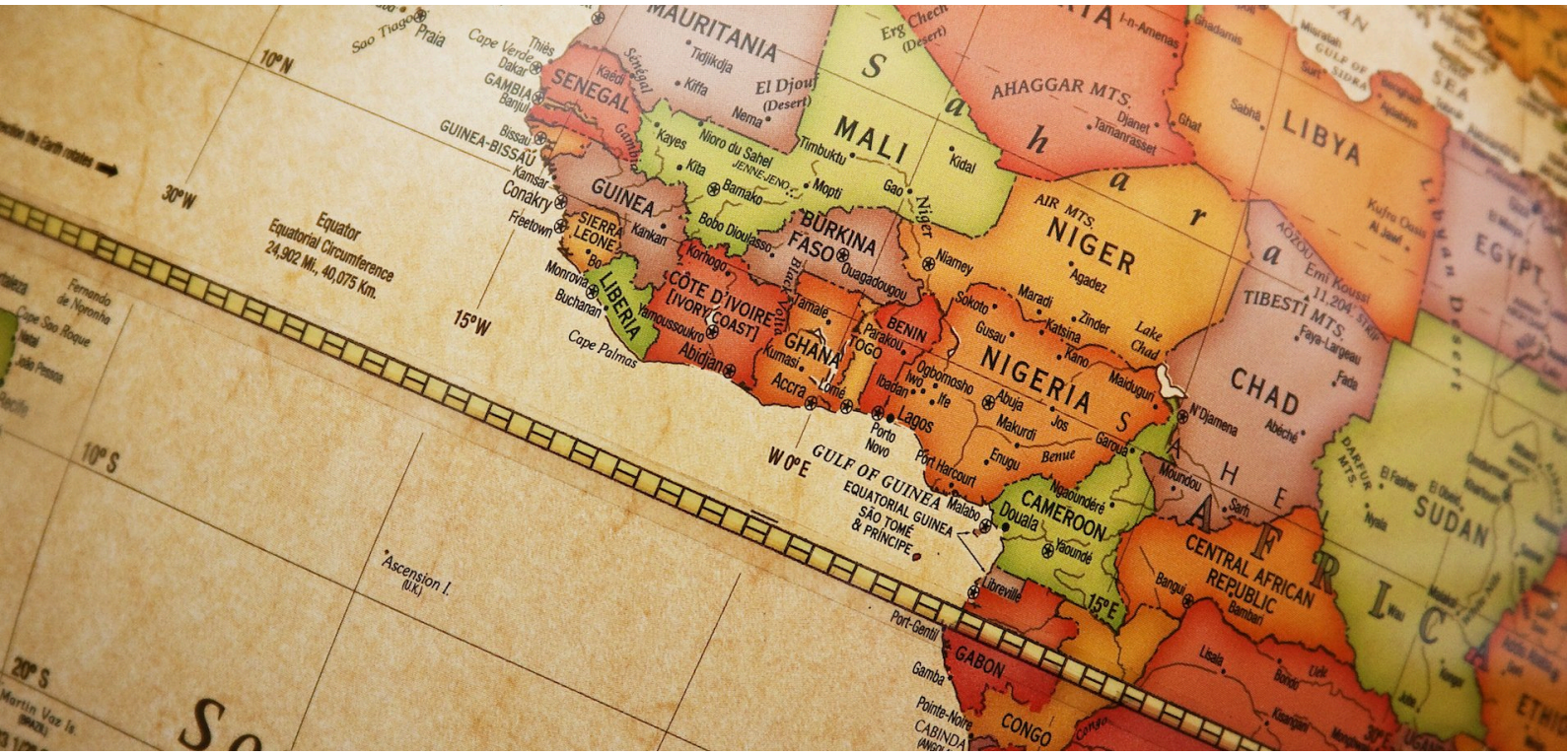
IPI Academy

MANAGEMENT forum




*Presented by*
**Management Forum**

# Pharmaceutical Regulatory Affairs in Africa

**22-23 July 2025**
+ 4-5 November 2025

Covering the key regions of South Africa, Namibia, Zimbabwe, Zambia, Malawi, Tanzania, Kenya, Uganda, Nigeria, Ghana and Maghreb countries - Algeria, Morocco, Tunisia

**Format:**
Live online

**CPD:**
12 hours for your records

Certificate of completion

# Course Overview

**The value of the African pharmaceutical market is increasing and growth is expected to continue at a rapid pace.** There are a number of distinct markets within the region, each with their own economic and regulatory characteristics. This event will explore the key areas of African regulatory affairs, including the new SAHPRA guidelines in South Africa, and will focus on practical aspects to assist with your regulatory activities. The expert speakers will share their knowledge of working in the region and the programme will include interactive discussion sessions to enable you to share experiences with other delegates.

Covering the key regions of Algeria, Botswana, Ethiopia, Ghana, Kenya, Malawi, Morocco, Mozambique, Namibia, Nigeria, South Africa, Tanzania, Tunisia, Uganda, Zambia, Zimbabwe.

