Pharma Regulatory Affairs
Risk Management

29 June - 2 July 2020  4-Day Live Online Learning | 9:00am-1:00pm (SGT)

Delivered in Live Online Learning Format

Course Director
Chuan Yao, Principle Consultant, ChemPharm
Chuan Yao has over 30 years’ experience in the pharmaceutical and medical device industry and has worked in China, New Zealand, Australia, Singapore and other ASEAN countries. He’d led Quality Assurance, Regulatory Compliance and Regulatory Affairs projects for various regions across the world. He has a wealth of knowledge in validations, project management, GxP, and has delivered consultancy and training courses to hundreds of clients.

Key Learning Outcomes & Case Studies Include

- 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
- Regulations and procedures for generics, biosimilars, orphan drugs, combination products, biologics
- Understanding markets and exclusivity – what is being regulated
- 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
- Ethical and legal issues in the importation of unlicensed medication from overseas or over the internet at patient’s own risk
- Emerging regulatory issues on data protection & privacy in the digitalisation of Pharma

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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 players. With rapidly changing regulations in place, regulatory approval is a tedious, time-consuming process that may significantly impact your time to market and bottom line.

This practical seminar delves into the nuts and bolts of the region's complex regulatory landscape and enables you to formulate strategies to access Asian pharmaceutical markets. Key focus areas will include the approval, submission, registrations processes and differences in requirements across various drug segments, pharmacovigilence and digitalisation.

ABOUT THE COURSE

Chuan Yao, Principle Consultant, ChemPharm

• Over 30 years’ experience in the pharmaceutical and medical device industry
• Worked in the industry in China, New Zealand, Australia, Singapore and other ASEAN countries

Expertise and Responsibilities include

• Led areas including Quality Assurance, Regulatory Compliance, Validations, Project Management, GxP and overall Regulatory Affairs
• Maintenance of regulatory compliance of active ingredient manufacturer’s drug master files (DMF) and European certificates of suitability (CEPs)
• Analytical testing and quality control experience, production engineering experience involving trouble shooting, process optimisation and long-term process/product development activities.
• GMP compliance auditing while employed by China State Food and Drug Administration (CFDA)
• Led GxP Compliance at Pacific Pharmaceuticals (New Zealand, now Merck Group), Go Medical Industries (Australia), Wyeth (Singapore, now Pfizer)
• Currently leading consultant teams to participate GMP/GLP/GDP/GVP projects in mainland China, Hong Kong, Taiwan, Australia, New Zealand and ASEAN countries.
• Appointed as a Drug Abuse Inspector with the China Drug Control Center, and assigned position as a drug inspector at the Beijing 11th Asian Games (Awarded an Honorary Diploma from the Olympic Committee)
4-Day Course Syllabus

**SESSION 1: ESSENTIALS OF PHARMACEUTICAL REGULATORY AFFAIRS**
- Regulatory affairs primer
  - The main regulatory bodies
  - The function and evolutions of regulation
  - Moves towards harmonisation – ICH
- The life-cycle of a drug product
  - Product development process
  - Nonclinical studies and Good Laboratory Practice
  - Clinical development and Good Clinical Practice
- Product registration
  - Regulatory strategy
  - Regulatory Intelligence
  - Common Technical Document (CTD)
  - eCTD
  - CMC
  - Interacting with Regulators
- Post marketing approval
  - Pharmacovigilance and risk management
  - Good Manufacturing Practice (GMP)
  - Variations and supplements
  - Advertising & Promotional Labelling
- Regulatory issues in the digitalisation of Pharma
  - Data protection and privacy
  - Digital health technology

**SESSION 2: REGULATORY STRATEGY – BIOLOGICS**
- Key terms related to Biologics
- Large-molecule (biologic) therapies & trends
- Different classes of biological products such as Vaccines, monoclonal antibodies and gene therapy
- Regulation highlights
- Steps to successful regulatory submissions

**SESSION 3: REGULATORY STRATEGY – GENERICS AND BIOSIMILARS**
- Hatch-Waxman Act
- Regulatory requirements for generics
- What is Biosimilar
- Biosimilar development process
- Choosing the reference product
- Regulatory pathways for the approval of biosimilars
- Biosimilar vs. Generic

**SESSION 4: REGULATORY STRATEGY - ORPHAN DRUGS**
- Rare disease development strategies
- Orphan Drug designation (US, European, China)
- Government incentives for Orphan Drugs
- Develop a “fast to market” orphan regulatory strategy
- Leverage academic and patient group to support Orphan Drug registration in China
- Regulatory environment about Orphan Drug in China – rare disease list
- China registration pathway
- Case studies

**SESSION 5: REGULATORY STRATEGY - COMBINATION PRODUCTS**
- What is Combination Products
- Type of Combination Products
- Similarities and differences in drug and device regulations
- Early development considerations for Combination Products
- Request for Designation (RFD)
- Quality Management System for Combination Products
- Regulatory route for Combination Product Approval
- Case studies

**SESSION 6: RX TO OTC SWITCH**
- Trends in Rx-to-OTC switching
- Advantages and disadvantages for switch
- The Rx-to-OTC switch process
- ASEAN country requirements
- OTC labelling

**SESSION 7: EMERGING TRENDS IN DRUG DEVELOPMENT AND REGULATORY CONVERGENCES IN ASIA PACIFIC**
- Focus on ASEAN – part 1
  - 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
- What’s next?

**SESSION 8: REGULATORY ISSUES IN PHARMA (ASEAN)**
- Overview on marketing and advertising rules of pharmaceutical products
- Online sale of pharmaceutical products and potential risks and issues
- Overview of key issues in pharmaceutical distribution agreements

**SESSION 9: SUPPLY CHAIN, PACKAGING AND LABELLING**
- Current regulatory issues
  - The Falsified Medicines Directive requirements in practice
  - Patient compliance and safety
  - Serialisation of pharma folding cartons
- Special requirements – readability, braille, child proof, tamper evidence
- Packaging – the patient to business interface
  - Primary packaging
  - Secondary packaging
  - ISO 15378:2017 Primary packaging materials for medicinal products
  - Concept of patient compliant packaging
- Artwork and labelling
  - Implementing a GMP compliant artwork process
  - Labelling for safety
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