health hazards. Moreover, it includes protective measures and precautions for the handling, storage and transport of the chemical to ensure safety.

The information included in this document usually is in English, but it could be provided also in other languages such as, in the case of this initiative where the Safety Data Sheet was provided both in English and in the language used by the Contract Manufacturer.

The document is composed of 16 Sections divided as following:

1. **Section 1 - 8**: contain general information regarding composition, hazards, identification, handling practices and emergency measures to ensure safety. This is the part that contains the right amount of information for someone who needs to get a quick overview;
2. **Section 9 through 11 and 16**: contains specific information regarding the technical and scientific aspects. This includes physical and chemical properties, toxicological information, stability and reaction information and others. It also includes data regarding the date of preparation and/or last revision;
3. **Section 12 through 15:** these sections contain information related to the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (Safety Data Sheets Brief, s.d.).

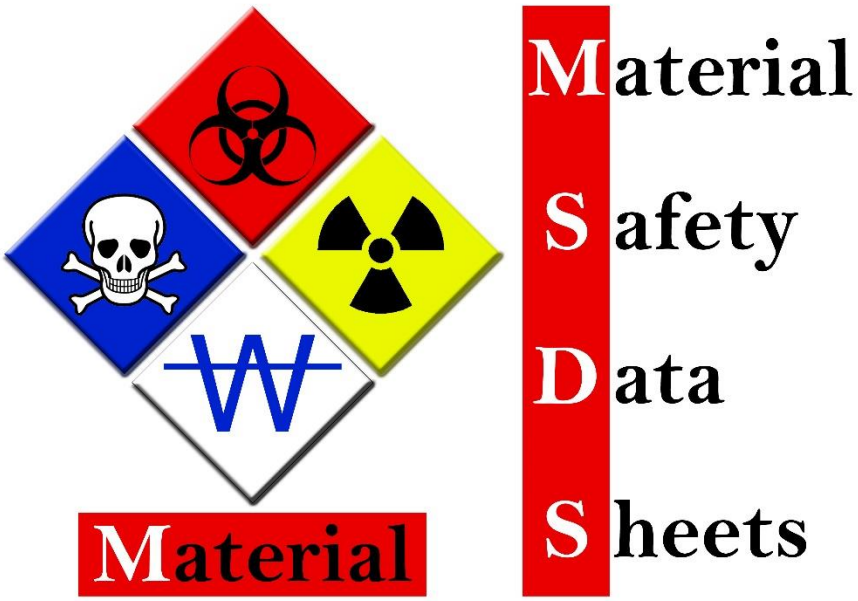


Figure 14: Material Safety Data Sheet

The Safety Data Sheets for the two formulas and the raw materials composing the formulas were provided by the Global Safety Data Sheet Service.

This team has strong connections with a variety of functions such as Product Development or Global Product Stewardship in order to ensure the correctness of the content included in the document. All the Safety Data Sheets are stored on a user-friendly platform, which enables easy access through product identification code, supplier, manufacturer and others.

In addition to Safety Data Sheets, **Import Documents** are a requirement for the shipment in the United States of America. This is a declaration of the materials to be shipped with additional classification before entering the United States. This paperwork is handled by the Procter & Gamble shipment team.

3.4.4 Qualification Document

In parallel to the various stages mentioned in the previous chapters, I started drafting the qualification document. During the first months of my internship at Procter & Gamble, multiple aspects of the Qualification Process for Making Initiatives were illustrated over the course of multiple training sessions. They were essential for my grasp of the project and the definition of the next steps to be performed by me as part of the Material Process Delivery Team in collaboration with the Contract Manufacturer Team defined for this initiative.
To guarantee the correct deployment of the initiative, multiple controls should be performed on various production aspects.
The main focus falls on:

- Initiative Scope;
- Equipment;
- Process Description;
- Changeover;
- Cleaning and Sanitization;
- Qualification Run;

In the specific, the qualification document is a key step for the practical deployment of the initiative.

Initiative Scope

The Initiative Scope covers all the key information needed for the deployment of the initiative. It includes the Product & Process Design Validation document of reference that has been

already approved by the Platform Quality Assurance single point of contact and the Technical Content single point of contact for the Air Care Business.
Moreover, the documents of reference related to the Market Clearance for the new initiative are mentioned. They indicate the list of markets in which the new initiative is going to be deployed once the qualification process is completed. All the products and formulations undergo a regulatory and Human Safety Assessment when they are cleared for Commercial Use by Global Product Stewardship.
Last but not least, a list of all the modified assembled products whose variants have been updated with the new formulas and the respective position and the list of assembled products chosen to mitigate the uneven formula runout.

