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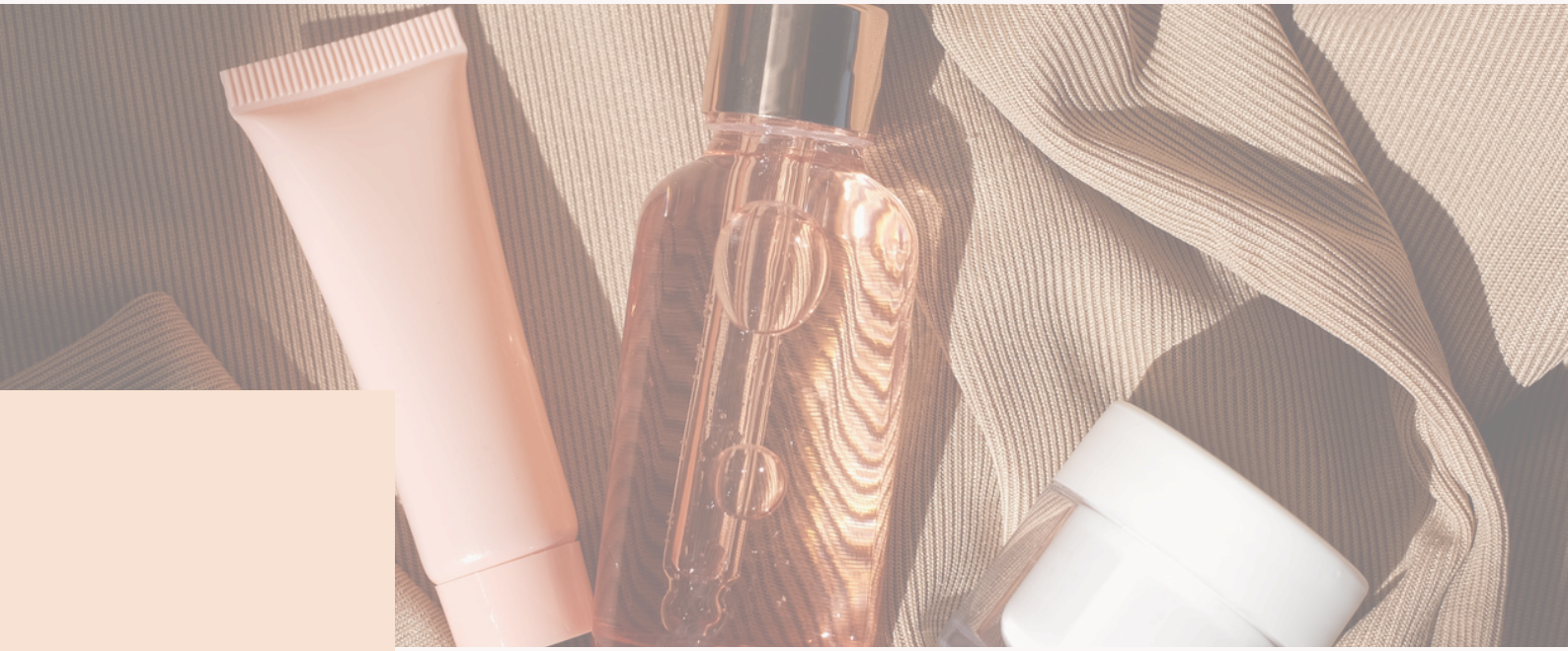
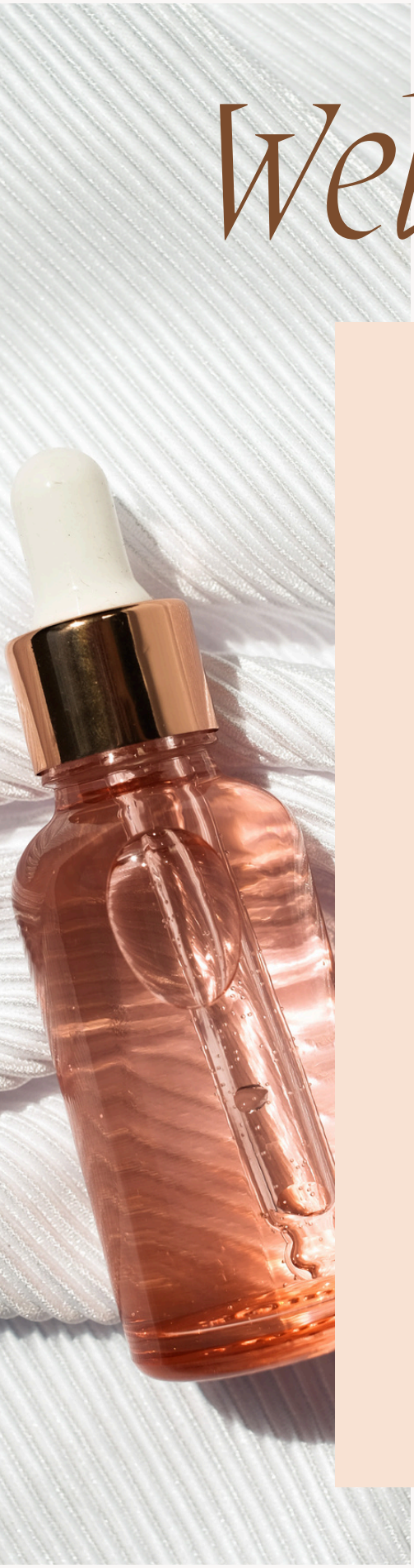


