Cosmetics: Digital Maturity and journey in Quality

Benedetta Suardi
Scientific Senior Director KIKO

KIKO MILANO

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Graduated with honours in Pharmaceutical Chemistry and Technology at the University of Pavia, after a scientific research experience in organic chemistry in the United States at Celgene Corp., she joined the pharmaceutical multinational AstraZeneca as Quality Assurance-Global Product Release in the sterile injectable anesthetics division.

Since 2001 she has held the role of Technical Director in well-known cosmetic skin care and make-up industries, dealing with R&D of cosmetic products and equipment for professional aesthetics, Product Development, Worldwide Regulatory, Quality Assurance and Control and scientific communication.

Benedetta is member of the scientific committees of well-known sector magazines, as well as member of the Technical Committee of Cosmetica Italia and of La Forza e il Sorriso , Advisory Board Member in varoius Start up company , and gives lectures for sector associations and Univesity such as Cosmis (Cosmetic Industrial Science) in Milan. Among other publications, she wrote the Cosmetologist's Manual, in collaboration with other authors.

AGENDA

- KIKO Milano
- Cosmetics Industry Overview
- Digitalization Roadmap
  - Artwork Management
  - Regulatory & Quality Management
- Conclusions & Next Steps

The Company

The Company

ABOUT US

KIKO Milano was founded in 1997 in Milan and since then has revolutionized how cosmetics are sold globally; We believe in supporting women in expressing themselves freely.

KIKO Milano identifies the beauty trends of the moment and makes them accessible to all. We understand the power of make-up and love that it can ignite a spark and make you feel fabulous. We want everyone to be able to create the right look, for every situation, with style but without losing one's individuality.

At KIKO Milano we would like you to experiment and chose the look that really represents you.

We thrive to offer an incredible variety of products, textures and colours a multi-sensorial experience, yet always at an affordable price.

Based in Italy, and truthful to our DNA, KIKO takes advantage of combining trustworthy product technology with creativity.

The Company

MANIFESTO

ITALIANITY

KIKO Milano was founded in 1997 in Milan and since then changed how cosmetics are sold globally. Over the past years the company was often referenced as «fashion forward» cosmetics.

SELF EXPRESSION

We want to everyone to be able to create the right look, for every situation, with style but without losing one's individuality.

HIGH QUALITY

100% MADE IN EUROPE
100% Safe and selected ingredients.
100% Audited and selected supplies.
100% Batches tested.

ACCESSIBLE

KIKO identifies the beauty trends of the moment and makes them accessible to all.
We strive to offer an incredible variety of products, textures and colours with hight quality, yet always at an affordable price.

COLOURFUL

We believe life is better in colour: we understand the power of make-up and love that can ignite a spark and make you feel fabulous.

INNOVATIVE

Together with the world-renowned suppliers, our scientific team creates innovative and qualitative formulas, textures and colours integrating latest generation actives and high-tech ingredients

The Company

OUR TARGET

BEAUTY LOVERS ARE
KIKO MILANO'S
TARGET CONSUMERS.

What do our consumers love about shopping at KIKO Milano?

- Our variety of colours, shades & finishes
- Spending a carefree moment browising & experimenting
- Great value for money,