Equipment

The Equipment used for the formulation process of the two new formulas is illustrated through diagrams and pictures of the current Equipment at the Contract Manufacturers' site. The correct functioning of the Equipment should be verified before usage to ensure the compliance with the success criteria from a Quality perspective. In the specific, Procter & Gamble owns a specific system at the Contract Manufacturers' site that guarantees that the correct quantities are mixed together to create the formulations and that the proper storage conditions are present for the various formulas produced. In particular, a defined number of Storage Tanks is present which means that with the creation of new formulations to be used for the 3Volution and/or the PLUG, some formulations created for a specific initiative or seasonal could be substituted with the new ones. A document keeps track of this modification which is defined in collaboration with the Contract Manufacturers' team. The Qualification document should contain the updated file with the modifications.

Process Description

In the Process Description multiple details related to the formulation process are shared to ensure that the correct procedures are respected as manufacturing instructions. In particular, the production instructions for the new formulas are mentioned step by step. In addition to this, the Control Strategy is highlighted in case it has undergone modifications or it remains unchanged for this process. Multiple information is shared regarding the Method List in use to evaluate the formulations and the density check to be performed at the Contract Manufacturers' site: the density of the samples arrived at the Contract Manufacturers' site should be compliant with the ranges present in the Formula Card. For the two new formulations, the one that we will define from now on as Formula A was compliant with the ranges while the one that we will define as Formula B was not. The main reason for this discrepancy is that at the time of the creation of the Qualification Document the formula cards of the two formulations were not yet updated with the values measured by the Research & Development team in the creation of the samples.

In Table 2 below, the density ranges of the two formulations present in the Formula Card **before** it was updated with the value measured at the creation of the samples can be found:

FORMULA	DENSITY [g/ml @ 20°C][1]		
	LSL	TGT	USL
FORMULA A	0,831	0,8424	0,8498
FORMULA B	0,834	0,8512	0,8764

Table 2: Density measurement in Formula Cards before update.

[1] The values present in this table have been multiplied by a constant factor.

Below in Table 3 the values of the measurement performed on the samples at the arrival at the Contract Manufacturer's site can be found:

FORMULA	DENSITY [g/ml @ 20°C][2]		
	LSL	TGT	USL
FORMULA A	0,839	0,8413	0,8475
FORMULA B	0,868	0,8705	**0,8778**

Table 3: Density measurements at Contract Manufacturer's site.

As shown in the third column the Upper Specification Limit measured on the samples at their arrival exceeds the Upper Specification Limit present in the Formula Card before the update.

In the Table 4 below the updated values of the Formula Cards are present: these new ranges include the density values measured on the samples at the Contract Manufacturer's site.

FORMULA	DENSITY [g/ml @ 20°C][3]		
	LSL	TGT	USL
FORMULA A	0,837	0,8523	0,8595
FORMULA B	0,864	0,8712	0,8784

Table 4: Density Measurements at samples creation

[2] The values present in this table have been multiplied by a constant factor.
[3] The values present in this table have been multiplied by a constant factor.

As a mandatory requirement, the formula cards should be updated before the approval of the Qualification document which will give the start for the qualification run to be performed at the Contract Manufacturer's site. In addition to this, another mandatory requirement before the qualification run is an authorization document which is provided by the Procter & Gamble Research & Development team in the United States. This authorization is drafted following some testing on the samples, shipped by the Research & Development single point of contact for the initiative, to ensure the meeting of the success criteria.

As part of the Process Description, the Safety Data Sheet a document mentioned in Chapter 3.4.3 Legal Requirements, is attached for the new ingredients present in Formula A and Formula B in English and the language of the Contract Manufacturer with the additional Raw Material Production Instructions.

Information regarding the shipping and storage are present for both Bulk Product and Finished Product. In the specific, if the formulas produced during the run meet the formula card success criteria, then they can be transferred in specific containers to be used for the creation of the finished product. After the packing production the pallets of finished product can be stored but not released until the Qualification Report is approved.

In case the measured values of density of the samples or during the qualification run are always close to the LSL or USL the Contract Manufacturer could require an adjustment of density. Any change in the density will be considered in the upgrade of the Formula Card for the production but, since there is no impact on the volumetric filling, the Contract Manufacturer will be allowed to release the finished products after the Qualification Run even if the density values differ.

Changeover

Changeover during production should follow specific rules and regulations which are mandatory in order to not encounter possible contamination changing from specific ingredients to others. In particular, the specifications related to the changeover procedure are approved by the Quality Assurance team in collaboration with the Contract Manufacturer's team on site.

Cleaning and Sanitization

Cleaning and Sanitization should follow the Manufacturing Instructions defined in collaboration with the Contract Manufacturer, in order to prevent micro contamination. The Manufacturing instructions follow the ISO standards mentioned in Chapter 2.5 Procter & Gamble's Quality Program above.

Qualification Run

The qualification run is the first production of both Formula A and B which qualifies that everything related to the making and packaging aspects is happening according to the quality standards. In particular, two finished products are chosen for the run, each one containing either Formula A or B: the minimum qualification run is specified for both the finished products and the corresponding run length which includes the creation of the formulations and packaging. The volume of the qualification run is subject to possible change according to planning needs. Moreover, the finished products chosen for the run could be updated according to market demand.

Furthermore, additional information is shared regarding the Success Criteria and Sampling Plan that characterize this run. The formulations should be compliant to the Safety Data Sheet shared in both English and the language of the Contract Manufacturer, they should be

approved on Enovia before the release in production. Moreover, the starting materials should be compliant with the raw material specification and should be reported in the Qualification Report. During the run, a total of four samples is taken, two for each new formulation: a sample will be taken from the bulk product and the second one from the finished product to ensure the compliance with the Formula Cards. Weight data should be available in the Qualification Report.

3.4.5 Approval

After the information was collected, I filled out the qualification document with all the information required to take a step forward in qualifying the new initiative.

After my supervisor double-checked that the information was accurate and that the equipment and process detailed were correct, I proceeded with the upload of the document on Enovia to be approved by the accountable parties. The approval process takes up to four or five working days as the content of this document is approved by four different parties which evaluate the correctness of different areas covered in the document. The approvers can either approve or reject the qualification document. In case of rejection, the document is sent back, and the process is stopped. Possible rejection causes could be the inaccuracy of the information mentioned, wrong process description or absence of mandatory documents to continue with the qualification run.

Once the joint approval by the four responsible parties is gathered, the approved qualification document is shared with the designed Contract Manufacturer's team which will proceed with the verification of the raw material quantities needed to perform the qualification run.

This check is usually performed even before the Qualification Document is approved in collaboration with the Initiative Organization Leader which will make sure that the Contract Manufacturer has received the correct quantities of raw materials before the Qualification Run, in order to not incur in possible delays.

3.4.6 Qualification Run

Once the approved document was shared with the Contract Manufacturer and the raw materials quantities were verified, the Contract Manufacturer's team proceeded with the Qualification Run.

The duration of the first production is dependent on a variety of factors such as

The run was documented to detect possible deviations from the success criteria mentioned in the paragraph Qualification Run above. The data obtained during the Qualification Run are the basis of the Qualification Report.

3.4.7 Qualification Report

Once the data related to the Qualification Run was available and shared with me by the Contract Manufacturer team, I proceeded with preparation of the qualification report.

The Qualification Report is a document that summarizes the result of the Qualification Run performed at the Contract Manufacturer's site. It is a statement of compliance with the Qualification Document and proof that the Contract Manufacturer can consistently produce the products scope of the initiative as per success criteria.

The report states that the raw materials used for the creation of the two formulas A and B are compliant with their Raw Material Specifications, before being used: this was verified with some incoming tests performed at the reception of the samples.

During production, all the ingredients of the two new formulas were added following the Formula Cards instructions with minimum variation from the target. In the specific:

- a bulk of 323 Kg of Formula A was produced;
- a bulk 389 Kg of Formula B was produced.

From a Quality point of view, all the formulas produced during the first production were compliant with different specifications as per their respective Formula Cards, matching the approved samples supplied by Procter & Gamble.

In terms of density, the bulks produced during the Qualification Run showed results within the ranges claimed during the density measurements that were performed by Research & Development team for Air Care.

Regarding the Formula Cards, they were updated as mentioned in the Chapters above, to reflect the new ranges measured at the creation of the standard samples, which were respected during the Qualification Run.

Specifically, the values measured during the run are the following, present in Table 5:

FORMULA	DENSITY RANGES [g/ml 20°C][4]	DENSITY RESULT	PASS/FAIL?
FORMULA A	LSL: 0,837 – TGT: 0,8523 – USL: 0,8595	**0,8496**	**PASS**
FORMULA B	LSL: 0,864 – TGT: 0,8712 - USL: 0,8784	**0,8678**	**PASS**

Table 5: Density Results of Qualification Run

[4] The values present in this table are multiplied by a constant factor.