**Benefits of attending:**

- Gain an overview of the regulatory requirements within African countries
- Understand requirements for company and product registration
- Learn practical information on compiling dossiers
- Discuss the new SAHPRA guidelines in South Africa
- Explore the harmonisation and cooperation initiatives in Africa, including the new African Medicines Agency

Participants will receive a course material folder containing comprehensive documentation provided by the speakers, which will be a valuable source of reference for the future.

## Who should attend?

This event will be of particular interest to all those who need to learn about successful marketing authorisation applications and regulatory compliance in key African areas. It will be useful as both an introductory and a refresher course on recent developments.

# Programme

## Day 1

**Basic terms and environment**

**Harmonization initiatives**

**Regional presentations**

Each regional presentation will cover:

- The development of drug control
  - The regulatory authorities
  - Other influences
- Regulatory submission strategy
  - How to determine an appropriate submission strategy
  - A practical approach
- The development of drug control
  - The regulatory authorities
  - Other influences
- Company and product registration
  - Regulations and guidelines
  - New products and line extensions
  - Labelling requirements
  - Registration samples and certification/legalisation
- Compilation of the dossiers
  - Contents and formats
  - Hints on success/failure
  - Specific country requirements
- Regulatory authority/agency assessment
  - Process
  - Timelines

**South Africa**

- Influences and changes
- The new SAHPRA guidelines
- Latest regulatory processes adopted by SAHPRA
- Complementary and alternative medicines status
- Marketing code for the advertising of medicines

**Namibia**

**Botswana**

**Zimbabwe**

**Zambia**

## Day 2

**Malawi**

**Tanzania**

**Kenya**

**Uganda**

**Nigeria**

**Ghana**

**Maghreb Countries - Algeria, Morocco, Tunisia**

# Presenters

**Salma Ismail**

Salma Ismail is the CEO of Twinz Regulatory Affairs Pharmacist Consultants based in South Africa. Salma has over 20 years of experience within the Pharmaceutical Industry and in Regulatory Affairs, which includes understanding of legislation, technical issues, marketing regulations and training people within the pharmaceutical industry.
Her company is very involved with the submission of product applications for registration to regulatory authorities in South Africa and English speaking Africa for products from a diverse area that includes new chemical entities, generic molecules, biological medicines, complementary medicines including health supplements, medical devices and applications to regulatory authorities within the SADC region. Her company also deals with product life cycle maintenance by dealing with variations for submission to the authorities.
She is also involved in academia by lecturing on relevant pharmaceutical regulatory matters in prestigious universities in South Africa as well as training people from within the pharmaceutical industry environment.
Salma is the former Chairperson of SAPRAA (Southern African Pharmaceutical Regulatory Affairs Association).

**Makram Nehme**

Makram Nehme is a Regional Regulatory Consultant having relevant experience with multiple multinationals including Parexel international, based in Lebanon. He has more than 10 years' experience in the Pharmaceutical and Medical Device Industry and is a Regulatory Expert covering the Middle East and North African markets. His experience includes negotiations with the Ministry of Health and Drug Agencies in the region, as well as training of key personnel and he has a proven record in regulatory submissions, analysis, product pricing and reimbursement across the MENA region.

# Course dates

| | | |
|---|---|---|
| **22-23 July 2025** | **Live online**<br>09:30-15:30 **UK (London)** (UTC+01)<br>*Course code 14756* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 17 Jun** |
| **4-5 November 2025** | **Live online**<br>09:30-15:30 **UK (London)** (UTC+00)<br>*Course code 15250* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 30 Sep** |

## How to book

**Online:**
ipi.academy/1767

Alternatively contact us to book, or if you have any queries:

**Email:**
info@ipiacademy.com

**Phone:**
+44 (0)20 7749 4749

## Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

## Further information

**Fee**
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

**Please note**
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

**Terms and conditions**
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

# Reviews

★★★★★

**Very good. I liked all parts of this event. Both [speakers] were communicative, expressed themselves perfectly, exposed the topic very well and detailed. I recommend.**

**Maria de Castilho Veloso**
Regulatory Affairs Junior Officer
Generis Farmacêutica S.A.
Nov 19 2024

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★★★★★

**Presentations/content and speakers were well rounded and provided valuable information for my job that showed the experience they had to give me confidence in the information provided. The whole program, process and all was well worth the cost and time. I will recommend to others - already have!**

**Angela Turner**
RA Director

May 26 2021

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★★★★★

**Very good, especially the opportunity to ask specific questions to the speaker with so much experience on the field.**

**Laia Gispert**
Regulatory affairs Expert
GALENICUM HEALTH, S.L.
Nov 11 2020

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★★★★☆

**Salma Ismail was very good. She did speak with passion and I liked her way how she presented the different topics. Makram Nehme was also very good.**

**Hildur Sif Pálmarsdóttir**
Submission Manager
LEO Pharma
Oct 1 2018

## Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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