YOUR GUIDE TO
Writing a PIF

A short guide
to write a Cosmetic Product
Information File

Welcome



Creating a Cosmetic Product Information File (PIF) is a crucial requirement under UK and EU cosmetic regulations. The PIF serves as a piece of evidence that your product is safe, complies with relevant legislation, and adheres to Good Manufacturing Practices (GMP).

This short guide provides step-by-step instructions to help you compile a comprehensive and compliant PIF.

Chapter 1: Overview of Regulatory Framework

The legal Framework for cosmetics in the EU and UK is aligned. The EU's compliance falls under Regulation (EC) No 1223/2009. In the UK, the relevant regulation is the UK Cosmetics Regulation.

Key elements of the regulatory framework are:

- Definition of a cosmetic product.
- Responsible Person (RP) obligations.
- Key timelines for maintaining compliance.
- Differentiating between cosmetic and other regulatory categories (e.g., medicinal products, biocidal products).

In the EU Regulation (EC) No 1223/2009 a cosmetic product is defined as:

"Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours."

Post-Brexit, the UK's definition mirrors the EU's definition with minor amendments for local applicability:

"A cosmetic product is any substance or mixture intended to be used on the external parts of the human body, or with the teeth or mouth's mucous membranes, for the purposes of cleaning, perfuming, changing appearance, protecting, maintaining, or correcting odours."