With respect to the Fill Level, all the finished products produced during this Qualification Run have been filled according to the level mentioned in the approved finished products.
Table 6 and Table 7 below are reporting the Fill Level check for Formula A and B. They are structured as following:

- **Identification Code:** is the code used to identify the Formula in the Procter & Gamble system which can be consulted by the Contract Manufacturer's Team during production;
- **Formula:** is the column that includes the specific Formula Card description for each Formula;
- **Filling Target [Kg]**: is a value in Kg that can be easily calculated by the relationship between Density and Volume (d[g/ml] = (m[g]*1000)/V[ml]). It indicates the Target in kilograms which makes easier to grasp the quantities used for the Qualification Run;
- **Density [g/ml]**: is the density checked on the incoming samples produced by the Research & Development team for Air Care. During the Qualification Run the density of each Formula is double-checked with the ranges present in the Formula Card once updated;
- **Filling Volume Target [ml]**: is the target present in the Formula Card in milliliters;
- **Samples**: is the number of samples taken during the Qualification Run;
- **Real Filling[ml]**: is the actual filling that took place during production;
- **Fail or Pass**: states whether the filling check is compliant with the success criteria or not.

As illustrated in Table 6, the Real Filling (ml) is compliant with the Filling Volume Target (ml) for Formula A, meeting the success criteria for the Qualification Run.

Identification Code	Formula	Filling Target (Kg)	Density (g/ml)	Filling Volume Target (ml)	Samp	Real Filling (ml)			Fail or Pass?
						Average	Min	Max	
AAAAAA	**Formula A**	**0.0057**	0.8518	5,9922	1	5,93	5,99	6.07	**PASS**
					2	5,92	5,96	6.06	
					3	5,92	5,98	6,07	
XXXXXX	Formula X	0.0058	NA (Formula already qualified)						
YYYYYY	Formula Y	0.0056	NA (Formula already qualified)						

Table 6: Fill Level Results Formula A[5]

As well as, Formula A, Formula B's Real Filling (ml) is also compliant with the Filling Volume Target (ml), meeting the success criteria.

Identification Code	Formula	Filling Target (Kg)	Density (g/ml)	Filling Volume Target (ml)	Samp	Real Filling (ml)			Fail or Pass?
						Average	Min	Max	
BBBBBB	**Formula B**	**0.0058**	0.8676	5,9751	1	5,92	5,98	6.08	**PASS**
					2	5,93	5,99	6.08	
					3	5,93	5,96	6,04	
WWWWWW	Formula W	0.0057	NA (Formula already qualified)						
ZZZZZZ	Formula Z	0.0057	NA (Formula already qualified)						

Table 7: Fill Level Results Formula B[6]

[5] The values present in this table have been multiplied by a constant factor.
[6] The values present in this table have been multiplied by a constant factor.

Since all the results achieved are in accordance with the success criteria and the respective documents are attached, the next steps can be defined for the release strategy which will be illustrated in the following paragraphs.

3.4.8 Report Approval

The same process described in Paragraph 3.4.5 Approval is applied for the Report Approval: once the data on site was shared by the Contract Manufacturer's team, I followed with the compilation of the document in detail. Once the document was completed, I uploaded it on Enovia and waited for the Approval of the responsible bodies for this Initiative.
Following the Approval of the report, the next steps were taken to successfully conclude the deployment of the initiative.

3.5 Time to Market

Time to Market of an initiative is affected by many factors that occur during at the outset of product development or at the end of the qualification process: possible delays could be caused by new law requirements, delays in orders of components needed for the production, or documents that took more time in being created.
An initiative is also affected by the business relationship that characterizes Procter & Gamble and the Contract Manufacturer: in some cases the qualification is completely led by the Contract Manufacturer and the External Supply Solutions team functions as support, checking that the Qualification is consistent and compliant with the success criteria set by Procter & Gamble; in other cases like the one described in this essay, the Qualification is led by the

External Supply Solutions team with the collaboration in all the steps of the way of the Contract Manufacturer's team on site.

The time to market of this initiative was strongly affected by the (Start of shipment) SOS anticipation which occurred by the beginning of December.

The anticipation occurred as new (Net Organic Savings) NOS opportunities opened in Italy.

Every initiative usually takes between six and nine months, taking into consideration all the stage to gate model steps that have been illustrated in the Paragraph Project Management.

