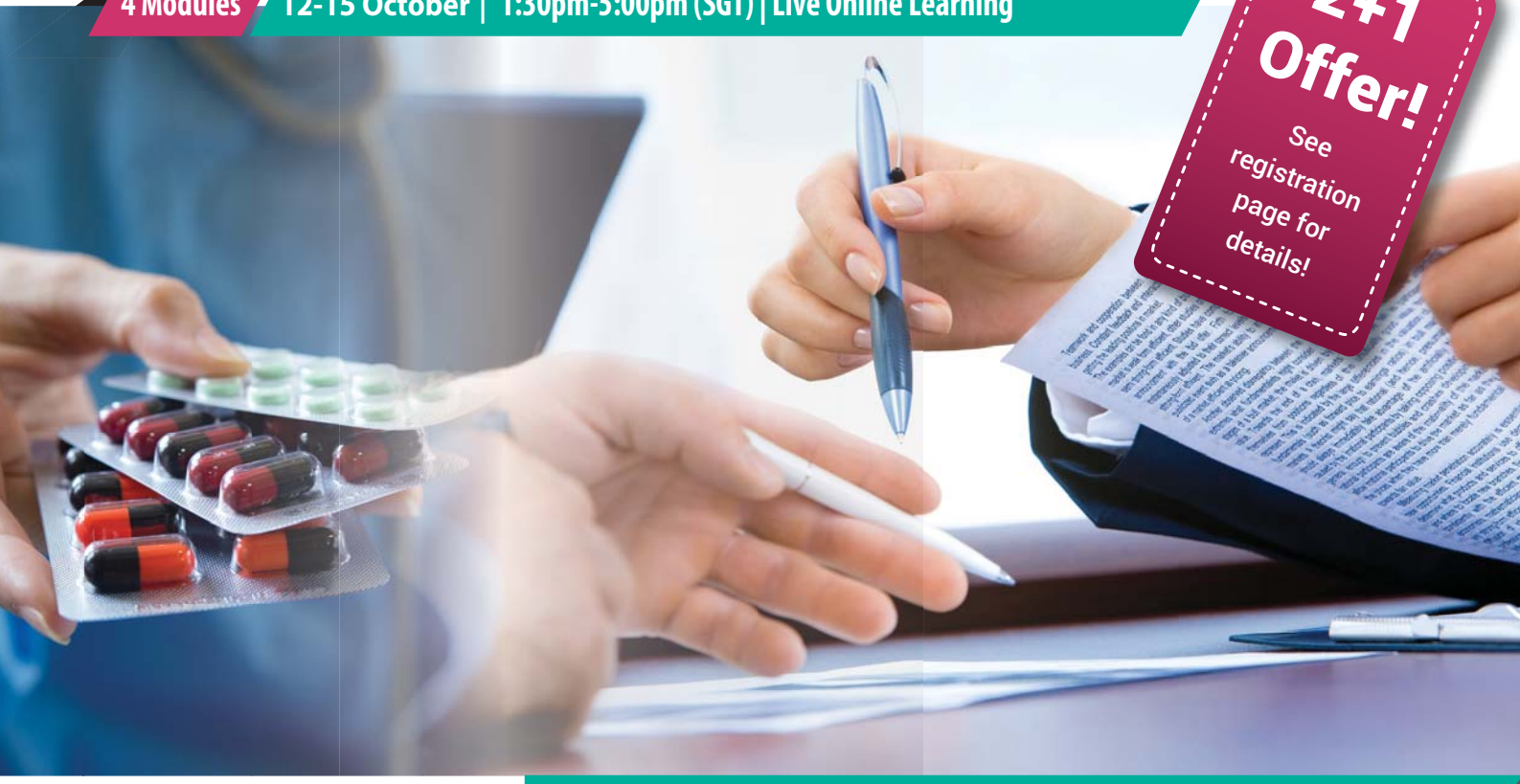
informa connect
Maritime Training Academy

Drafting & Negotiating Commercial Contracts in Pharma

4 Modules | **12-15 October | 1:30pm-5:00pm (SGT) | Live Online Learning**

2+1 Offer!
See registration page for details!



Delivered in **Live Online Learning** Format

Course Directors

Linda Hsu (PhD)
Founder
Astracrux Clinical Trials and Consulting Inc

Sebastian Handorf
Senior Legal Consultant
Compliance & Data Privacy

Key Learning Outcomes & Case Studies Include

- Commercial law for pharmaceutical industry: competition law, antitrust, antibribery among others
- Drafting & negotiating key commercial contracts: Licensing, collaborative research, drug co-promotion, co-marketing & distribution
- Key issues in clinical trials, clinical manufacturing and impacts on agreements
- Development in regulatory compliance, the implications on contractual rights & obligations
- Exercise clinical contract budget negotiation – Fair market value, mechanisms & processes
- Intellectual property rights enforcement and infringement issues
- Commercial dispute, violation, infringement pharma industry and legal cases

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

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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

Designed for legal and commercial managers working closely with various pharmaceutical agreements, this masterclass offers important touchpoints on contract law, the complex regulatory systems, as well as practical considerations in negotiating & drafting commercial contracts.

Through examining practical legal aspects & real-world case studies ranging from competition law, CRO contracting to licensing, co-promotion & distribution agreements, you will gain advanced understanding on interpreting key contractual clauses and effective negotiation skills.

COURSE DIRECTORS

Linda Hsu (PhD), Founder,
Astracrux Clinical Trials and Consulting Inc

- Linda has Doctor of Philosophy and Law degrees. She provides multinational clinical trial legal consulting services and managing contract negotiations.
- Experienced in both biotech and the CRO industry. Served as APAC Regional Head for Site Contract Lead team at one of the world's largest CROs, delivering 1,000+ clinical site agreements annually.
- Specialised on Clinical Trial Agreements (CTA), Master Service Agreements, Vendor agreements and other contracts in relation to clinical trials for more than 50 pharmaceutical companies and CRO worldwide.
- Admitted as a Lawyer of the Supreme Court of Victoria Australia and a Barrister and Solicitor of the High Court of New Zealand.

Sebastian Handorf, Senior Legal Consultant,
Compliance & Data Privacy

- Provides legal, contract management consulting services and GDPR compliance. Developed and implemented contracting strategy to adjust +700 clinical agreements.
- Acted as Americas regional head, leading site contract management team for the region.
- Specialized in rendering contract management and legal services in EU and Americas related to FCPA; Data Privacy; GDPR; Compliance; Risk-Assessment and Intellectual Property.
- Master's degree in Laws and Information.

WHAT PAST PARTICIPANTS SAID

"Informative & insightful. It'd been a great opportunity to network and discuss with other participants"
Chng Kien Peng, Executive Director, **Xepa-Soul Pattinson (S) Pte Ltd**

"Practical examples and case studies were very helpful."
Dinyar D Elavia, CCO, **Micro Labs Limited**

"The instructors experience and skills to manage the variety of scenarios discussed in the class."
Chantal Cho, Special Assistant, **Chunghwa Chemical Synthesis & Biote Co Ltd**

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

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- Module Commencement: **1:30pm** (SGT)
- Module Conclusion: **5:00pm** (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

CONTRACT LAW FOR PHARMACEUTICAL INDUSTRY

- Introduction to industry related agreements. What makes the industry unique from a contractual stand point
- Competition law: merger, collaboration & distribution
- Anti-bribery/anti-corruption
- An introduction to regulatory law
- Sample clauses
- Anti-monopoly
- Export controls in pharma/biotech
- Drug price transparency

INTERPRETATION AND PRINCIPLES OF KEY PHARMA COMMERCIAL CONTRACTUAL CLAUSES

- Introduction to Key Pharmaceutical Commercial Agreements
- Clinical trial agreements/CRO agreements
- Licensing agreements /co-licensing
- Co-promotion, co-marketing and distribution agreements (covered by guest speaker)
  - Contingencies and termination
  - Reduced & exclusive distribution agreements
  - Scope of rights and responsibilities, restrictions, minimum purchase requirements, territory
- Collaboration and R&D agreements (covered by guest speaker)

