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Life Science Training Academy

Regulatory Affairs for Clinical Trials

23-24 June 2020 | Mandarin Orchard Hotel, Singapore

2+1 Offer!
See registration page for details!

Our Expert Course Instructor

Dr. Salma Michor
(PhD, MSc, MBA, CMgr, RAC-Treasurer), CEO, Michor Consulting
Salma has advised hundreds of global clients across Health and Food industries, including J&J, Novartis, Pfizer, Baxter, BSI, Shire. She is an independent expert to the European Commission, a member of the RAPS Board of Directors and a lecturer at Denube University Krems (Austria). Salma is recognised for her expertise in Clinical Project Strategies, Medicinal Products' Regulatory Affairs, Labelling & Packaging, Quality & Risk Management and Pharma Business Leadership.

Key Learning Outcomes & Case Studies Include

- Legal aspects underpinning clinical trials (globally and Asian region): Data Privacy and Integrity, Ethical Principles, Financial Transparency and Authorisations
- Important and amended regulations in clinical trials and how they affect study designs & protocol
- Risk-based quality management in clinical trials especially for Asia
- Key considerations in use of technology in clinical trials
- Develop effective study designs for multi-country clinical programmes
- Regulatory risk assessment and mitigation
- Best practices in inspection preparation
- Case studies of protocol deviation, violations and prevention

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ABOUT THE COURSE

Clinical trials are booming in Asia as sponsors are investing to gain access to large population of patients. As cost and complexity continue to increase, extensive understanding of local regulations, ethical obligations, GCP guidelines shortens startup times and heightens chance of clinical approval.

Hands-on and succinct, this seminar encapsulates legal & regulatory aspects underpinning clinical trials globally and with particular spotlight on Asian countries. Through real-world case studies and group exercises, you will develop effective approaches to assessing, monitoring, identifying and mitigating nonconformance risks. Practical discussions will include ethics committees' submissions, patient affairs, clinical data integrity, regulatory inspection preparation, technology vs compliance considerations, among many more.

WHO SHOULD ATTEND

Executives involved in Clinical Trials, Risk Management, Regulatory Affairs & Quality Control from Pharmaceutical Manufacturing, CRO, Consulting companies:

- Medical Affairs
- CRO Management
- Site Management
- Regulatory Affairs
- Budgeting & Outsourcing
- Project Management
- Quality Assurance, Quality Control
- Patient Affairs/Patient Recruitment
- Data Management, Data Operations, Clinical Statistics Management
- Contract, Finance, Purchasing, Project Controller
- Clinical Trials (Oversights, Development, Outsourcing, Monitoring)

WHAT DELEGATES LIKED ABOUT OUR COURSE DIRECTOR

"Trainer has excellent knowledge. Training materials are informative and good opportunity to engage in conducive group works. The programme builds awareness over quality control and SOP within supply chain especially regarding products' labelling"
Hussain Raaidh Mohamed, Manager – Hospital Supplies Division, **State Trading Organisation**

"Course director presents and instructs very clearly regulatory aspects and case studies across different countries"
Cheong Yong Kang, Senior Engineer, **Hoya Medical Singapore**

"Trainer is knowledgeable and offers comprehensive end-to-end experience on contract manufacturing"
Moe Khine Zaw, CEO, **Pacific Pharmaceuticals USA**

"Experienced facilitator. Lot of suggestions gained from group exercises relating to quality agreement preparations and communication process"
Lee Jong Nyung, TO Manager, **Janssen**

EXPERT COURSE INSTRUCTOR

Dr. Salma Michor (PhD, MSc, MBA, CMgr, RAC-Treasurer), CEO, Michor Consulting

Salma has advised numerous global clients across Pharmaceutical, Medical and Food industries, including J&J, Novartis, Pfizer and Shire and many more.

She had previously worked for Torrex-Chiesi (Chiesi Farmaceutici S.p.A); Wyeth Whitehall Export, and Croma Pharma GmbH and had been the Director of Global Supporting Operations – Medical Devices and Pharmaceuticals (Ophthalmology & Orthopedics) where she was in-charge of technical and leadership of four departments - including Regulatory Affairs and Compliance; Medical and Vigilance; Change Control and Life Cycle Management; as well as Packaging and Pharmaceutical editing. Her duties included overall leadership & personnel management, budgeting and strategic planning, liaison with external contractors, doctors and customers in 60 countries worldwide. Here she also gained first-hand experience with submission of clinical trials phases: I-III as well as turnaround management of post-Mergers and Acquisitions integration operations.

Her experiences include:

- Post-acquisition phase-out and closedown after M&As
- Managing DCP registrations
- Consolidation of Multi-language labelling texts for pharmaceutical products and medical devices
- Forming clinical and registration strategies for medicinal products (combination, generics)
- Labelling compliance for drugs & food supplement
- Authoring CMC sections for drug products or drug/device combination products
- Preparing pharmaceutical and medical device companies for internal and FDA audits
- Managing large company-wide compliance projects (CAPA, GMP, ISO, etc)
- Preparing companies in 3rd countries for EMA, MHRA and AGES inspections and managing the whole biotech registration and clinical testing in the EU

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Informa Connect Singapore is the Trading name for IBC Asia (S) Pte Ltd. Our name has changed but our vision and purpose remain the same.

