IPI Academy

MANAGEMENT forum




*Presented by*
**Management Forum**

# Medical Device Regulations in Asia-Pacific Markets

**2-3 March 27**
+ 15-16 September 27

As the Asia-Pacific market grows, new regulations emerge. Gain expert insights to navigate compliance and maximise opportunities.

**Format:**
Live online

**CPD:**
6 hours for your records

Certificate of completion

# Course overview

**With the European medical device market now well established, the next major opportunity lies in the Asia-Pacific region**. Countries like China, Hong Kong, and Singapore have introduced - or are in the process of implementing - their own medical device regulations, shaping the future of market access.

This course offers a deep dive into the evolving regulatory landscape, equipping you with the knowledge and practical guidance needed to navigate compliance and successfully access these high-growth markets. Learn how regulatory requirements are being interpreted and enforced, and gain the confidence to apply this understanding in your role.

Seize the opportunity to stay ahead in one of the fastest-growing medical device markets - armed with the expertise to make an impact.

## Benefits of attending

- **Gain** an overall understanding of the medical device regulatory system in Asia
- **Learn** the key requirements in major markets
- **Understand** how to make product registration or launch more efficiently
- **Explore** how to manage regulatory stakeholders in Asia

## Who should attend

This course will be relevant to personnel from the medical device industry in the following departments:

- Business development
- Regulatory affairs
- Registration
- Quality assurance
- Marketing
- Manufacturing
- R&D and technical affairs who would like to gain an understanding of the regulations in this region to gain access to these newly regulated markets

# Programme

## Day 1

**Overview of medical device regulatory in Asia**

- Basic regulatory framework
- Criteria to get regulatory approvals
- Discussion (How to make regulatory approval more efficient based on regulatory framework understanding)

**Overview of medical device regulatory in Asia continued**

- Key stakeholders in regulatory system (ASEAN, GHWP, Regulators etc)
- Discussion (How to manage key stakeholder relationships in Asia)

## Day 2

**New medical device regulations in key markets (China, Japan, Korea, SEA, Hong Kong)**

- Overall system
- Regulatory submission process
- Product classification
- General timeframe/costs
- Hints and tips for success

# Presenter



**Jack Wong**

Six Sigma Black Belt certified by IASSC

Over 20 years of Regulatory, Quality, Clinical Trial and Pharmacovigilance experience in Asia with good knowledge in the field of Medical Devices, Pharmaceuticals, Nutritional, Consumer Healthcare and Biological products. Received awards on improving process (reduced 20% time in product launch time) and developing People (Watson Wyatt Survey to all direct reporting staff indicated that 100% of them able to contribute to their fullest ability).

Externally, playing a leading role among all the Regional Regulatory professionals in AHWP (Asian Harmonization Working Party). Developed the First Asia Regulatory Affairs Certificate course since 2007 with over 2800 students in industry, government and universities. Being the founder of ARPA (Asia Regulatory Professional Associations) since 2010 with over 3600 members. Wrote the first Asia Regulatory Book in Asia, Handbook of Medical Device Regulatory Affairs in Asia, 2nd edition now.

Qualified Auditor of ISO 13485, Japanese Regulations for Medical Devices and ISO 9000 Lead Auditor by BSI (British Standards Institution)

# Course dates

| | | |
|---|---|---|
| **2-3 March 27** | **Live online**<br>09:00-13:00 **UK (London)** (UTC+00)<br>*Course code 17023* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 05 Jan** |
| **15-16 September 27** | **Live online**<br>09:00-13:00 **UK (London)** (UTC+01)<br>*Course code 17322* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 21 Jul** |

## How to book

**Online:**
ipi.academy/1832

Alternatively contact us to book, or if you have any queries:

**Email:**
info@ipiacademy.com

**Phone:**
+44 (0)20 7749 4749

## Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

## Further information

**Fee**
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

**Please note**
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

**Terms and conditions**
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

# Reviews

★★★★☆

**I wanted help with finding out where to source information on relevant countries and this was covered during the training. I found the way the speaker took the course to be useful in that we were participating throughout and not just reading through notes. He kept us involved, asked if we had had experience in any of the areas and offered advise that was both amusing and helpful, and also included stories where relevant to aid the understanding etc. He was not patronizing but very encouraging in moving forward. We also overran slightly and did not hurry us to leave while we still had questions.**

**Tracy Charlton**
Regulatory Affairs Specialist
Research Instruments
Nov 3 2025

## Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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