TOPIC

Variations to Market Authorisations: SAHPRA & EU Guidelines & Requirements

PRESENTER:

Salma Ismail
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Salma Ismail who has a B.Pharm. MSc Med. MAP; is the CEO of Twinz, Regulatory Affairs Pharmacist Consultants based in Johannesburg.
As a young Wits graduate, Salma entered the Pharmaceutical Industry sector and moved from R & D into production of pharmaceuticals and then entered the pharmaceutical regulatory science sector.
Her responsibilities are to evaluate and understand legislation to ensure practical implementation within the pharmaceutical industry.
Her experience covers many countries within the SADC region, with particular attention to NCE (new chemical entity) submissions, generic submissions and Biologicals and Biosimilars.
Her expertise lies in Regulatory Affairs including Legislation, Technical issues, Marketing Regulations and Training.
Salma was former CHAIRPERSON of SAPRAA (SOUTH AFRICAN ASSOCIATION OF PHARMACISTS IN REGULATORY AFFAIRS) and has represented SAPRAA on the Industry Task Group (ITG) as VICE CHAIRPERSON, ITG. Salma is also involved in academia by lecturing on relevant pharmaceutical REGULATORY matters at various Universities in South Africa.
Through a branch of her company known as TWINZ FOUNDATION FOR PHARMACEUTICAL SCIENCES, Salma also conducts training of Regulatory Affairs Professionals on various matters pertinent to the Pharmaceutical Industry and courses may be specially tailored to the Pharmaceutical Industry Client's needs. She also facilitates training for the Management Forum UK, in London annually as well as to select Training firms in Saudi Arabia.

COURSE OUTLINE:

eCTD variations play a critical role in the **regulatory lifecycle of pharmaceutical products**, ensuring that post-approval changes meet compliance requirements while maintaining product quality, safety, and efficacy. In South Africa, **SAHPRA's Variations Addendum** aligns closely with the **EU Variations Guide**, providing a structured framework for the submission and classification of variations.
In this workshop, we will explore the **theory and regulatory requirements** surrounding eCTD variations, with reference to the **European Commission (EC) system** and SAHPRA's latest guidelines. We will examine the classification of variations, procedural requirements, and best practices for submission.
A structured review of key variation categories will be conducted, including:

- **Introduction to the European Commission System for Variations**
    - Understanding the regulatory foundation and global implications.
    - Classification, submission pathways, and approval processes.
- **Review of SAHPRA's Latest Requirements and Finalised Guidelines** – Key updates and differences between SAHPRA and EU processes.
- **Pharmaceutical and Clinical Variations** – Regulatory expectations and documentation requirements.
- **Biological Variations** – Specific considerations for biological products and biosimilars.
- **Practical Advice on the Preparation and Submission of Variation Applications** – Step-by-step guidance for efficient and compliant submissions.

Finally, we will discuss practical approaches to **compiling and submitting variations** in South Africa, including strategies to ensure regulatory success and minimize delays. Real-world case studies and examples will be reviewed to reinforce key learnings and provide actionable insights for industry professionals.

WHO SHOULD ATTEND THE COURSE:

This training is ideal for professionals involved in the regulatory, legal, or compliance aspects of pharmaceutical and healthcare product management. The course is specifically designed for:

- **Regulatory Affairs Professionals**: Those involved in managing market authorisations, submissions, and approvals for pharmaceutical products in South Africa and the EU.
- **Product Development Teams**: Professionals involved in the development of pharmaceutical products who need to understand regulatory changes and variations that affect market authorisations.
- **Pharmacovigilance and Safety Officers**: Individuals responsible for monitoring product safety and adverse reactions, ensuring compliance with reporting requirements under varying regulatory frameworks.
- **Regulatory Affairs Trainees or New Entrants**: Professionals who are new to regulatory affairs or those looking to expand their knowledge on regulatory variations in South Africa and the EU.

This course will provide valuable insights for anyone involved in navigating the regulatory landscape of pharmaceutical product market authorisations and variations, equipping participants with the knowledge to manage changes and ensure compliance in both the South African and EU markets.

WORKSHOP OUTCOMES:

By the end of this workshop, participants will:

✅ **Understand the European Commission (EC) System for Variations** – Gain insight into the regulatory framework governing post-approval changes in the EU and its influence on global regulatory practices.

✅ **Apply Current Variations Regulations and Procedures** – Learn how to classify and submit variations effectively in line with EC and SAHPRA guidelines.

✅ **Navigate SAHPRA's Latest Requirements and Guidelines** – Understand the most recent regulatory updates, including classification and documentation expectations for variation submissions in South Africa.

✅ **Differentiate Between Pharmaceutical, Clinical, and Biological Variations** – Recognize the specific requirements and considerations for different types of variations.

✅ **Prepare and Submit Compliant Variation Applications** – Develop the skills to compile accurate, complete, and well-structured eCTD variation submissions to meet regulatory expectations.

✅ **Identify Common Challenges and Best Practices** – Gain practical insights into avoiding deficiencies and streamlining the submission process.

✅ **Implement a Strategic Approach to Variation Management** – Learn how to integrate regulatory knowledge into an efficient variation submission strategy for successful approvals.

WORKSHOP AGENDA:

DAY 1

Time	Topic
08:30 – 08:45	Course Objectives & Introduction

08:45 – 10:00	• Product Life-Cycle Variations/Amendments
	  o What is a variation/amendment?
	  o Terminology
	• World Health Organisation (WHO)
	• The European Medicines Agency (EMA)
	• EMA General Regulatory Procedure Types
	• EU Variations
	  o EU Categories of Variations
	  o Grouping of Variations
	  o Work-sharing of Variations in the EU
	• EU Editorial Changes
	• Polls

10:00-10:15	TEA BREAK
10:15 – 12:00	• EU Variation Guideline • EU Scoping of Variations o Variation Code • EU Variations Special Cases • Unforeseen Variations • Supporting Documentation • European Medicines Agency post-authorisation procedural advice for users of the centralised procedure
12:00 – 12:30	• Assessment Workshop Online

DAY 2

08:30 – 08:45	Recap from Day 1

08:45 – 10:00	• SAHPRA Variations Addendum
	  o Exceptions and clarifications
	  o Documentation requirements – Clinical
	  o Urgent safety restriction notices (USRN)
	• SAHPRA Biological variation Guideline

10:00-10:15	TEA BREAK
10:15 – 12:00	• Grouping of Variations in South Africa • Published SAHPRA submission matrix • SAHPRA Approval Timelines • Reliance • SAHPRA Responses • Variation Fees • Module 1.2.1; Module 1.2.5; Module 1.5.2.1; QOS & QIS • APIMF Procedure • Priority Review Requests • SAHPRAs eCTD Submission Portal • SAHPRA Online Portal
12:00 – 12:20	• Poll • Questions from the Team
12:20 – 12:30	• Closure