IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Digital CMC: The Key To Realising Pharma 4.0

1 December 2025

Whether you're looking to optimise existing processes or lay groundwork for a digital transformation, the course will teach the tools to leverage Digital CMC as a cornerstone of Pharma 4.0 success.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

The pharmaceutical and biotech industries are under increasing pressure to enhance operational efficiency, meet evolving regulatory requirements, and accelerate time-to-market while maintaining product quality. These demands, coupled with the complexities of global supply chains and the need for seamless collaboration across diverse teams, highlight the critical role of Chemistry, Manufacturing, and Controls (CMC) in ensuring success. However, traditional CMC processes often become bottlenecks, impeding progress due to their reliance on manual workflows, siloed data, and outdated systems. Digital CMC offers a transformative solution, leveraging digital tools, data analytics, and integrated platforms to reimagine CMC processes. This course introduces participants to the concept of Digital CMC within the broader context of Pharma 4.0, a vision for the future of pharmaceutical development and manufacturing that emphasises agility, automation, and data-driven decision-making.

Through this interactive session, participants will explore the industry forces driving the shift toward digital transformation, understand the specific challenges Digital CMC addresses, and learn about its operational and regulatory advantages. The course will also provide actionable insights through case studies from global pharma and biotech companies that have successfully implemented Digital CMC solutions, demonstrating their impact on product lifecycle management and regulatory compliance.

Benefits of attending

By the end of this course, participants will be able to:

- **Identify** the key challenges driving the need for pharmaceutical and biotechnology organisations to increase their operational efficiency
- **Understand** the role of Digital CMC in addressing traditional bottlenecks in pharmaceutical development and manufacturing
- **Assess** the operational and regulatory benefits of adopting Digital CMC practices
- **Analyse** case studies showcasing the successful implementation of Digital CMC in leading pharmaceutical and biotech organisations
- **Develop** a roadmap for integrating Digital CMC into their own organisational workflows to enhance efficiency and regulatory compliance

Who should attend?

This course is ideal for personnel in these departments:

- MS&T
- Process development
- Technical operations
- CMC
- R&D
- Quality assurance
- Manufacturing
- Supply chain
- Business IT professionals (R&D IT and manufacturing IT etc.)

More broadly, any professionals working in a digital capacity within any of the aforementioned domains within a pharmaceutical/biotechnology organisation. This course is suitable for all levels (scientists, managers, and senior leadership).

Programme

Introduction

- What is Pharma 4.0?
- What is Digital CMC?
- What is the relationship between Pharma 4.0 & Digital CMC?

Industry forces pressuring pharmaceutical and biotech companies to increase operational efficiency

- An industry failing to commercialize its exquisite scientific breakthroughs
- Companies facing elongated development timelines & rising development costs
- Companies facing increased competition across all therapeutic modalities
- Traditional data management practices unable to handle the exponential growth of data

Recognising the CMC bottleneck

- Diagnosing the cause of the bottleneck: unstructured & siloed CMC information
- Why unstructured & siloed CMC information is a burden for the whole organisation
- Why today's technology stack falls short when it comes to resolving this

Digital CMC represents a novel solution

- The need to structure and centralise CMC information
- How to build a CMC source of truth using a 3-step framework
- Proposing a grand vision for CMC to alleviate the bottleneck

Leveraging digital CMC to drive operational & regulatory efficiencies

- Building a digital bridge between development & manufacturing; accelerating technology transfers
- Connecting technical requirements (product/process) to business requirements (demand/supply planning)
- Accelerating business process execution across the entirety of technical operations
- Enhancing data integrity by building traceability between information sets irrespective of their origin (internal/external) or location (document/digital system)
- Enabling organisations to develop & demonstrate enhanced product & process understanding

Demonstrating digital CMC via cloud-based software platform

- Deep dive: digital product definition
- Deep dive: digital process definition
- Deep dive: digital control strategy
- Deep dive: digital technology transfer
- Deep dive: automating development reports, visualisations and regulatory filings

Real world use cases of digital CMC

- Case study: top 10 pharmaceutical company
- Case study: top 10 pharmaceutical company
- Case study: top 25 pharmaceutical company
- Case study: top 25 pharmaceutical company
- CasesStudy: top 50 pharmaceutical company

Presenter

Lewis Shipp

Lewis Shipp is a published pharmaceutical scientist and a recognised expert in drug development & manufacturing across a range of therapeutic modalities. Lewis currently works at the intersection of science & technology as a Digital CMC Specialist at QbDVision, helping organisations both large & small leverage digital technology to accelerate the delivery of therapies to patients. Additionally, Lewis has contributed to ISPE's Pharma 4.0 Special Interest Group & BioPhorum's Technology Strategy Forum as an SME in the application of digital technology to solve business process challenges within the pharmaceutical industry. Lewis has also given several presentations at internationally recognised conferences on varying topics pertaining to digitally-enabled drug development and manufacturing.

Course date

1 December 2025

Live online
09:00-16:00 **UK (London)** (UTC+00)
Course code 15546

GBP **649** ~~749~~
EUR **909** ~~1,049~~
USD **1,043** ~~1,199~~
Until 27 Oct

How to book

Online:
ipi.academy/3207

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

Email:
info@ipiacademy.com

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+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

Run this programme in-house for your whole team

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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.

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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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