IPI Academy

MANAGEMENT forum

Presented by
Management Forum

The Common Technical Document

8-9 July 2024
+ 25-26 November 2024

A comprehensive review of the regulations and technical requirements for chemistry, manufacturing and control (CMC) management of your application.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course Overview

This interactive two-day course will provide you with a clear and comprehensive understanding of the regulatory and technical requirements for CMC management of your full and generic application in major markets of the EU and USA. Furthermore, the course examines the requirements for global roll-out of the dossier to ROW regions including LATAM, ASEAN, MENA and CIS territories.

You will increase your ability to manage all aspects of development of the CMC applications after two days of intensive lectures, group work and discussion sessions, covering everything you need to know about compiling the chemistry and pharmacy section of your generic dossier.

Skills you will gain include:

- Effective compilation of the Common Technical Document (CTD) and critical review of documentation
- Quality by design (QbD), critical attributes and developing new product using the CQA pyramid model
- Compiling and submitting Module 3 (CTD) of your registration dossier
- Identifying the extent of content expected by EU and US regulators
- Achieving the quickest turnaround of your submission
- Managing the pharmaceutical and quality aspects of your developments and registration dossier in Europe and the US
- Ensuring right-first-time development
- Meeting the legal framework and guidelines for the CMC/quality part of the dossier and links to GMP

Who should attend

- Senior analytical chemists
- Formulation chemists
- Technical services chemists
- Registration staff (all levels)
- Quality managers
- Quality control directors
- R&D project managers

Programme

Day 1

What is the CTD?

- Pharmaceutical medicine and documents
- Introduction to CTD, ICH and eCTD
- Introduction to data standards relevant to module 3 (incl. EMA SPOR, ISO-IDMP)

The importance of chemistry/manufacturing and controls (CMC)

- Setting the scene for the module 3 deep-dive

Assessment of biologics and why the CMC section for these products is more extensive

A deep-dive in Module 3 – examining the content of all sections

- Module 3.2 for the substances (32S)
- Module 3.2 for the final products (32P)
- Appendices and regional information in Module 3 (32A and 32R)
- Additional data for generics in the US (ANDA tables)
- Process validation deep-dive (S25 + P35)
- Comparability across batches (ICH Q5E)
- Quality-by-Design and Quality Target Product Profile (ICH Q8, Q9 and Q10)
- Analytical method deep-dive (ICH Q2 and beyond)
- Process analytical technology
- Pharmaceutical quality system (ICH Q10)

Post-approval maintenance

- What and why?
- EU eCTD lifecycle management
- US eCTD lifecycle management
- Product lifecycle management (ICH Q12) and established conditions

Day 2

Potential scenario's for Module 3

- EDQM certificate of suitability of monographs of European pharmacopeia (CoS/CEP)
- Active substance master file (ASMP)
- US drug master files (DMFs)

Basic principles for eCTD authors (incl. focus on global dossier roll-out)

- Separating content from contexts
- Applying the right document granularity
- Lean and structured authoring

Trends, developments and future outlook

- Identification of medicinal products (IDMP)
- FDA Knowledge-Aided-Structured-Assessment and Structured-Application (FDA-KASA)
- FDA Pharmaceutical quality/Chemistry manufacturing and control (PQ/CMC) data elements
- EMA Digital Application Dataset Integration (DADI) project
- Accumulus synergy – global information exchange platform

Summary of Module 3 and what should stand out from the Quality Overall Summary (module 2)

Presenter

Andrew Willis

Andrew Willis is an independent consultant providing expert advice and training on global regulatory solutions and pharmaceutical development. Previously, he worked for Catalent Pharma Solutions as VP Regulatory Affairs & Consulting Services, where he was head of a team of internal and external regulatory affairs consultants.

He qualified as a Chemist from the University of Glamorgan, after which he furthered his understanding of pharmaceutical development, working as a research chemist with Parke Davis. He had 10 years manufacturing and analytical experience prior to entering regulatory affairs as a Senior Executive Officer with responsibility for submission of European MAAs and project management of development programs. He has over 30 years' pharmaceutical experience with extensive knowledge in the development and manufacture of sterile, solid oral, inhalation, topical and biotech pharmaceutical products. These experiences have allowed knowledge of many biotech products requirements with experiences of growth hormones and multiple cancer treatments, including development and clinical registration of the first genetically modified live bacterium for such treatment.
He has extensive experience of major European and US regulatory projects, in the clinical and marketing authorisation stages, and has significant experience in coordinating and managing meetings with European and US Health Authorities.

Course dates

8-9 July 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 13763*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 03 Jun**
25-26 November 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 14045*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 21 Oct**

How to book

Online:
ipi.academy/2182

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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

★★★★★

The speaker was excellent, with a lot of knowledge and experience. I really liked the examples on which we practised what needs to be included in some CTD dossier.

Martina Kunštić
RA Specialist
Genera Inc./Dechra Pharmaceuticals
Mar 12 2024

★★★★★

The webinar has great content for us who work with CTD's in the pharma industry, I think there was so much helpful information on this for beginners and medium level on CTD. I think Andrew is great and gives a truly expert opinion, he demonstrated his expertise and really had you thinking.

Gabriela Gutierrez
International Regulatory Affairs Specialist
Zeyco
Mar 12 2024

★★★★★

very good, well organized

Evdoky Harran
Regulatory Affairs Associate
Pierre Fabre
Nov 28 2022

★★★★☆

Very good

Richa Dcruz
officer
Shorla Oncology
Nov 28 2022

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:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy