

Packaging & Labelling in Pharmaceutical Industry

4 Modules | 2-5 Nov 2020 | 1:30pm-5:30pm (SGT) | Live Online Learning

**2+1
Offer!**

See
registration
page for
details!



Delivered in **Live Online Learning** Format

Course Director



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 Denebe 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

- ▶ International standards and regional perspectives on medicinal packaging & labelling (P&L)
- ▶ The roles of P&L in mitigating drug supply chain risks
- ▶ Key elements of successful track-and-trace and drug anticounterfeiting systems
- ▶ Important guidelines in drug packaging, storage, handling & transportation
- ▶ Important guidelines in drug labelling and artwork
- ▶ Key considerations in maintaining a GMP-compliant artwork process
- ▶ Practical strategies for maximising patient adherence through P&L processes
- ▶ Practical case studies: OTC, biosimilars, combination products, API products and others
- ▶ Approaches for resourcing and auditing P&L suppliers
- ▶ Technological advances and applications in P&L
- ▶ Potential legal issues pertaining to labelling violations, contamination, recalls, marketing, medical affairs and more

REGISTER NOW > www.informaconnect.com.sg/packaginglabel

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WHY LIVE ONLINE LEARNING

The current Covid-19 pandemic has put strains on various areas of business, especially when it comes to deriving commercial value from new initiatives. During this phase of self-isolation and working from home, we can help you meet your professional development needs and you can still take your professional development plans to the next level.

To support your learning goals we have converted our face-to-face trainings to LIVE Online Sessions. This way you can continue to attend live and interactive training sessions within the virtual classroom space where you can see and speak, with your Subject Matter Expert and other participants.

- Progress through the course with fellow participants as you would in a classroom
- 20% price advantage, plus travel budget savings
- Controlled environment with speaker managing the Q&A and discussions
- Module based approach to help manage your time
- Earn your Digital Certification and broadcast your achievements to your peer

Trainer/Participant Interaction

- Conduct Q&A with course directors in real time
- Interactive format including breakouts, group discussions, real-time collaborative exercises and sharing of results
- Engage in live tests & polling, get immediate results and evaluations
- Chat with your fellow participants with text messages or by voice
- Follow online presentations or whiteboards in real-time
- Virtually "raise hand" to put forward Q&As with trainers
- Seamlessly receive case studies, video, documents

Learning Platform

GoToTraining

Hardware/Software Requirements

- Desktop or mobile device manufactured no earlier than 2016
- WiFi Connection, Cable or Fibre Broadband with minimum 1 Mbps of bandwidth available
- A USB headset with microphone, or a microphone and speakers built into your device

Participant Onboarding

1. Book a demo **here:** <https://www.goto.com/training>
2. Alternatively, request a personal onboarding session with Informa (only for confirmed participants) by contacting: register@informa.com

ABOUT THE COURSE

Packaging, labelling (P&L) & artwork processes play significant roles in maintaining medicinal products' quality, promoting safe use, patient adherence and responsible distribution. With various risks threatening drug supply chain integrity (drug traceability, counterfeiting, medication errors, supply shortage), regulatory guidance and compliance technologies governing the P&L procedures across jurisdictions are transforming and becoming increasingly sophisticated.

This masterclass offers global insights into and practical guidelines for ensuring P&L compliance throughout manufacturing, artwork, drug registration and distribution processes. Attendees will revise important global & regional regulations relating to P&L, how GMP-compliant artwork processes & technologies maximise drug supply chain integrity as well as disputes related to drug P&L quality. Case studies including OTC, Biosimilars, Combination products, APIs will also be examined in detail to offer attendees practical case studies in real-world setting.

COURSE DIRECTOR



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

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

- Technical leadership across 4 departments: Regulatory Affairs and Compliance; Medical and Vigilance; Change Control and Life Cycle Management; Packaging and Pharmaceutical Editing
- Forming clinical and registration strategies for medicinal products (combination, generics)
- Consolidation of Multi-language labelling texts for pharmaceutical products and medical devices
- Labelling compliance for medicinal products and food supplement
- Managing large company-wide compliance projects (CAPA, GMP, ISO, FDA etc)
- Preparing companies in 3rd countries for EMA, MHRA and AGES inspections and managing the whole biotech registration and clinical testing in the EU
- Post-acquisition phase-out and closedown after M&As

WHAT PAST PARTICIPANTS SAID

"The programme includes good overview information on pharma strategies across the ASEAN region. I enjoyed the global drug trends discussion" **Shahanar Sulaiman**, Deputy Operations Director, **Pharmaniaga Manufacturing Berhad**

"Instructor makes a complicated topic easier to understand. Great interaction with participants to discuss about projects, initiatives & market access" **Christy Oi**, Regional Financial Controller, **IPSEN Pharma Singapore**

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- Module Commencement: **1:30pm** (SGT)
- Module Conclusion: **5:30pm** (SGT)

Timing is based in Singapore Time (GMT+8) unless otherwise stated. These timing schedules act as a guide and may be modified slightly on the depth of class discussion and whether assessments are being conducted.