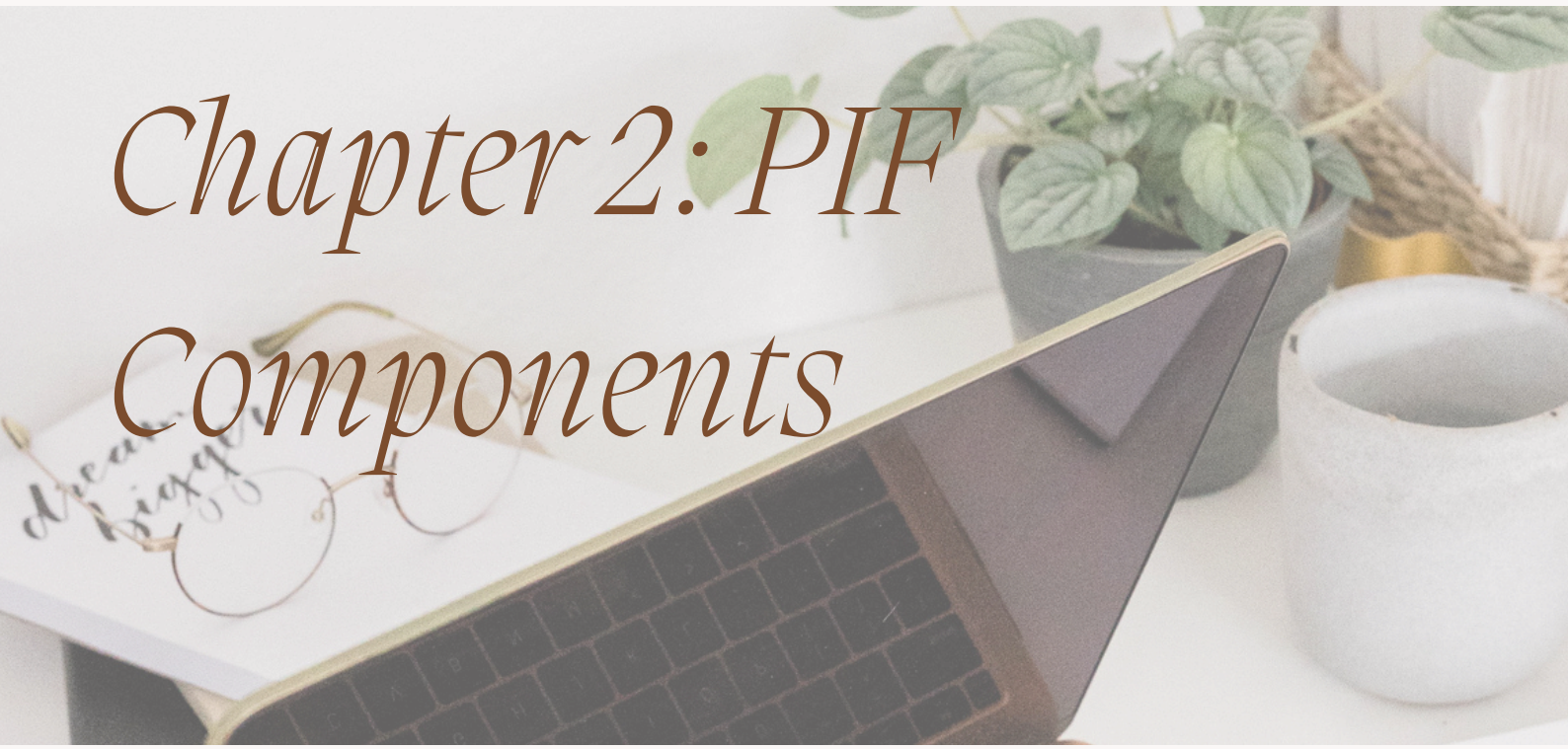
Cosmetic product is defined as any substance or mixture intended to be placed in contact with the external parts of the human body

The Responsible Person (RP) ensures cosmetic products comply with UK and EU regulations. Obligations include: ensuring safety assessments are conducted, maintaining the Product Information File (PIF), registering products on relevant notification portals (e.g., CPNP for the EU or SCPN for the UK), ensuring proper labeling, verifying compliance with Good Manufacturing Practices (GMP), and acting as the contact for regulatory authorities.

KEY TIMELINES

- ✓ Pre-Market Registration: register the product to the relevant notification portal *before* placing it on the market
- ✓ Keep the PIF available for inspection at the RP's address from the first market date until *10 years* after the product's last batch release.
- ✓ Obtain the Cosmetic Product Safety Report (CPSR) *before* market entry.
- ✓ *Annual review* of formulations for regulatory changes, such as ingredient restrictions or bans.
- ✓ Investigate serious undesirable effects (SUEs) immediately and report to relevant authorities *within 15 days* of awareness

Differentiating between cosmetics and other categories ensures the product meets the correct regulations. Cosmetics focus on cleaning, beautifying, or protecting external body parts, while medicinal products treat or prevent diseases, and biocidal products eliminate harmful organisms. Misclassification can lead to regulatory non-compliance, incorrect labeling, and enforcement penalties.



