

Guidelines for Control of Cosmetic Products in Malaysia

Do you know the guidelines for control of cosmetic products?

Do you have sufficient knowledge to register cosmetic products?

Introduction

The Control of Cosmetic Products Guidelines has been produced to offer assistance to the cosmetic industry in compliance with the provisions of the ASEAN Cosmetic Directive (ACD). The course is for the manufacturers to understand that Cosmetic products in Malaysia are regulated under the Control of Drugs and Cosmetic Regulations (CDCR) 1984, which were promulgated under the Sale of Drugs Act 1952. Cosmetic products in Malaysia are controlled through notification procedure starting from 1st January 2008. Cosmetic Notification Holder (CNH) who responsible for placing the cosmetic product in the market is required to COMPLY with all requirements stated in the guideline and to make a declaration upon notification to the Director of Pharmaceutical Services (DPS) through National Pharmaceutical Regulatory Agency (NPRA). This training is to create awareness of the Control of Drugs and Cosmetic Regulation (CDCR 1984), Regulation 18A (1) that is: No person shall manufacture, sell, supply, import, possesses any cosmetics unless the cosmetic is notified. It is an offence for anyone to conduct such activities without prior notification to the DPS.

Program Objectives

This training aims to:

- Understand the notification procedure for cosmetic products with regards to the CDCR 1984.

Learning Outcomes

After completing this training, participants should be able to

- Explain the cosmetic notification process
- Understand the responsibility of CNH
- Explain the regulatory requirements for cosmetics
- Understand the post-market surveillance program
- Understand the certificate of free sale and Halal requirements

Who should attend?

Non-managerial, First-line management, middle management, and anyone who needs to deal with regulatory affairs.

Methodology

Case studies, forum discussion, role-play, presentations, gamification

Program Outline

Time	Day One
9.00am– 10.30am	Cosmetic Definition In this module, the participants would learn the Product Types, Product Presentation, Labelling Requirement, Label Displays, Listing of Ingredients and Nomenclature of Ingredients
10.30am-11.00am	Morning Break
11.00am-1.00pm	Product Notification This module helps to enable a participant to understand the product notification. The topics include who should do the Notification, How to submit the notification, Responsibility of the Cosmetic Notification Holder, Submission of Notification, Language, Privacy Marking and Fee, Notification Validity Period, Manufacture or Importation of Product. Changes in Notification Particulars and Notification Number
1.00pm-2.00pm	Lunch
2.00pm-3.30pm	Regulatory Requirements for Cosmetic Products In module focus on the topics including Product Particulars, Safety Requirements, Cosmetic Ingredients, Labelling Requirements, Cosmetic Claims, Cosmetic Advertisement, Product Recall, and Reporting of Adverse Event
3.30pm-4.00pm	Tea Break
4.00pm-5.00pm	Product Information File (PIF) In this module, the participants would learn the administrative Documents and Product Summary, Quality Data of Raw Materials, Quality Data of Finished Product, Safety and Efficacy Data, Who responsible for PIF and PIF Audits.

Time	Day Two
9.00am– 10.30am	Post Market Surveillance Programme This module helps the participants to manage and conduct the post Market Surveillance (PMS) Activities and product Sampling Requirements
10.30am-11.00am	Morning Break
11.00am-1.00pm	Regulatory Action Rejection of Notification Submission Cancellation of Notification Note and Punitive Action/Penalty is the topics that would cover in this module.
1.00pm-2.00pm	Lunch
2.00pm-3.30pm	Notification Withdrawal and Notification Exemption In this module, the participants would learn the Market Sampling, In–House Evaluation, Product for Export Only (FEO) or Re-Export, In-Transit, Product to be Sold or Supplied in Free Trade Zone or International Carriage and methodology on Entering or Leaving Malaysia.
3.30pm-4.00pm	Tea Break
4.00pm-5.00pm	Enhancing Services In this module, the participants would learn Certificate Of Free Sale (CFS) and the HALAL requirement that applies to the cosmetic products in Malaysia.