For this specific initiative, some steps impacted the critical path defined by the Site Initiative Leader more than others: the steps that took more than 10 days are highlighted in red, to underline which activities lasted the most. As you can see in the Figure 15 below, the request for the Import Papers took twelve days. Usually, a standard request takes between two or three weeks. Moreover, transport lead times should be considered for the sample shipment.

The greatest challenge was the restricted timing of the project delivery, which was successfully mitigated by the team's flexibility and pre-work to face this unforeseen event. Together with the proactiveness of the Contract Manufacturer's team, we were able to perform the Qualification Run in the minimum time possible in order to accelerate the draft of the Qualification Report which is the last step necessary to move to the release strategy chosen for the initiative.

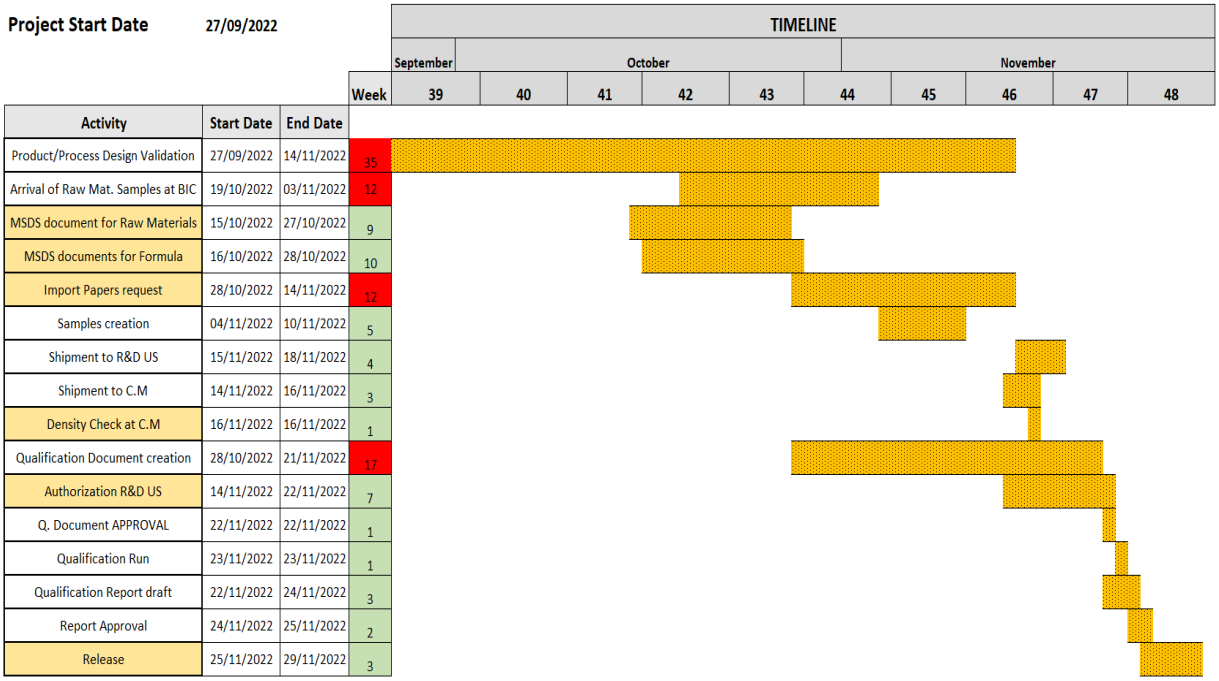


Figure 15: Gantt Chart Initiative

3.5.1 Start of Production

Start of Production or SOP is the start of the serial production phase when the affected product is compliant both from the making and packaging perspectives and ready for all life. Most of the time SOP is also referred to as 'Product Launch'. It is one of the major phases of the product life cycle, closing the 'Product and Process Validation' phase illustrated in Chapter 3.4.1 Product & Package Design Validation.

From the Start of Production, all the components and finished products are produced under standardized conditions, in a serial way. Before reaching these conditions, risk and variation are minimized in order to provide a reliable serial production. All the conditions and

requirements checked from a Quality point of View are performed during the first production run at the Contract Manufacturer.

3.5.2 Stock on Ground

The term 'Stock on Ground' refers to the finished products produced during the Qualification Run: once the Qualification Report is approved that stock could be either used as a first shipment to a reference market or scrapped, depending on the release strategy. Most of the time, if the Report did not deviate from the Qualification document, then it is used as a first shipment.

3.5.3 Start of Shipment

Start of Shipment is the final step of the initiative deployment: once the finished products are compliant with the success criteria defined, they can be produced in a serial way in order to supply the orders received by the customers.