Chapter 2: PIF Components

Each PIF must contain the following essential elements:

- Product Description
- Cosmetic Product Safety Report (CPSR)
- Manufacturing Information
- Proof of Claimed Effects
- No Animal Testing-declaration

The product description must include detailed information about the product, such as its category (e.g., cream, shampoo), intended use (e.g., moisturizing, cleansing), visuals (photos or diagrams of the packaging and product), and consumer demographics (e.g., children, adults, sensitive skin).

CPSR must have two parts: Part A for Safety Information and Part B for Safety Assessment. It should be performed by a qualified assessor with experience and education in toxicology, dermatology, and/or microbiology.

Manufacturing Information should detail manufacturing processes and state compliance to GMP. It should also describe traceability systems in place for quality control.

If the product claims any effects, they have to be proved and documented (e.g., "anti-wrinkle" or "dermatologically tested"). There has to be a summary of supporting evidence, such as clinical tests, consumer trials, or literature reviews. Subjective and objective claims must be differentiated.

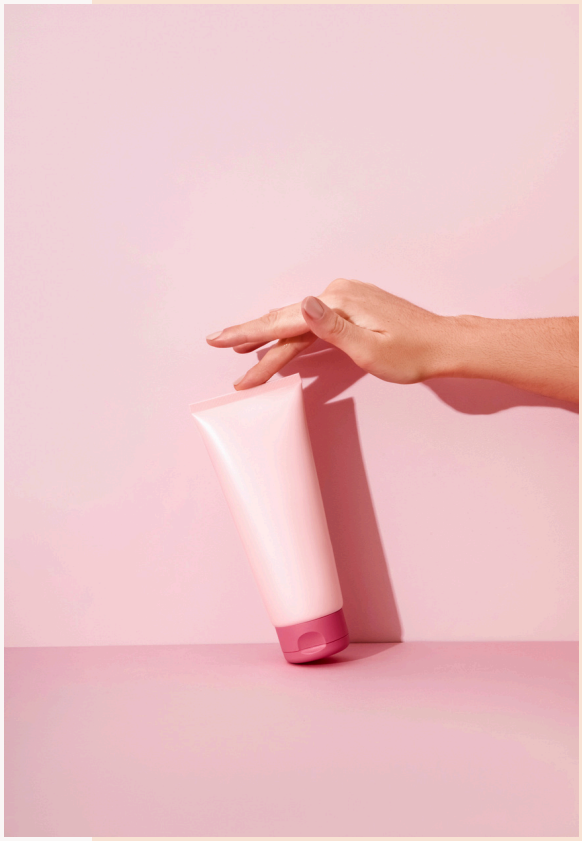
NO ANIMAL TESTING - DECLARATION

Declare compliance with the ban on animal testing for finished products and ingredients.

Provide traceability evidence for cruelty-free claims, i.e. by attaching suppliers' cruelty-free statements for the ingredients.

Chapter 3: How to Create the PIF

This chapter describes the creation of each component of the PIF in six steps.



Step 1: Product Description

- Draft a detailed product overview.
- Include photos from multiple angles, focusing on any claims or instructions visible on the packaging.
- Mention unique identifiers such as batch numbers and barcodes.