MODULE 2

INTELLECTUAL PROPERTY AND LICENSING

- Key commercial terms, including:
  - Governance and dispute resolution
  - Performance obligations
  - Termination rights
- Boilerplate clauses:
  - Law and Jurisdiction
  - Infringement and enforcement
  - No challenge clauses
- Structure of Pharma/Biotech IP contracts
- Supplementary protection certificates
- Lucinda Osborne,The in/out licensing deals in ASEAN
- Joint ownership issues
- Third party rights
- Valuation of licensing deals
- Forms of IP Licenses
- Structure of Pharma/Biotech IP contracts
- Commercial considerations
  - Territory, Loans, Field of use, upfront payments, royalty rates, development cost sharing, profit sharing, sales-based milestones, co-promotion rights, lead party

CLINICAL TRIAL-RELATED AGREEMENTS

- Introduction to types of contracts for Clinical Research Industry: Definitions, frame, context.
- CRO Agreements/Sponsor Agreements
- Clinical Agreements: Definitions, frame, context.
- Boilerplate clauses and contracting structure
- Confidential information and Publication
- Sponsor/CRO obligations
- Monitoring and reporting
- Commercial considerations
- Applicable law

Case study: *Clinical agreement negotiations in China and/or across ASEAN*

Exercise: *Clinical Trial Budgets – Development, Compliance & Negotiation*

- Introduction to clinical trial budgets
- Regulation/Applicable Law / Best practices. GCP guidelines
- Structure of Clinical Budgets
- Compliance in clinical budgets: concept of improper payments
- Risk mitigation and mitigation strategies
- Development of clinical budgets

MODULE 3

REGULATORY FRAMEWORKS AND KEY OBLIGATIONS ON COMMERCIAL CONTRACTS

- GCP
- CMP
- Applicable Law
- International instruments and declarations

WORKSHOP: NEGOTIATION PROCESSES AND SKILLS

how are big Pharmas and CROs structuring globally. The negotiation in the Start-up Phase. Budget development & negotiations

- Clinical Contract and Budget negotiation mechanisms and processes
- Negotiation strategies
- Technical and commercial skills

KEY CONSIDERATIONS ON CONTRACTUAL GOVERNANCE DURING COVID-19

- Mitigation and pre-emptive strategies to overcome COVID Era
- Risk analysis and key considerations

MODULE 4

NEGOTIATING A BALANCED LICENSE

- Establishing intended outcomes
  - Performance obligations
  - Financial terms
  - Dispute resolutions
- Relative bargaining positions
- Identifying points of conflict and points of agreement
- Win-win vs positional negotiation
- Seven strategies of effective negotiations
- Specific issues relating to negotiating an IP licence

COMMERCIAL DISPUTES IN PHARMA

- Arbitration
  - Co-marketing/co-promotion performance
  - Use of IP under licensing agreements
  - Royalty payment claims
- Governance and dispute resolution

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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.informaconnect.com.sg/pharmacontracts

Social Media LinkedIn 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 7 August 2020	NORMAL RATE Register and Pay after 7 August 2020
❑ 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)

Register **2 Delegates** & the **3rd** attends

FREE!

**Applicable to Normal Rates only*

For Bank Transfer; Payment Terms & Conditions; Cancellation & Substitution Policies, please visit **https://www.informaconnect.com.sg/terms/**

- 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.

TRAIN THE TEAM!

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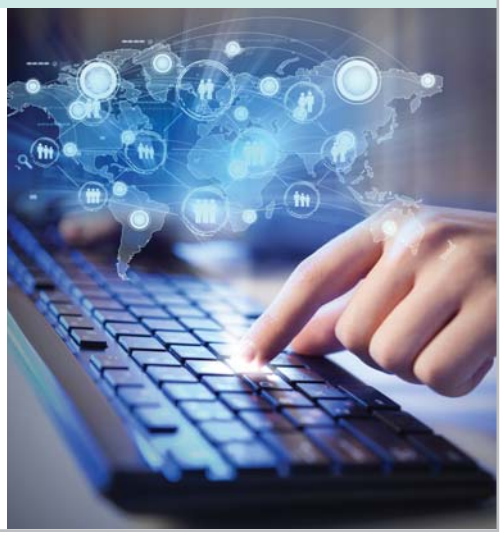
To talk through the many options available please call our training specialist:

Devi Nyunt
+65 6508 2477
onsite.training.sg@informa.com

DATA PROTECTION

The personal information entered during your registration/order or provided by you will be held on database an may b shared with companies in the Informa Group in the UK an 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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