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Pharma Regulatory Affairs

28 - 29 June 2018 | Mandarin Orchard Hotel, Singapore

Key Learning Outcomes

- Current priorities in regulatory compliance across the Globe and Asian Markets
- Understand the approval, submission, registrations processes and differences in requirements for R&D products and generics
- Understanding markets and exclusivity – what is being regulated
- Regulations and procedures for biosimilars and generics
- Discuss harmonisation initiatives including ASEAN opportunities
- Discover general country specific and regional requirements
- Regulatory strategies for OTC products
- Pharmacovigilance and individual country requirements
- Tackling supply chain, packaging and labelling regulations
- Emerging regulatory issues in the digitalisation of Pharma

Dedicated Case Studies and Exercises on:

- ASEAN generic launch
- Asian OTC products
- European /US opportunity

Who Should Attend

Personnel from

- Analytical Research and Development
- Clinical Development
- Quality Assurance
- New Business Development Departments
- Regulations and Compliance
- Market Access, Market Development and Marketing professionals

Course Director

Peter Wittner, B.Sc., is an independent consultant specialising in the commercial aspects of generics with nearly 40 years' pharmaceutical experience. The major part of this has been spent in the generic industry. He was Managing Director for the UK subsidiary of the Indian generic leader Ranbaxy, having joined them to set up the business before returning to consultancy work.

Before that, Peter had headed the European Sales & Marketing department of the UK generics companies Evans Medical and H.N. Norton, which later became part of IVAX and then Teva.

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- All participants receive a Course Certificate

Pharma Regulatory Affairs

About the Course Director

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In the field of generics, Interpharm works with new market entrants on developing commercial strategies, compiling competitor intelligence, assisting in business development and gaining EU-GMP approval for companies outside the EU that are trying to enter the market. Peter has also assisted in generic product in- and out-licensing negotiations both in the EU and US markets. Recently, he has become increasingly involved in the field of biosimilars.

On the other side of the equation, Interpharm has also worked with originator companies that are looking at ways of defending their major brands from generic incursion or are themselves considering entry in to the field of generics.

Peter is a regular speaker at generic and biosimilars conferences, and runs workshops on generic and Biosimilars topics for various organisations as well as conducting training seminars. He has written a number of reports on generics industry topics and a series of reports for Decision Resources and other publishers. Originally based in north London, Peter has now relocated to Israel.

About the course

Navigating through the complex environment of Pharma regulatory affairs to gain market access

Being up-to-date with current requirements and understanding individual authority interpretation of guidelines is critical for all pharma companies. The challenge in Asia is the frequency of changing regulations and increasing time-lag for regulatory approval. These factors can significantly impact your time to market and bottom line.

The most crucial stage for a pharmaceutical company to launch a new drug is getting the regulatory approval. The process is tedious, time-consuming and often lacking clarity that doubles up the effort and time needed to launch a new drug. Asia poses a potential and vast market for pharmaceutical companies but the channel to launch a pharma product could be extremely complicated. Asian countries have their own regulatory structure that requires different norms for drug approval. A global pharmaceutical company needs to follow different regulatory process of each Asian country in order to launch one pharmaceutical product.

This unique seminar will take a practical approach and delve into the nuts and bolts of region's changing and complex regulatory landscape and enable you to formulate strategies to access and penetrate the Asian pharmaceutical market.

Key focus areas will include the approval, submission, registrations processes and differences in requirements for generics, brands, biosimilars and OTC drugs, regulatory harmonisation, pharmacoviligence and digitalisation.

What Past Delegates Liked About our Pharmaceutical Courses

"Exercises were useful and trainer is knowledgeable"
~ Noor Aida Binti Jaafar, Head of Marketing & Specialty Care, CCM Pharmaceutical

"Case Studies and the workshop activities really helped a lot and more practical"
~ Praveen Kumar, Senior Manager, Pharmaniaga

"Informative & insightful. Had a chance to network and share discussion / cross learn from participants"
~ Chng Kien Peng, Executive Director, Xepa-Soul Pattinson (S) Pte Ltd

"The course is very relevant to my job. The case studies and the workshop activities really helped a lot and were practical."
~ Avadhanula Yagna Praveen Kumar, Senior Manager Intellectual Property, Pharmaniaga BHD

"Very informative. It covers all scopes under the topics"
~ Norliza Binti Abdullah Zawawi, Legal Assistant Manager, Pharmaniaga Berhad

IBC Asia Upcoming Related Events:

Pharma Pricing
– Commercial and Regulatory Strategies
26 – 27 June 2018, Singapore

Pharmacon Asia 2018
(18 – 21 September 2018, Singapore)

- Pharmaceutical Regulatory Affairs Asia
- Pharma Market Access & Pricing Asia
- Accelerating Clinical Trials in Asia
- Digital Pharma Asia

COURSE OUTLINE

Course Registration: 8:30am
Course Commencement: 9:00am
Course Conclusion: 5:00pm

Explanation of Timings: These times act as a guide and may be modified slightly on the depth of class discussion and whether assessments are being conducted.

Course Programme: This program is a guide and may be altered to better address participant requirements on a consensus basis.

2-DAY COURSE OUTLINE

DAY ONE

THE BACKGROUND – WHY DOES REGULATION EXIST?