Step 2: Gathering Safety Information

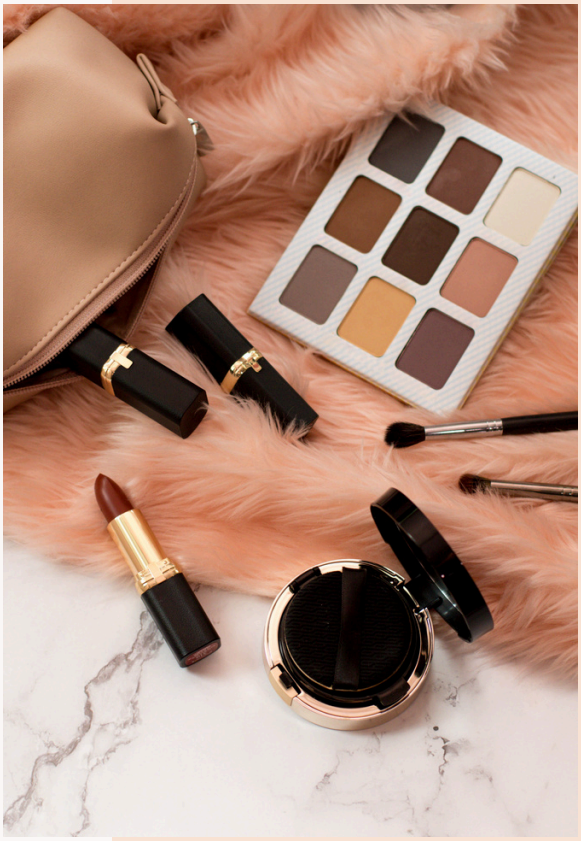
- Obtain ingredient specifications from suppliers, including:
  - INCI names and CAS numbers.
  - Certificate of Analysis (CoA)
  - Safety Data Sheet (SDS)
  - IFRA certificate
  - Allergen declaration
  - Concentration ranges.
  - Regulatory status within the EU and UK.
- Stability and microbial challenge tests on the product - see the tip on the right
- Record conditions such as temperature and humidity in the stability assessment.

TIP:
Anhydrous (waterless) products do not need microbial testing.

TIP: IF YOU WANT TO SELL YOUR PRODUCTS IN THE EU, THE CPSR MUST STATE THAT IT CONFORMS WITH THE EU REGULATIONS.

Step 3: Appointing a Qualified Safety Assessor to prepare a CPSR

- Ensure that the safety assessor meets legal competency standards (e.g., having a toxicology degree).
- Provide them with:
  - The formulation breakdown.
  - All test results.
  - Impurities and material trace data.
  - Risk assessments for potentially hazardous materials.
- Usually the safety assessor provides an application form which will guide you with the required documents



Step 4: GMP Compliance

- Implement and document manufacturing processes in compliance with ISO 22716.
- Retain batch records, quality control processes, and personnel training logs.
- Conduct regular internal audits to verify adherence to GMP.

TIP:
Some cosmetic ingredient suppliers also sell qualified and affordable CPSR services.

TIP: KEEP ALL DOCUMENTS RELATED TO EACH PRODUCT IN THEIR OWN PRODUCT-SPECIFIC FILES, BOTH IN DIGITAL AND PRINTED FORMAT.

Step 5: Supporting Evidence for Claims (if any made)

- Gather documentation like:
  - Laboratory test results for efficacy claims.
  - Dermatological testing data.
  - Published peer-reviewed studies to support product benefits.

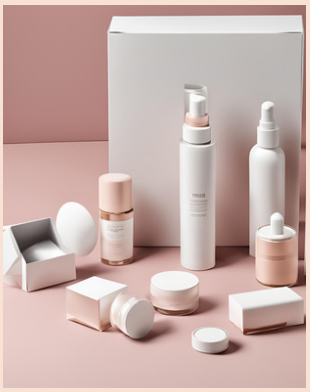
Step 6: Assembling the Animal Testing Declaration

- Ensure the documentation proves that no prohibited tests were performed.
- Reference EU Cosmetic Directive provisions or relevant UK clauses.
- Retain agreements with suppliers confirming compliance with cruelty-free standards.

TIP:
Many suppliers publish a cruelty-free statement in their website. If you can't one, contact the supplier to provide it.

Chapter 4: Maintaining and Updating the PIF

It is a good practice to conduct periodic reviews on the PIF, for example, once a year.