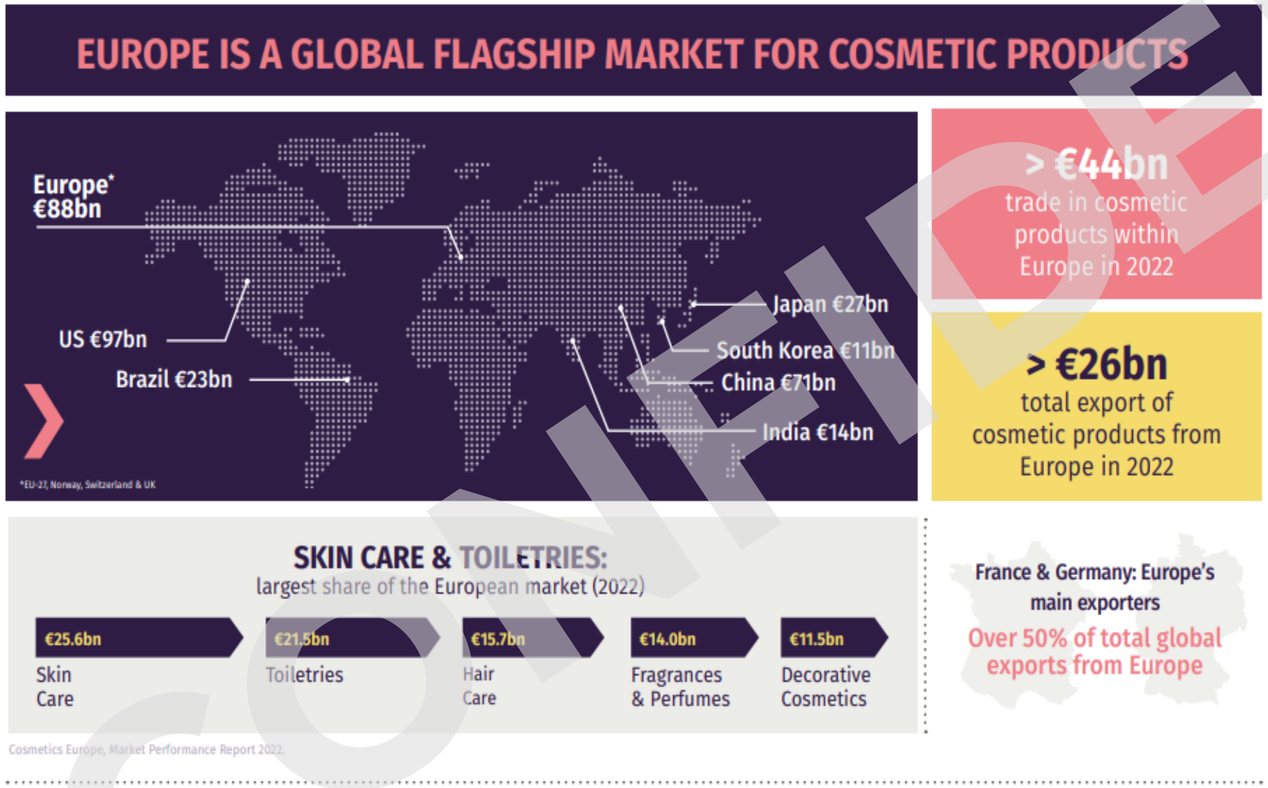
Our target consumer chooses us because of our affordability and color offer, but we are strengthening and elevating our relationship by:

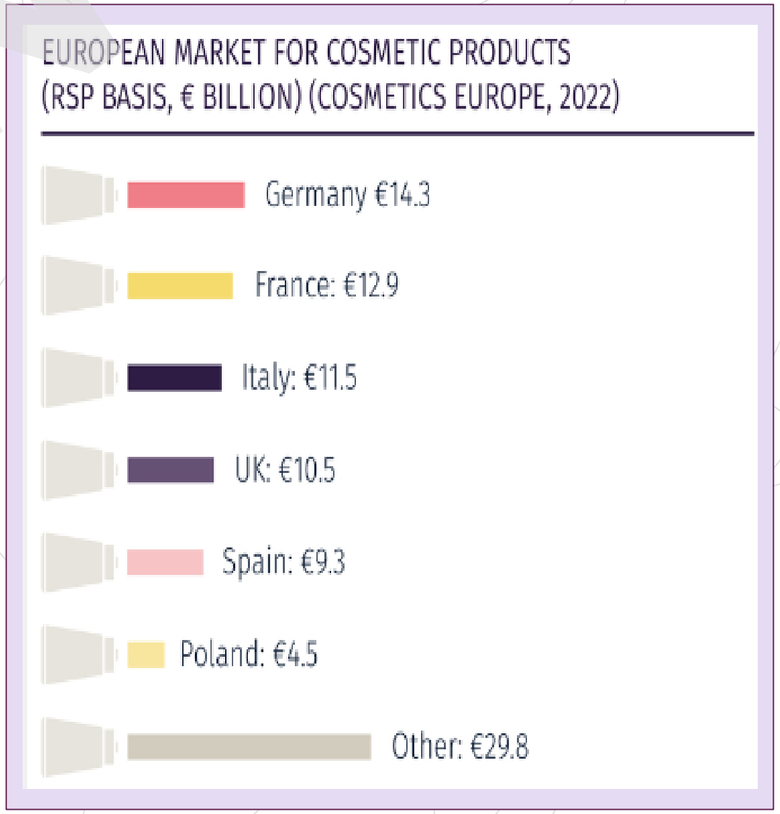
- Carefully guiding them to discover their own style
- Offering them on-trend and customizable products to better express their Beauty
- Engaging with them on social networks, so that they are more likely to become a loyal customer

Cosmetic Industry Overview

Cosmetics And Personal Care Industry Overview

Valued at **€88 billion** at retail sales price in 2022, Europe is a global flagship market for cosmetics and personal care products.