3.6 Release Strategy

Once the Qualification Report is approved, it is then shared back with the Contract Manufacturer's team.

From this point, the Release Strategy is defined for the Qualification Run by the ESS Quality Assurance single point of contact for the Air Care Business.

The finished products produced during the Qualification Run are released via authorization of the ESS Quality Assurance single point of contact.

After this qualification, the Contract Manufacturer will be qualified to produce any finished product that contains the new formulations for both 3Volution and PLUG without the need to perform another qualification, through Start of Production authorization.

Two of the samples arrived at the Brussels Innovation Center after the Qualification run can be found in Figure 16.

Figure 16: Samples sent to Brussels Innovation Center

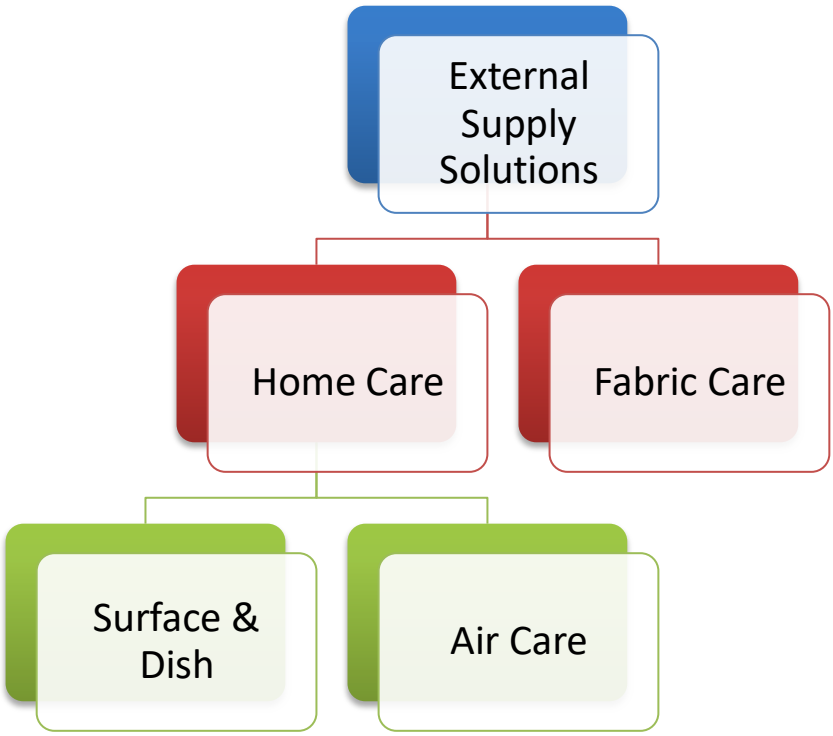
4. Optimization of the Qualification Process

4.1 ESS Segment Division

After the deployment of the XXX Initiative illustrated in the previous Chapters, multiple queries were raised on whether it would be possible to accelerate the deployment of qualifications.

The External Supply Solutions department in which I performed the research for this essay principally focuses on two main sectors: Home Care and Fabric Care.

In the following diagram the division of both Home Care and Fabric Care can be found as shown, the Home Care sector is the biggest as it includes Surface & Dish Care and Air Care.



For this reason, the number of initiatives in the Home Care sector is higher than the initiatives in the Fabric Care sector.

The business with the highest number of initiatives per year is the Air Care business because it includes the brands with the highest number of variants: both AmbiPur and Febreze cover different products like the 3Volution, or the PLUG illustrated in the Project Scope section of the Initiative described in the previous chapters.

In addition to these products, aerosols and bathroom and car fresheners are also part of the same segment: in the Figure 17 below an example of each can be found.

Figure 17: Air Care Products

It is comprehensible how the Air Care business presents the highest number of variants: they are created from new formulations that are introduced during the year (Seasonals) or Special Holidays such as Christmas or Halloween.

The new initiatives impact not only the Starter Kits like the one shown in Figure 11 but also the refills in different sizes and each one is paired with a new Artwork.

4.2 Reasons behind the optimization

The optimization of the qualification process has always been considered as a potential improvement but was never evaluated in detail until now as it would be time consuming to re-evaluate the qualification process in its length without a starting point.
With the deployment of the initiative illustrated in the previous chapter, the ESS team realized that some qualifications do not bring any new processes or equipment to be evaluated in detail such as in case of new formulations to be qualified for Seasonals or specific holidays.
Such qualifications do not impact the product design and they are the ones that occur more frequently.
Many reasons are behind the process qualification optimization, some that the team evaluates as more effective than others will be illustrated as following:

- Time to Market;
- Resources;
- Ongoing Validation;
- Paperwork.