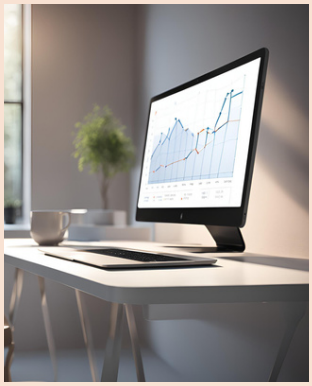


The PIF must be reviewed and the file updated when:

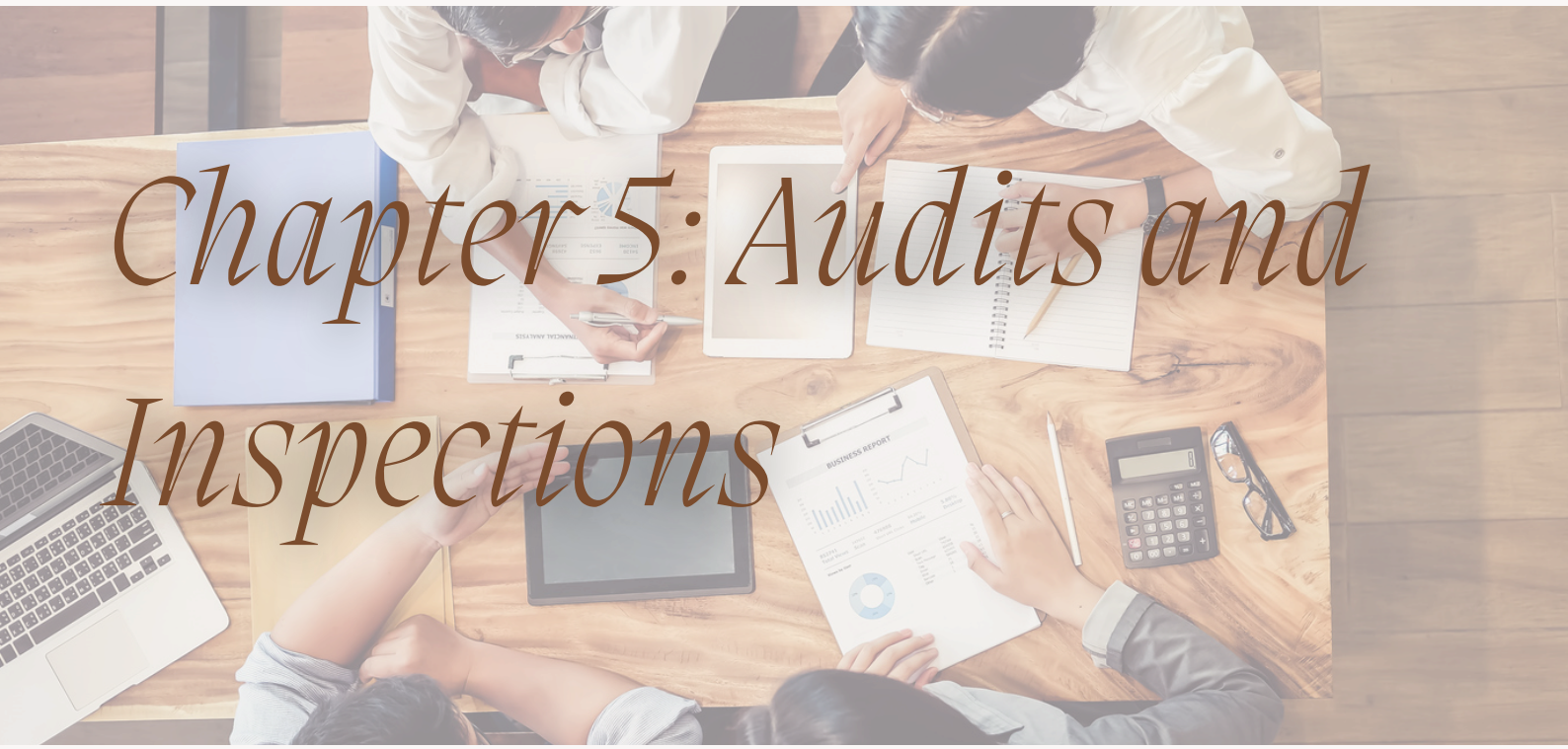
- There is a formulation change.
- The product packaging is updated/changed, or
- There are new test results for the product or new claims are added.