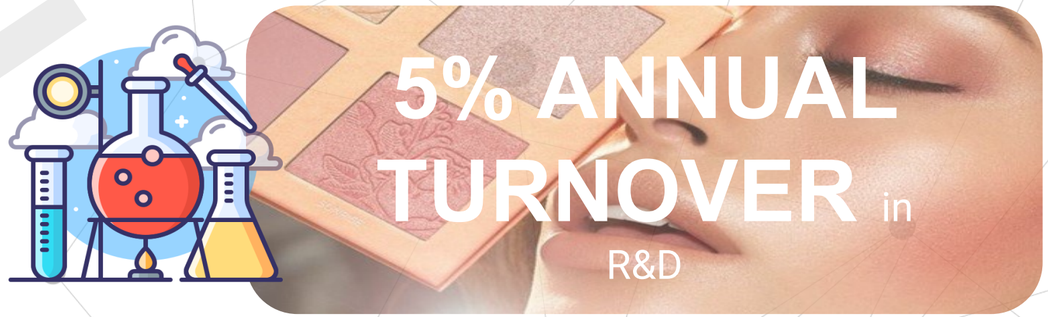




Cosmetics And Personal Care Industry Overview

Including direct, indirect and induced economic activity, the industry supports over **3.6 million jobs**. In 2022, over 254,259 people were employed directly, and a further 2.78 million indirectly in the cosmetics value chain.

The cosmetics and personal care industry is a **science-driven and highly innovative sector** which makes large investments in R&D. Large companies in our industry spend around **5%** of their annual turnover (sales) on R&D (within Europe).



In view of the sector's ability to respond, 2023 will also record positive figures, with **turnover up by +8%,** accounting for €14.3 billion and **consumption up by +6.3%**, accounting for €12.2 billion of purchases.

Italy Is The Cosmetic Valley

- According to report taken from ISTAT data, in 2022 the largest concentration (near to 61%) of cosmetics companies continued to be in **northwest Italy**, in line with the percentage of the previous year.

- Subcontractors generated a **total turnover close of over €1,810 million** (up by 8.5% compared to 2021), of which **76% was concentrated in Lombardy**, that remained - with a value close to €1,380 million - the region with the highest production rate in the Italian industrial cosmetics system.

Geographical distribution of cosmetics companies in 2022

(values %)

Abruzzo	0.6%	Molise	0.2%
Calabria	0.3%	Piedmont	4.5%
Campania	1.5%	Puglia	0.8%
Emilia-Romagna	10.5%	Sardinia	0.3%
Friuli-Venezia Giulia	1.2%	Sicily	0.6%
Lazio	5.3%	Tuscany	5.9%
Liguria	1.5%	Trentino-South Tyrol	1.1%
Lombardy	54,9%	Umbria	1.7%
Marche	2.5%	Veneto	6.6%

The Science Behind Beauty

- Cosmetic is a science and its products intended to "care" the skin are the results of scientific innovation. Idea for new cosmetic products come from a variety of sources:
  - ★ Scientific advances
  - ★ Changes in consumer preferences and expectations
  - ★ Continuous industry innovation

Before a cosmetic product goes to market…

1. Product safety and compliance with regulatory requirements is paramount and is factored into ingredient selection, final formula selection, and packaging choices to ensure that they are safe for all users.

2. Efficacy evaluation is performed to ensure the cosmetic product delivers on the claims and benefits that are expected by the consumer.

3. Microbiology conduct test to determine which preservative system is best in order to prevent growth of fungi, bacteria and yeast that could cause cosmetic products to spoil.

4. Stability evaluation is conducted to ensure the cosmetic product formulation and packaging is compatible so that the product remains stable and safe throughout its life.

5. Process development scales up the cosmetic product formulation from a smaller beaker in the lab all the way to huge vats at the manufacturing site, ensuring quality control is maintained no matter where is manufactured in the world.

6. Supply Chain purchases the materials to make finished cosmetic product, including raw materials, packaging, and labelling so that the product can be produced in the quantities and quality needed by retailers and customers.

…Lastly post-marketing surveillance

REGULATIONS

Companies in food, supplement, pharmaceutical, personal care, medical device and cosmetics industries are under a **higher pressure** than ever to assure the compliance with ever-changing regulations and, at the same time, to **remain competitive and innovative** in the global marketplace .

The challenges concern different aspects of the business, from developing new products to sumbit approvals to the regulatory bodies and implementing a path to market access.

As the **volume and strictness of international and local regulations increases**, the **need to develop sustainable products**, marketing foods, drugs, supplements, personal care products, cosmetics or medical devices into new territories requires a well-structured regulatory strategy that enables companies to tackle complexities and achieve success by innovating.