First of all, a reduction of the qualification process will reduce the **Time to Market** of an initiative which is one of the key parameters in addition to Quality and Cost in the scorecard, to evaluate whether an initiative was compliant with the success criteria.
It is essential that the initiative respects the deadlines chosen by management in order to meet the targets of start of production and start of shipment.
To enable this to happen, the qualification of new equipment, new process or/and any new formulations used should be as rapid as possible: it ensures that all the quality criteria are met and that the Contract Manufacturer is able to produce the chosen product and its variants in a serial way.

In addition to this, optimizing the qualification process would reduce the time that a resource would spend on an initiative on both the ESS side and the Contract Manufacturer side: this would open multiple opportunities to invest time in other projects that for time constraints were set to the side. It would give the opportunity to navigate the business and find new product design optimizations or savings opportunities.

Consequently, it would mean optimizing the resource itself: each resource would be able to take on more projects and improve its long-term impact on the team.

Moreover, less paperwork would be needed to ensure that the initiative and any process, equipment and/or formulation is compliant with the success criteria. This will be described in detail in the next paragraphs where a first optimization document will be illustrated.

The final idea would be to create an ongoing validation process at the Contract Manufacturer's site that in specified time frames will ensure the compliance with the Quality criteria set forth.

4.3 Wave 1

With the qualification deployment with the support of both the MPD and QA team, I started to analyze the process in place for the qualification of the initiative and identify the potential improvements from a bureaucratic point of view.

The creation of the Gantt chart shown in Figure 15 during the execution of the initiative was helpful to identify the key steps that lasted the longest: the activities that had as duration more ten days are highlighted in red.

It was a great starting point to highlight possible optimization opportunities to be evaluated for a possible future application.

In the specific, I identified multiple opportunities to improve the activities in red, in need of improvement and some activities are not in red but could benefit from additional optimization.

They were presented in a joint meeting with my supervisor for the MPD Process side of the Air Care Business and the ESS QA leader to assess whether these identified opportunities could be implemented or not.

As the Import Papers request has a lead time of fourteen to twenty-one days and it is a requirement in order to ship outside Europe in parallel with the Safety Data Sheet for the raw materials present in the samples, a possible alternative would be to request the authorization document needed from the R&D department in the United States to one of the Procter & Gamble's European facilities.

This would significantly reduce the lead time needed to ship the samples and perform the test needed to obtain the authorization to proceed with the qualification.

However, this proposition was rejected as at the moment there is not the capability or equipment needed to move this procedure to one of the European countries.

Another proposition was to create a Time Commitment Agreement with the various parties involved in the initiative. In particular, it would impact the upstream of the qualification: the creation of the Product/Package Design Validation. It is created by the R&D department for the Air Care business, and it is a detailed document that needs information coming from different sources as described in the paragraph 3.4.1 Product & Package Design Validation above.

The scope of the Time Commitment Agreement is to create a defined time frame among the parties that will not involve any follow ups: it will reduce the distractions, allowing each party to concentrate on the project with no daily or weekly reminders until a defined date when then follow ups would be allowed near the deadline.

It was taken into consideration, and it will be object of discussion for the next initiative even though it does not provide a significative time reduction in the creation of the PDV.

Moving to the activities that could benefit further optimization, one of the propositions was to improve the Safety Data Sheet created for Raw Materials and finished formulas.

In the specific, the proposal was to create a standard Safety Data Sheet for the new formulas under specific conditions such as same process, same equipment and others in collaboration

with the GPS department. It would enable a time reduction in the creation of the Safety Data Sheets for specific initiatives.

At the moment, a standard Safety Data Sheet model is already in place for some products in the Air Care Business under specific conditions: it represents a great starting point for the creation of a scorecard to assess whether it would be possible to create a standard SDS model for each product or specific type of initiative.

Last but not least, the creation of a standard model for the documents characterizing the Qualification process would improve the timing of qualification. Moreover, it would reduce or rather eliminate the discrepancy present between qualification documents created by different people in the same business.

In addition to this, the definition of a standard model for the Qualification documents enables a reduction of redundance present in said documents to make them as thorough as possible to avoid possible misunderstandings for other parties both internal and external.

The identification of the success criteria for the qualification process and the subsequent definition of a validation matrix would enable a consistent reduction of the elements to check during the qualification. This proposition will be further illustrated during the description of the second wave in the following paragraphs.