Additional triggers for review:

- Any changes in regulatory guidance.
- Emerging safety concerns for existing ingredients.
- Post-market surveillance findings.



TIP: Subscribe to newsletters from the regulatory bodies to keep updated with any changes in the regulations.



Chapter 5: Audits and Inspections

WHAT IS AN AUDIT?

"An audit systematically examines and evaluates processes, records, or systems to ensure compliance with regulations, standards, or objectives. It often identifies areas for improvement or verifies accuracy and reliability."

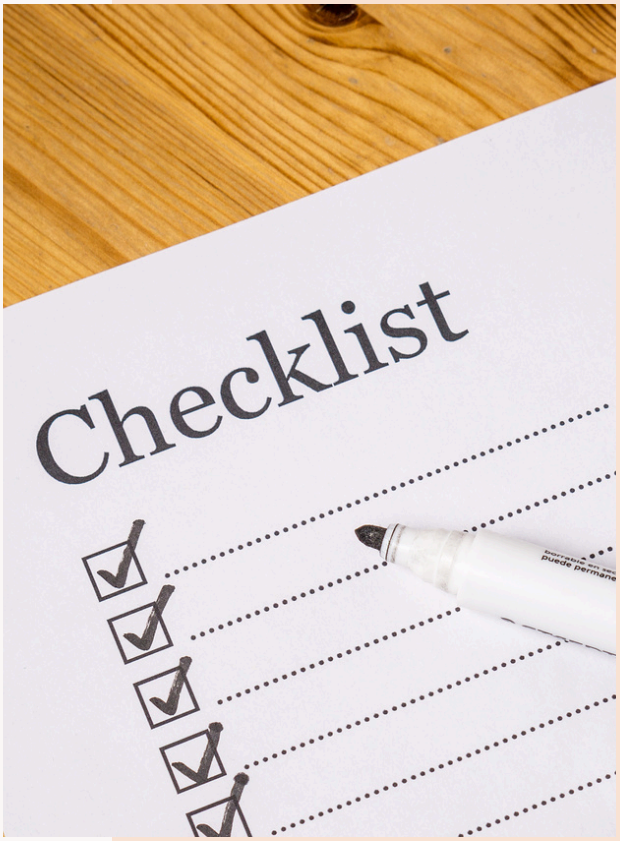
GMP and ISO 22716 for cosmetics require all manufacturers to conduct periodic internal audits to ensure compliance with quality standards, identify gaps, and verify the effectiveness of processes. Regardless of business size, this is crucial to maintain product safety and regulatory adherence.

A sole trader or a small business cannot audit themselves, but they can ask a colleague to help them by using a checklist to review processes against GMP standards, inspect documentation and facilities, identify gaps, implement corrective actions, and keep records for compliance.

TIP: get help from your community for the internal audit! Ask another small business to audit you to improve the audit process.