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2-Day Agenda Outline

LEGAL ASPECTS UNDERPINNING CLINICAL TRIALS

- Regulatory obligations of a Private Investigators (PI) – guidelines from GCP, IRB
- PDPA, GDPR and equivalents globally
- Health products (Clinical Trials) Act and Medicines (Clinical Trials) Act
- Informed consent/consent requirements. Specific issues:
  - Consent requirement for minors
  - adults lacking capacity
- Subject projection
- Investigational medicinal product (GMP Directive)

OVERVIEW OF THE FRAMEWORK OF CLINICAL TRIAL REGULATIONS

Global, Europe & US

- Understanding the history of clinical trial regulations
- EuradrLex 10 contents explained - Pharmaceutical Clinical Trial legislation
- ICH and its importance
- ICH GCP principles to apply to all clinical trials
- Problems experienced complying with regulations and guidelines for running clinical trials - group discussion to share experiences
- Key FDA requirements which differ from EU requirements – what are the key differences?

Asia Region

- Understanding the clinical trial regulations
- Overview of the current requirements
- What have the main problems and challenges? Examples of real scenarios
- Overview of the major new requirements of the Clinical Trial Regulations
- Specific focus in
  - China, Hongkong and Taiwan
  - Singapore, Thailand and Vietnam
  - Indonesia, Malaysia, Philippines

GOING GLOBAL: SIMULTANEOUS DEVELOPMENT IN CHINA, US, AUSTRALIA, EU

- Should You File IND in the US Before/After or Simultaneously Alongside Your China IND?
- What Are the Opportunities and Benefits of Conducting Trials in Australia
- Identify the Best Trial Management Strategies for Running your Clinical Development Programs in the US + China
- Learn from Case Studies from Biotechs Who Have Successfully Received IND Approval from US FDA

Case Study *– Develop a global strategy for a new oncology drug trial*

ETHICS COMMITTEE (EC) SUBMISSIONS AND APPROVAL

- The role of the sponsor and investigators in completing the Ethics Committee applications (group discussion to share experiences of how to efficiently obtain EC approvals)
- Subject advertising
- Informed consent requirement
- Ethical issues with clinical trials and protocol design
- Ethical considerations for running trials including in countries outside of traditional countries

CLINICAL TRIAL REGULATORY AUTHORISATION AND AMENDMENTS

- The CTA (Clinical Trial Authorisation) application for submission to the regulatory authority
- The CTA and amendments
- Clinical Trial Notification
- Clinical Research Materials
- Substantial amendments/"substantial modifications" and non-substantial amendments – discussion of the differences
- Ongoing and end of study reports
- Regulatory requirements for clinical trials – Example: US IND & IND

Group Exercise: *Ensuring Data Integrity In Your Clinical Trials*

OVERVIEW OF RECENT DEVELOPMENT IN CLINICAL TRIAL REGULATIONS

- EU inspection guidelines e.g. inspection of sponsors and CROs
- EMA guideline on requirements for first-in-man clinical trials of potential high-risk medicinal products
- EMA reflection papers including: risk-based quality management of clinical, on data from third countries, electronic Trial Master Files
- Transparency in clinical trials – clinical study reports being available
- FDA guidance risk-based monitoring
- Guidance for Industry– Electronic Source Documentation in Clinical Investigations
- Guidance for IRB continuous review of studies
- Event Reporting- Improving Human Subject Protection
- Financial Transparency in Clinical Trials
  - FDA guidance on Financial Disclosure
  - Global compliance obligations in transactional reporting
  - Centralisation of data and financial activities related to clinical trials
- Postmarketing studies and Clinical trials – risk identification & analyses system

Case Study *– What risk-based aspects of global clinical trials are relevant for Asia*

ACCELERATING CLINICAL TRIALS IN ASIA

- How can clinical trial timelines be accelerated in Asia?
- Where are the opportunities for clinical trials in Asia?
- How do you ensure readiness for FDA inspections in Asia?
- How do you ensure efficient and cost-effective trial operations in Asia?
- What is the key to successful global clinical trial conduct in Asia?
- How do you integrate risk-based monitoring for trials in Asia?

Exercise: *Regulatory Affairs in Conducting Multi-national Trials*

PHARMACOVIGILANCE AND ADVERSE EVENT REPORTING

- Adverse event reporting – requirements and definitions
- Safety reporting requirements
- What are the reporting requirements for SUSARs, DSURS, adverse events and adverse reactions?