EU Main Regulations
Examples

- REGULATION EU 1223/2009 EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 30 NOVEMBER 2009 ON COSMETIC PRODUCTS
  - 40 Articles
  - 9 Annexes
- DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 3 DECEMBER 2001 ON GENERAL PRODUCT SAFETY
- EUROPEN UNION CUSTOMS CODE 952/2013 - MADE IN DEFINITION.
- REGULATIONS CE 1272/2008 – CLP - CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES
- REGULATIONS REACH
- DIRECTIVE 75/324/CEE E 2013/10/UE - AEROSOL
- RECO N.2006/647/CE ON THE EFFECTIVENESS OF SUNSCREEN PRODUCTS AND RELATED INDICATIONS.
- REGULATION (EU) 2020/2151 OF 17 DECEMBER 2020 LAYING DOWN PROVISIONS RELATING TO THE HARMONIZED MARKING SPECIFICATIONS FOR SINGLE-USE PLASTIC
- THE LEGISLATIVE DECREE 3 SEPTEMBER 2020, N. 116 WHICH TRANSPOSES IN ITALY THE DIRECTIVE (EU) 2018/851 AND THE DIRECTIVE (EU) 2018/852 ON PACKAGING AND PACKAGING WASTE
- FRENCH AGEC LAW AND DECREE NO. 2021-835 OF 29 JUNE 2021
- EUROPEAN COMMISSION - REGULATION (EU) 655/2013 - COMMON CRITERIA FOR THE JUSTIFICATION OF CLAIMS
- NEW REGULATION AMENDING REGULATION (EC) NO 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS LABELLING OF FRAGRANCE ALLERGENS IN COSMETIC PRODUCTS . NEW REGULATION 2023/1545 , published last July, 27th

Main Regulations Extra-EU

Examples

USA

- FDA : MoCra Modernization of Cosmetics Regulation Act (MoCRA) issued last December 2022
- US Federal Food, Drug and Cosmetic Act (FDC Act), Bureau of Alcohol, Tobacco and Firearms (BATF) (for denatured alcool)
- California Proposition 65

PRC

- Cosmetics Supervision and Administration Regulation
- Administrative Measures on Cosmetics Registration and Filing
- Administrative Provisions for Cosmetics Registration and Filing Dossiers
- Administrative Measures on Cosmetics Labels
- Cosmetics Classification Rules and Classification Catalogue
- Standards for Efficacy Claims Assessment
- Technical Guidelines for Cosmetics Safety Assessment
- Inventory of Existing Cosmetic Ingredients
- Safety and Technical Standards for Cosmetics
- Working Procedures for the Administration of Supplementary Test Methods of Cosmetics
- Technical Guidelines for the Study and Drafting of Supplementary Test Methods of Cosmetics
- Administrative Measures on Cosmetics Sampling Inspection
- Cosmetics Supervision and Administration Regulation for children
- Supervision and Administration Provisions for Children Cosmetics
- Announcement about Symbol for Children Cosmetics
- Supervision and Administration Measures for measurement of packaged commodities (NEW)

DISRUPTIVE INNOVATION

Companies in food, supplement, pharmaceutical, personal care, medical device and cosmetics industries are under a **higher pressure** than ever to assure the compliance with ever-changing regulations and, at the same time, to **remain competitive and innovative** in the global marketplace .

The challenges concern different aspects of the business, from developing new products to sumbit approvals to the regulatory bodies and implementing a path to market access.

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Digitalization Roadmap

Project Context

Cosmetics Industry

- **Continuous changes in regulatory requirements**
- **Increase in business and product complexity**
- **Growing demand for product traceability and auditability**

→ **Need to automate business processes and improve data integrity**

- In this context, KIKO demands the utmost **efficiency in processes** to ensure **timely responses to the market without compromising the level of product quality**, while also **ensuring compliance** with the evolving regulations.

- To answer the cosmetic market needs, KIKO started to **analyze current operational processes and digital systems in 3 main business areas** with the aim of identifying process critical issues and potential improvements.

Why a Digitalization Roadmap?

- The on-going project aims to define **a multi-year intervention plan toward digitalization** for the achievement of compliance and process optimization.
- The main objectives of the Digitalization Roadmap are:

Increasing overall **processes efficiency**

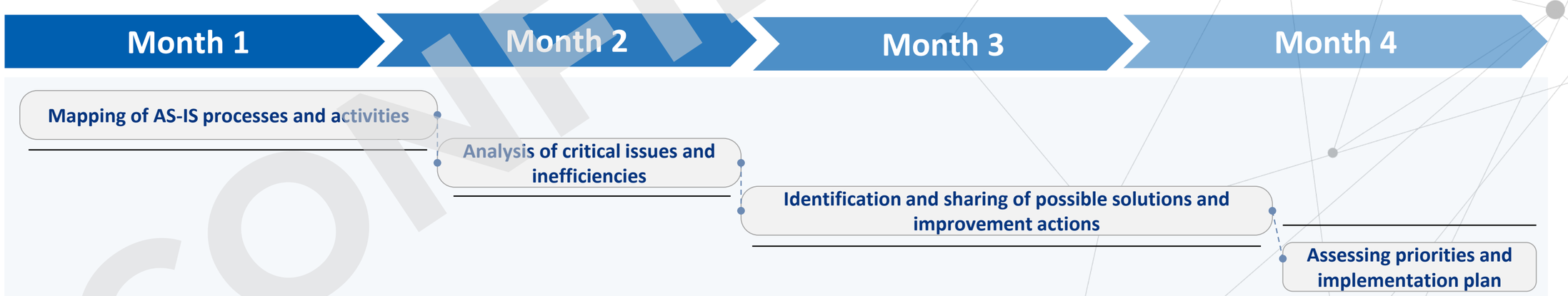
Reducing **non-value-added activities**

Data centralization and enhancing **data quality**

Adapting to continuously **evolving regulatory constraints**

Implementing digital solutions to ensure **Data Integrity and Compliance**

- The project plan consists in 4 different phases that cover each of the investigated areas:



Digitalization Roadmap

- **Artwork Management**
- **Regulatory & Quality Management**

Digitalization Roadmap

Artwork Management Context

- The project started from the **most critical area** with the analysis of the process of **creating, approving, and maintaining KIKO artworks and blueprints**.

- The artwork approval and creation process is currently supported by the **PLM system.**

Who is involved in the process?

Some numbers...

KIKO manages every year a high number of artworks and blueprints that must be checked and signed by different departments before being released and sent into production:

15.000 **TOTAL ARTWORKS PER YEAR**

800 **New products/year**

Digitalization Roadmap
Artwork Complexity

- **For each product**
  normally **3 artworks** to manage

  - Artwork Primary Packaging
  - Artwork Product Label
  - Packaging Secondary Artwork