- Why is registration necessary?
  - » History of regulatory requirements
  - » The Pharmacopoeia
  - » How Thalidomide changed everything
- History – overview of how the regulations developed
  - » The main regulatory bodies - who, what and how
  - » UK's CSM
  - » US FDA
  - » Europe – the EMA
  - » Moves towards harmonisation – ICH
- Overview of differences between requirements for R&D products and generics
  - » Hatch Waxman (US)
  - » European directives
    - * EU definition of a generic
  - » Biosimilars – simplified, but still complex

UNDERSTANDING MARKETS AND EXCLUSIVITY – WHAT IS BEING REGULATED

- Impact of patents and Data Exclusivity
  - » Europe – quality, safety and efficacy
  - » Europe – launching before patent expiry
  - » US – challenging patents by filing an ANDA
  - » US – what is Paragraph IV?
- What is data exclusivity?
- ASEAN considerations
  - » How do the national regulations compare?

GENERICS AND BIOSIMILARS

UNDERSTANDING BIOSIMILARS REGULATIONS

  - » Why the interest?
    - * Hybrid products – not originators, but not really generics
    - * Markets and products
    - * Success stories
  - » History of biosimilar regulatory procedures
    - * Europe – path finders
    - * USA – slow starters
    - * ASEAN countries
    - * India and China
- Regulatory requirements for generics
  - » Relevant legislation – US, Europe and key Asian markets in focus
  - » Impact of regulatory processes on the market
- Legislation –a bit more detail
  - » Hatch Waxman (US)
    - * Why was it introduced?
    - * Advantages for originators
    - * Advantages for generics
  - » European directives
    - * Removing the barriers
    - * Generic definition
    - * European reference product
- European Regulatory mechanisms
  - » Centralised, DCP, MRP systems
    - * Who reviews the dossier?
      - – The different European bodies
- Bioequivalence
  - » What is it?
  - » Which reference products can be used
  - » CTD European style
- Moves towards international harmonisation
  - » ICH – purpose and aims
  - » From paper to CDs and on-line filing – eCTD
    - * The five modules:
      1. Administrative information and prescribing information
      2. Common technical document summaries
      3. Quality
      4. Nonclinical study reports
      5. Clinical study reports

BRAND TO OTC SWITCH

- Why switch?
  - » Advantages
  - » Disadvantages
- Rules and regulations – overview
  - » What can be switched?
  - » Are the rules uniform everywhere?
- Individual ASEAN country requirements
  - » Singapore, Malaysia, Indonesia and Philippines

REVIEW OF DAY 1 TOPICS AND QUESTIONS

DAY TWO

FOCUS ON ASEAN – PART 1

Guest Speaker: Vicky Han, Senior Director, Policy Group Lead for Asia Pacific, Global Regulatory Affairs, **Janssen Asia Pacific,** Singapore

- Current priorities in regulatory compliance in APAC with focus on ASEAN countries
- Key areas of noncompliance, and frameworks to manage them
- Regulatory updates - harmonization, new policy, clarity and speed in licensing, submission and approval in the region
- Recent Trend of Pharmaceutical Regulations – Approvals, Submissions, Registrations, Pharmacovigilance, New Medicine Development, patient labelling
- eCTD and RPS – APAC Progress in eSubmissions
- Accelerating Drug Approval in Asia - Overview of Time-Frames, Drug Registration Procedures, Opportunities and Challenges
- Regulatory strategies for OTC products - Registration, License, Compliance, Safety and Risk Control
- Accelerating Drug Approval in Asia: Time-Frames and Procedures
- Whats next?

FOCUS ON ASEAN – PART 2

- After registration ASEAN
  - » Pharmacovigilance – monitoring safety
  - » Individual country requirements
- Variations
  - » Definitions and Types
    - * What is needed?
- Pharmaceutical competition law
  - » What are the issues?
  - » ASEAN focus

SUPPLY CHAIN, PACKAGING AND LABELLING

- Supply Chain regulations
  - » Counterfeit drugs
    - * Overview of the problem – how big is it?
    - * Can you spot the fakes?
  - » Patent infringement – not the same as counterfeiting
  - » EU – FMD - Falsified Medicines Directive
    - * History
    - * Aims
  - » US – DSCA - Drug Supply Chain Security Act
    - * History
    - * Aims
    - * Deadlines
  - » Solutions
    - * Meet EPCIS (Electronic Product Code Information Services)
  - » Asia – a fragmented approach
- Measures to avoid counterfeiting
  - * Serialisation
  - * 2d barcodes -
- Packaging text regulations
  - » What should the text show?
    - * Prescription packs
    - * OTC packs
  - » What should it not show?
- Leaflet texts
  - » What do they need to show?
  - » Physician's leaflet and patient leaflets – the same but different
- How ASEAN countries view the issue

PHARMA 4.0 – EMERGING REGULATORY ISSUES IN THE DIGITALISATION OF PHARMA

- Data protection and privacy
- Digital Health Technology (DHT) – what does it mean?
- Other areas?

REVIEW OF DAY 2 TOPICS AND OPPORTUNITY FOR QUESTIONS

Pharma Regulatory Affairs

5 EASY WAYS TO REGISTER

MAIL the attached registration form with your cheque to
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(Assistant Director Of Business Development, Catering Sales)
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Payment must be received 10 business days prior to the event. To take advantage of discounts with an expiry date, registration and payment must be received by the cut-off date.

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