CLINICAL TRIAL REGULATORY RISK ASSESSMENT AND MITIGATION

- Structured approach to noncompliance risk assessment and mitigation
- GCP Corrective action and preventive plans in conducting and reporting clinical trials
- Identification and definition of risk factors: CT protocol/study design, asset, operational factors

REGULATORY INSPECTION

- How to prepare for inspection
- The latest inspection policies and findings
- What questions do inspectors ask? And tips on how to answer these

COMPLIANCE CONSIDERATIONS REGARDING TECHNOLOGY USE IN CLINICAL TRIALS

- Mobile technologies in data collection, storage, analyses, access and transfer in CT
- Real time data sharing with study participants – decision support tool
- Privacy implications

INFORMACONNECT TRAINING ACADEMY UPCOMING EVENTS

- **Pharma Pricing - Reimbursement, Market Access & Regulatory Strategies**
  21-22 May 2020, Singapore
- **Pharma Regulatory Affairs Risk Management**
  20-21 April 2020, Singapore
- **Generic Drugs – Regulatory, Market Access and Product Development Strategies**
  25-26 June 2020, Singapore
- **Biosimilars - Regulation, Drug Development and Commercialisation**
  16-17 July 2020, Singapore

Regulatory Affairs for Clinical Trials

Informa Connect is A Trading Name of IBC Asia (S) Pte Ltd

23-24 June 2020 | Mandarin Orchard Hotel, Singapore

5 Easy Ways to Register

1. **MAIL**
the attached registration form with your cheque to **IBC Asia (S) Pte Ltd**
c/o Informa Regional Business Services
103 Penang Road, Visioncrest Commercial #04-01, Singapore 238467

2. **Telephone**
Customer Service Hotline +65 6508 2401

3. **Email**
register@informa.com

4. **Fax**
+65 6508 2407

5. **Web**
www.informaconnect.com.sg/clinicaltrials

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RESERVE YOUR PLACE TODAY!

❑ Yes! I/We Will Attend **Regulatory Affairs for Clinical Trials**
23-24 June 2020
Mandarin Orchard Hotel, Singapore

Register 2 Delegates & the 3rd attends FREE!
**Applicable to Normal Rates only*

FEE PER DELEGATE	EARLY BIRD RATE Register and Pay on or before 30 April 2020	NORMAL RATE Register and Pay after 30 April 2020
❑ 2 Day Training Course	SGD 3,395 (SAVE SGD 200)	SGD 3,595

- Special Group Discount pricing is applicable to groups of 2 or more delegates from the same organisation registering for the same event, at the same time.
- Fee stated is the discounted price PER DELEGATE. Only one discount applies - either the early bird rate OR the Special Group Discount.
- All fees stated include luncheons, refreshments and complete set of documentation. It does not include the cost of accommodation and travel.
- A 7% Goods & Services Tax (GST) is applicable to all Singapore based companies for Singapore venue.

Delegate 1 Details

Name: Dr/Mr/Ms
Job Title:
Department
Tel: Mobile No.:
Email:

Delegate 2 Details

Name: Dr/Mr/Ms
Job Title:
Department
Tel: Mobile No.:
Email:

Delegate 3 Details

Name: Dr/Mr/Ms
Job Title:
Department
Tel: Mobile No.:
Email:

Who is Head of your Department?

Delegate 4 Details

Name: Dr/Mr/Ms
Job Title:
Department
Tel: Mobile No.:
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Who is Head of Training?

Company Information

Company Name: | Main Business/Activity:
Address: | Postal Code:

Please photocopy for additional delegates

Payment Method (Please tick:)

❑ I enclose my bankers draft / cheque payable to IBC Asia (S) Pte Ltd

❑ I am paying by bank transfer (copy attached)

❑ Payment by Credit Card. (AMEX, VISA or MasterCard accepted)

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The best way to pay by credit card is through our secure on-line registration process, simply log on to the website at **www.informaconnect.com.sg/clinicaltrials** and click "Register On-line". If you would prefer to pay over the phone please complete the contact name and details and our Customer Services Team will call within 24 hours to take payment. As we treat your credit card information in the strictest confidence, please do not send payment details by email.

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HOTEL INFORMATION

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Contact Person: Tan Ai Li
(Assistant Director Of Business Development, Catering Sales) Email: aili.tan@meritushotels.com
Website: www.meritushotels.com

PAYMENT TERMS

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.

- Payment by bankers draft or cheque in S$ or US$ should be made in favour of "IBC Asia (S) Pte Ltd" and mailed to:
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- Payment by Credit Card (AMEX, VISA or MasterCard). The best way to pay by credit card is through our secure portal built into the website. To pay by phone please indicate the contact name and details below and our Customer Services Team will call within 24 hours to take payment. Please do not send credit card information by email.

CANCELLATIONS / SUBSTITUTION

Should you be unable to attend, a substitute delegate is welcome at no extra charge. Cancellations must be received in writing at least 10 business days before the start of the event, to receive a refund less 10% processing fee per registration. The company regrets that no refund will be made available for cancellation notifications received less than 10 business days before the event.

IMPORTANT NOTE

Please quote the name of the delegate, event title and invoice number on the advice when remitting payment. Bank charges are to be deducted from participating organisations own accounts. Please fax your payment details (copy of remittance advice, cheque or draft to +65 6508 2407).

Attendance will only be permitted upon receipt of full payment. Participants wishing to register at the door are responsible to ensure all details are as published. Informa Connect Singapore assumes no further liability or obligation, beyond the refund of the paid registration fee, in the event of postponement or cancellation by Informa Connect Singapore.

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