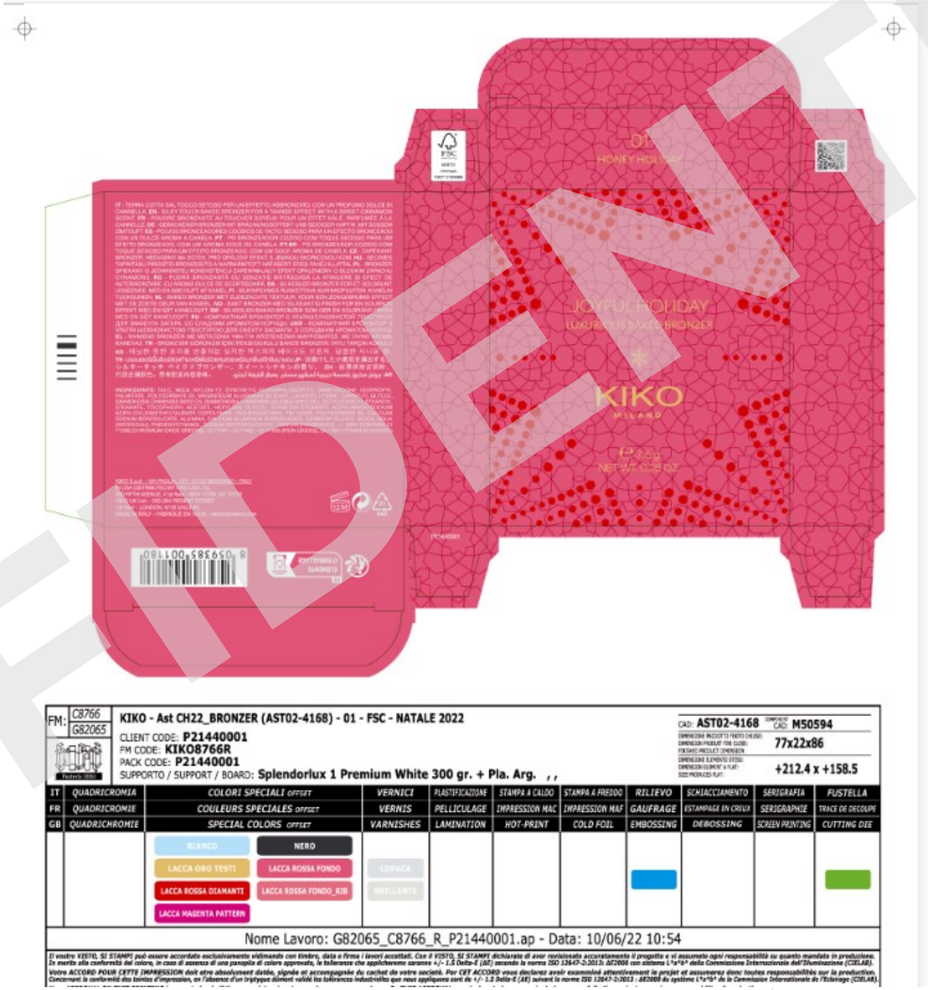
- **For each artwork:**

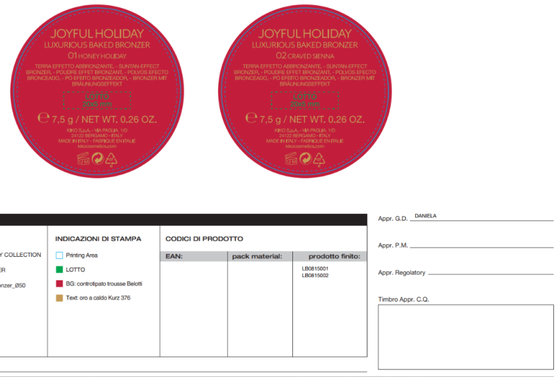
  data to manage:

  - Design
  - Cutting Die
  - Technical specifications
  - Graphic elements (Logo, etc.)
  - Color specifications
  - Texts
  - Translations
  - Ingredients lists

  data approval processes

  printer vendor outcome verification (blueprint) etc.



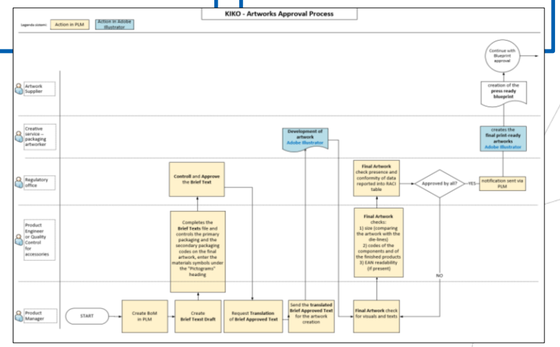


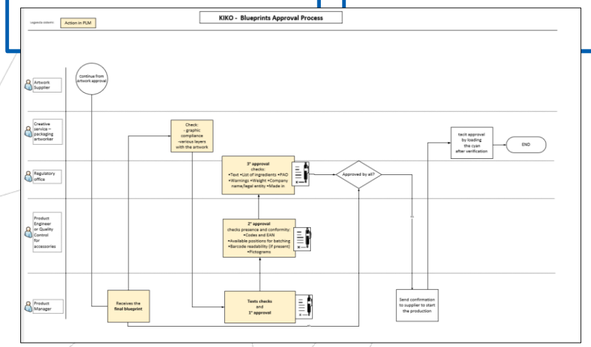
Digitalization Roadmap
Artwork – AS-IS Mapping

- The main steps of the as-is artwork management system have been schematized in order **to identify issues and paint points** that slow down the release of new products.

ARTWORK MANAGEMENT AS - IS

1	2	3	4	5	6	7
Artwork Management starts in PLM with the creation of the Brief Text	Creation of the graphic artwork in a separate file	Translations & text approvals manage out of the workflow	Creation and verification of the Blueprint file	Storage of the files in a dedicated repository	Control of the first real sample of product (PPS)	Quality Control of print samples
PLM	Graphic design tool	Email/Paper	Human check	Manual Check	Manual Check	Manual Check





Digitalization Roadmap

Artwork – Findings & Critical Issues

- In this slide are presented the results of the analysis conducted on KIKO **artwork management process** with a focus on the findings that **impact process efficiency and data integrity**.

Current System is **not a specific artwork management system and** does **not automatize the approval flow**.	**Manual work and waste of time**
The internal and external stakeholders use **different tools** and **exchange many data out of the systems**.	**Duplicate data-entry and risk of errors**
The **comparison** between artwork and blueprint is **performed by human check**.	**Visual check and risk of errors**
The **storage of artwork is done manually** and metadata are not used.	**Risks of errors / risks for data integrity**

Digitalization Roadmap

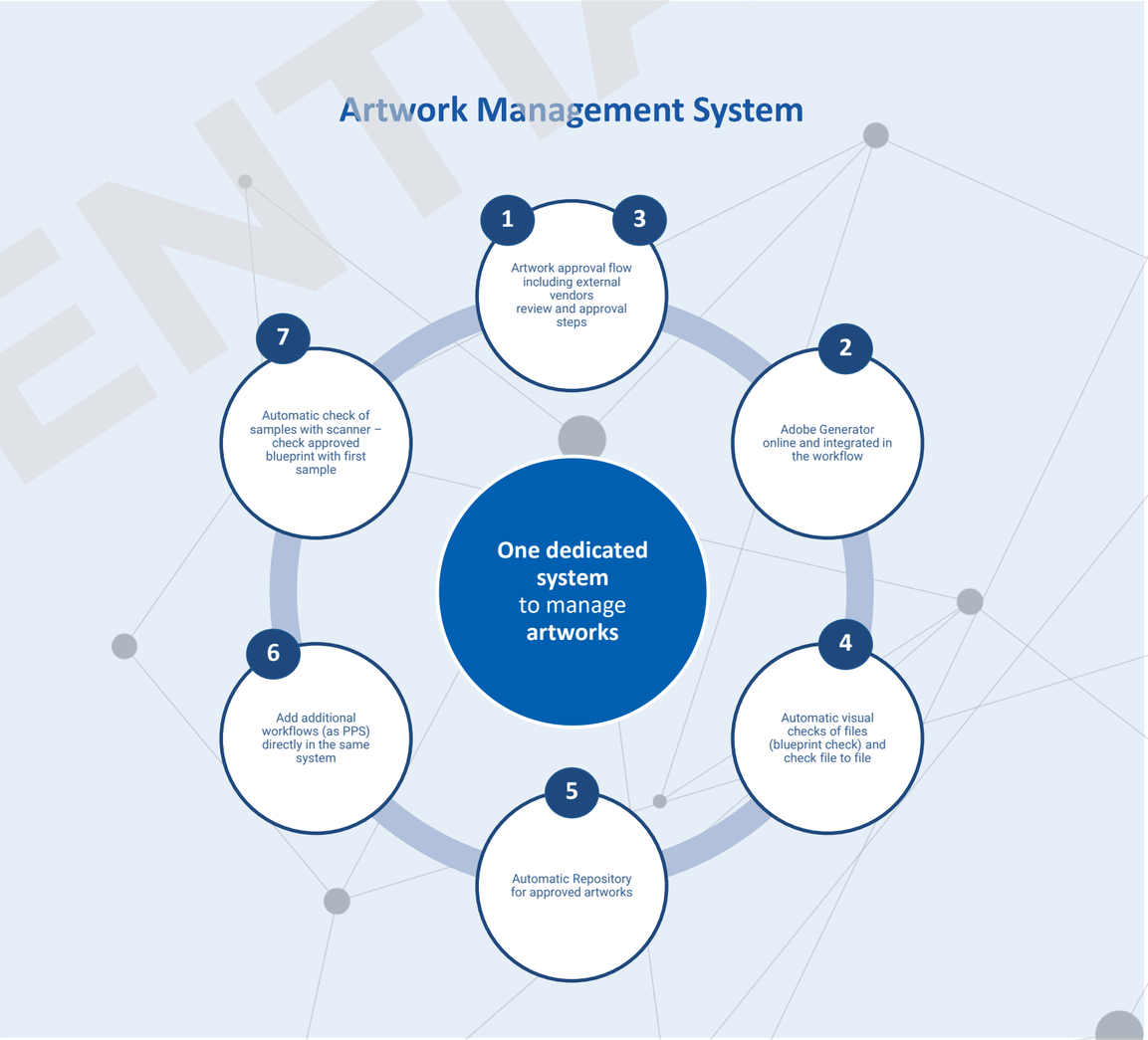
Artwork – Solutions and Improvement actions

- An optimization of the actual process and tools is necessary to make the **TO BE Artwork workflow management more efficient**. Most of the findings have areas of improvement as **Process Efficiency** and risks related to **Data Integrity**.

- The recommendation is to **centralize the management of artworks within a single system** capable of automating the various process steps, reducing manual processes, simplifying approval cycles across departments, thereby increasing overall efficiency.

- The introduction of new tools and technologies can open up to **future developments** (e-labeling, 3D packshot renders, Anti-Counterfeiting, etc.)

- These improvements are being analyzed to elaborate a **Digitalization Roadmap** for the next years.



Digitalization Roadmap

Artwork – Software Selection

- To identify **the most suitable artwork management system for KIKO's needs**, a vendor and software selection activity has been conducted.

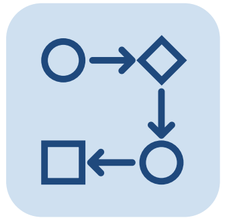
- Starting from a panel of solutions, we have analyzed each of them investigating how much their **functionalities fitted with KIKO's requirements**. Following the steps of the selection process:

    1. Definition of High-Level User Requirements
    2. Selection of Main Vendors and solutions
    3. Mapping of Vendors' solution functionalities with URS at high level to evaluate and compare the different technologies available on the market
    4. Selection of a shortlist of the most suitable solutions
    5. Participation to customized demonstrations with selected vendors

Digitalization Roadmap

Artwork – Objectives & Benefits

Organizations are finding that with artwork management tools they can reduce time to produce and change artwork and labels from many months to just a few months.