4-Module Course Syllabus

MODULE 1

GUIDELINES IN MEDICINAL PACKAGING, LABELLING & ADVERTISING

- International standards (ISO, GMP, GDP)
- EMA/CHMP and FDA perspectives
- EU practices on SmPC, package leaflets and product labelling
- Falsified Medicines Directive (FMD) Compliance and potential applications in ASEAN
- ASEAN harmonised labelling requirements and country-specific regulatory updates
- Private labelling law

DRUG SUPPLY CHAIN RISKS

- Drug supply chain integrity and control
- Traceability, counterfeit & drug supply shortage
- Facilitated medicines in Southeast Asia
- Adverse drug events and medication errors

ANTI-COUNTERFEITING AND SUPPLY CHAIN VISIBILITY

- Serialisation of Pharma Folding Cartons & Track-and-trace solutions
- Countries' regulation of process compliance
- Key elements of a successful track-and-trace system
- System validation, security, handling and maintenance

MODULE 2

LABELLING & ARTWORK GUIDELINES

- Creation of labelling from SmPC
 - ❖ Labels, PIL, label-leaflet variants, Patient package inserts' (PIs) replacement and supplement
 - ❖ Difference between Generics/Rx/OTC labelling
- Concept of readability and guidelines of readability testing
- Serialisation requirements
- Specific requirements
 - ❖ Formatting, quality, material, braille, symbols, multilanguage, storage information
 - ❖ Labelling in foreign countries

PACKAGING, STORAGE & HANDLING GUIDELINES

- Creation of package
 - ❖ Primary, secondary & tertiary packaging
 - ❖ Packaging component specifications, materials, folds, carton, blisters
- ISO 15378:2017, ISO 21976:2018
- Specific requirements
 - ❖ Safety, manufacturing efficiency, eco-conscious
 - ❖ Codes and verification of codes on packaging equipment
- Mitigating damage in the supply chain
 - ❖ Breakage, spillage, sterility, impermeability, contaminationproofing, temperature range

IMPLEMENTING A GMP-COMPLIANT ARTWORK PROCESS

- Packaging & labeling errors
- Artwork lifecycle workflow
- Content control and recordkeeping
- SOPs and Change Control considerations
- Minor and major variations submissions/reply to deficiency letters

CASE STUDIES: OTC LABELLING & PACKAGING

- Self-medication and safety issues
- Inconsistency and variability issues

MODULE 3

PROMOTING PATIENT ADHERENCE THROUGH LABELLING & PACKAGING STRATEGIES

- Data-driven insights on patient adherence
- Key barriers and factors influencing adherence
- Adherence packaging for patient compliance
 - ❖ Multimed packaging
 - ❖ Medication therapy management best practices
- Patient-centred prescription drug label

CASE STUDIES: NAMING, LABELLING FOR BIOSIMILARS

- New FDA guideline
- Documentation on immediate plastic packaging

- ❖ Types of administration
- ❖ Dosage forms
- Labelling requirements:
 - ❖ Unique device identification
 - ❖ Instructions for use
- Design reviews, verification, validation, document input/output data

AUDITING PACKAGING & LABELLING SUPPLIERS

- Product quality, specification, cost & security of supply
- ISO testing standards
- Delivery time and speed-to-market considerations
- Technical and quality agreement (TQA), Service level agreement (SLA)
- Flexible resourcing approach

CASE STUDY: PACKAGING OF COMBINATION PRODUCTS AND MEDICAL DEVICES

MODULE 4

MATERIALS, PACKAGING, STORAGE & HANDLING OF APIs

- New FDA guidance on APIs packaging, repackaging, labeling & distribution

TECHNOLOGIES IN PACKAGING & LABELLING

- Anti-counterfeiting
 - ❖ e-labels, self-destructive labels
- Secure & Sustainable packaging
 - ❖ Biodegradable packaging
 - ❖ Pre-fillable syringes
 - ❖ Smart packaging sensors
- Labeling & artworks
 - ❖ DNA authentication technology
 - ❖ Ink technology
- RFID tags
- Tamper-evident technology
- Nanotechnologies & plastics
- Blockchain

LEGAL ISSUES SURROUNDING THE ASIAN REGIONS

- Contamination issues
- Labeling violations
- Statutory warnings
- Unapproved prescription drugs
- Recalls

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

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EASY WAYS TO REGISTER



Telephone

Contact Devi Nyunt +65 650 82476



Email

register@informa.com



Web

www.informacconnect.com.sg/packaginglabel



Social Media



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Facebook

Live Online Learning!

- **20%** Price Advantage
- **Save** on Travel budgets
- **Replicate** on site classroom experience
- **Tools** for Enhanced Participant / Trainer interaction
- **Onboarding** for all attendees
- **Proven** and **secure** training platform

FEE PER DELEGATE	EARLY BIRD RATE Register and Pay on or before 11 September 2020	NORMAL RATE Register and Pay after 11 September 2020
<input type="checkbox"/> 4-Module Live Online Learning	SGD 3,395 SGD 2,716 (20% Learning Fee Discounted)	SGD 3,595 SGD 2,876 (20% Learning Fee Discounted)

- 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.
- A **7% Goods & Services Tax (GST)** is applicable to all Singapore based companies for Singapore venue.

Register 2 Delegates & the 3rd attends
FREE!

**Applicable to Normal Rates only*

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DATA PROTECTION

The personal information entered during your registration/order or provided by you will be held on database and may be shared with companies in the Informa Group in the UK and internationally. Occasionally, your details may be obtained from or shared with external companies who wish to communicate with you offers related to your business activities. If you do not wish your details to be used for this purpose please contact our Database Department at Email: database.sg@informa.com, Tel: +65 6508 2400 or Fax: +65 6508 2408.



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