Analyzing in the detail the qualification documents I noticed that various parts respond to the same manufacturing instructions to ensure the proper functioning and compliance with the quality criteria set forth: for this reason, all these information could be summarized under the same section which indicates the specific manufacturing instruction to follow.

Moreover, it would be faster to include the SDS for both raw materials and formulations in the same section with all the different language versions needed in order to create a single point to be consulted to find this specific kind of information.

Furthermore, in the paragraph Equipment is mentioned the document updated in collaboration with the Contract Manufacturer on which formulations should be substituted with the new ones because of the fixed number of storage tanks.

At the moment, this document is created as new each time and then uploaded in the qualification document. The proposition would upload a standard file with the modifications on Enovia to be updated each time a new initiative comes in.
This proposition will definitely be implemented in the future initiative that provides new formulations.
A model with the improvements listed above was created to define a standard document for all future qualifications to be implemented in the Air Care business. Further specifications will need attention for a possible extension of the standard model to the initiatives of the other business units.

4.4 Wave 2

After the different inputs on possible optimizations of the qualification process, a more advanced proposal was shared to improve the Time to Market of the initiatives.
In particular, for this proposition both making and packing qualifications are taken into consideration for the pilot: they have been classified on the basis of the level of complexity whether low or high level.
Specifically, for instance a low complexity level qualification is the qualification of a new formula or a light reformulation of the same formulation and so on for the making projects while an example of low complexity qualification for the packaging initiative is the adjustment of an existing equipment or an equipment modification for a new machine.
On the other hand, an example of a high complexity qualification for the making initiatives is a new equipment qualification or any saving project whether small or large while for a packaging initiative is a secondary pack change or the qualification of new equipment.
The main idea at the basis of this optimization would be to move the ownership from the ESS MPD Team to the Contract Manufacturer: the low complexity qualifications would not require anymore a qualification as complex as the one illustrated in the previous chapters of this essay.

The Contract Manufacturer would gain the lead of the low complexity qualifications with the support of the MPD team while in case of the high complexity qualification the lead would remain with the Site Initiative Leader with the support of the Contract Manufacturer like the initiative illustrated in the previous chapters.

This proposal comes from the need to address the losses linked to small changes within the ESS organization and the Contract Manufacturer: it would create added value for the business by delivering initiatives faster and investing more in pilots with the same resources. The objective would be to clarify the change of ownership with the Contract Manufacturer and track the changes implemented on their side.

A possible solution to simplify this change would be to create a platform to track and request small changes approval: this would reduce the time needed to deploy a low complexity initiative bypassing the qualification process in its length.

The platform would include all the ESS SPOC responsible for Change Management with the participation of the Contract Manufacturers: low complexity qualifications or small changes would be requested with a detailed description of the effects. All the functions will be able to have a complete overview of the changes happening at the CM. This would enable better end-to-end vision of the multiple projects present at the CM site and the resources involved in each project.

One of the key elements would be to align on the qualification plan whether a smaller qualification is needed for a specific initiative or there is no need at all for a qualification.

In addition to this, the definition of the qualification owner (Whether Procter & Gamble or Contract Manufacturer owned) is essential to assess the next steps in the process.

As mentioned in the previous sections of this essay, the Contract Manufacturers do not always have the same type of business relationship with Procter & Gamble: this implies that there are different project lead styles across different CMs and different tracking for the projects.

This data should be documented in order to assess the future changes in case of change management.

5. Conclusions

This essay tried to reply to the question “What is the qualification process to deploy an initiative in a consumer goods company? How can it be optimized?”.

On that note, the deployment of an initiative was illustrated in order to highlight the mandatory constraints that are required for the procedure to ensure the compliance with the success criteria defined beforehand. In particular, the description of an initiative in the Air Care business highlighted the complexity of the qualification process and the possible unforeseen events that could cause potential delays for the deployment of the initiative, missing out on the success criteria for the initiative based on Quality, Time and Cost.

In particular, this initiative was a great starting point to analyze more in detail potential optimizations to be applied to the qualification process in particular of the qualification of Seasonals in the Air Care business which is the business unit that presents the highest number of qualifications during a year due to the elevated number of variants present. Multiple were the proposals as illustrated in Chapter 4: all were evaluated in detail, and some will be implemented in the next future after the appropriate analysis will be conducted.

However, this analysis was specifically focused on the optimization of the process for the sole Air Care business: this would imply a further investigation to be conducted in order to apply the potential optimizations found to the other business units.

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