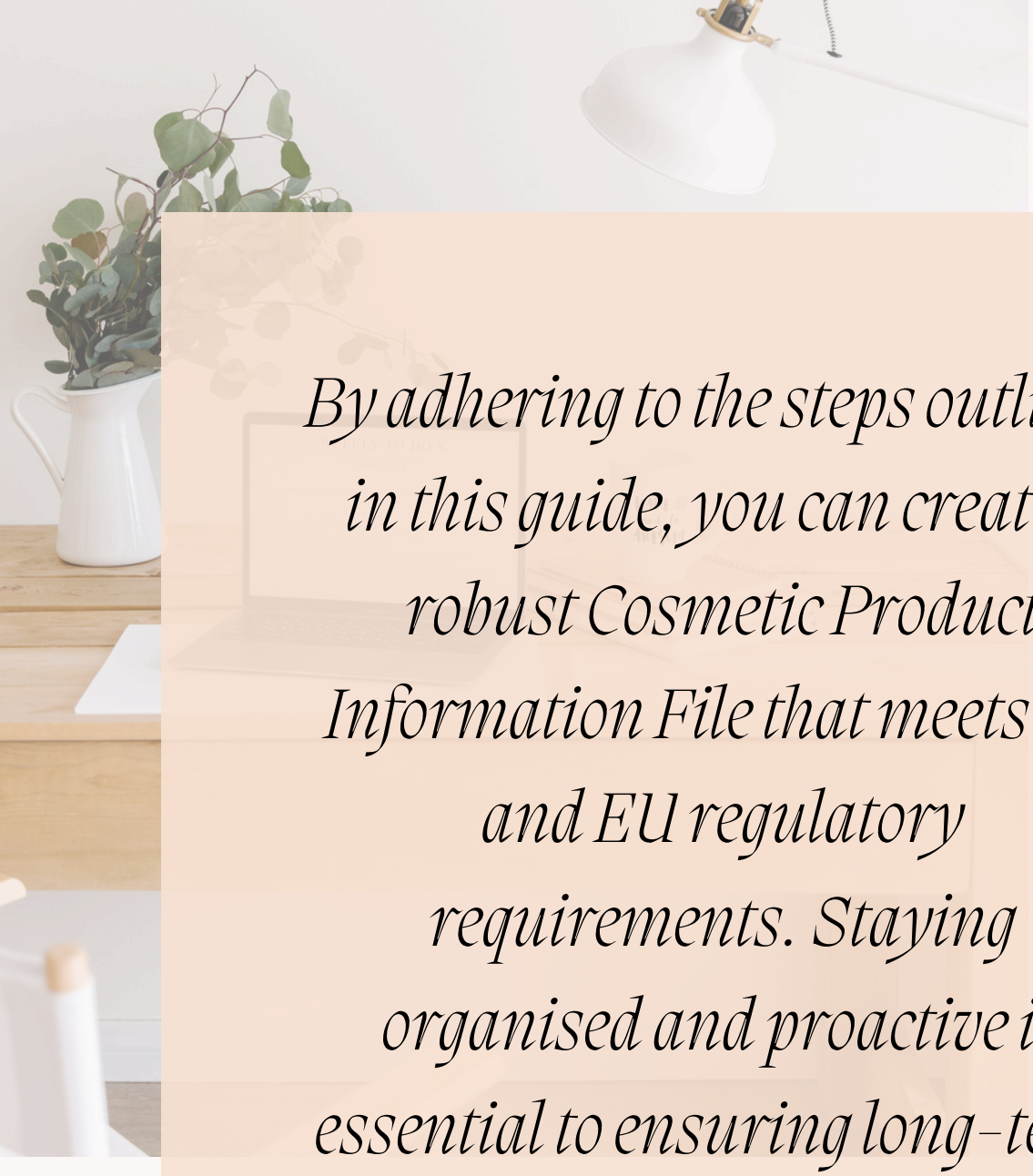
When is a cosmetic maker subject to a regulatory audit?

When authorities, such as UK Trading Standards or EU market surveillance bodies, must verify regulation compliance. Audits are usually triggered by routine Inspections, consumer complaints (safety or labelling issues), Serious Undesirable Effects (SUEs), or random spot-checks.



- Preparing for Regulatory Audits:
  - Ensure the PIF is readily available upon request.
  - Provide translations where required (for the EU market).
  - Practice with mock audits to identify potential gaps.
- Key Red Flags to Avoid:
  - Incomplete ingredient specifications.
  - Missing documentation for claims.
  - Failure to provide stability test results or inadequate microbial safety data.
- Post-Inspection Follow-up:
  - Address corrective actions immediately.
  - Maintain open communication with regulatory authorities

TIP:
Requirement to comply with GMP does not require being certified to ISO 22716.



By adhering to the steps outlined in this guide, you can create a robust Cosmetic Product Information File that meets UK and EU regulatory requirements. Staying organised and proactive is essential to ensuring long-term compliance and market success.

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