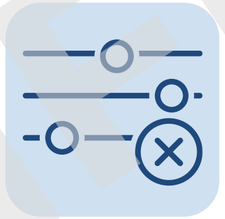
Streamline processes through the product lifecycle

Improve collaboration with internal and external stakeholders

Eliminate delays caused by inefficient manual processes

Ensure accuracy and consistency with centralized content management

Enable control and compliance



Identify and eliminate bottlenecks

Gain full visibility on review cycles and changes controlling version and traceability

Reduce risks and shorten time to market

Digitalization Roadmap

Regulatory Management Context

The second area to be assessed is the **Regulatory Management** where project analyses are still ongoing.

During the **as-is discovery phase**, **potential improvements** have been identified in the following processes:

- Product Registration
- Import of product ingredients list from suppliers
- Dossier Manager Report Download for authorities or foreign countries / Product information File (PIF) generation
- Renewal management
- Regulatory updates management

- These findings can be solved with the implementation of new solutions to streamline and automate processes

ON GOING ACTIVITIES

- **Refinement of User Requirements Specifications for Regulatory Management**
- **Verification on the most suitable solutions of Regulatory Information Management (RIM) for cosmetic context**

Digitalization Roadmap

Quality Management Context

- The last area to be assessed is the **Quality Management** that includes **Quality Control** & **Quality Assurance**.

- During the **as-is discovery phase**, **potential improvements** have been identified in the following processes:

Quality Control	Quality Assurance
• Quality Control tests and result analyses • Supplier rating • Movement of released/not released products • Shelf-life management • Certificate of Analysis Management	• Change Management • Non-compliance management • Audit and inspections management • KPI and quality reports management

- These findings can be solved with the implementation of new solutions to streamline and automate processes

ON GOING ACTIVITIES

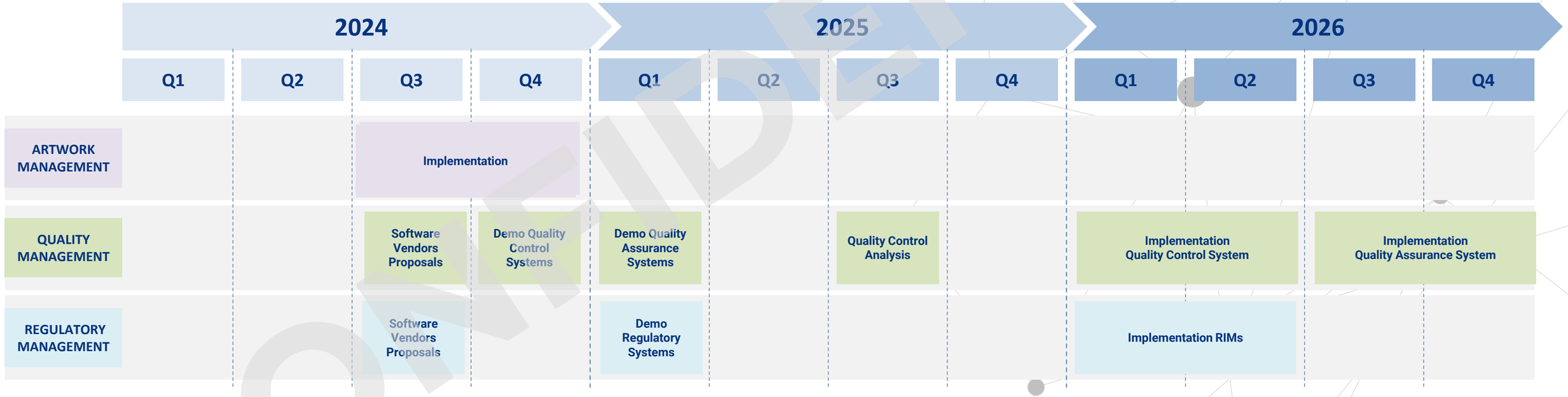
- **For Quality Control, evaluation of the possibility of extending current systems functionalities**
- **For Quality Assurance, analysis of the most suitable solutions of Quality Management System for cosmetic context**

Conclusions & Next Steps

Digitalization Roadmap

Conclusions & Next Steps

- Results identified in terms of both **increased efficiency** and **improved quality** in the artwork management process can be achieved in stages and through sequential implementation of the proposed actions, selecting the appropriate solution and introducing it in KIKO's infrastructure.
- In the next phases of the project, the **Quality and Regulatory areas will be deeply analyzed** with the aim of standardizing processes and finding improvement actions to optimize the currently critical functionalities.



Grazie

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