IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Pharma Facility Project Management: Delivering GMP-Compliant Sites On Time and Within Budget

8-9 February 27
+ 15-16 September 27

A two-day course on planning and delivering GMP-compliant pharmaceutical facilities, covering project scope, scheduling, risk management, and regulatory readiness.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

As the pharmaceutical facility projects become increasingly complex, regulated, and time-sensitive, organisations are under intense pressure to design and commission new manufacturing facilities that are GMP-compliant from the beginning. Demand for additional production capacity, spanning sterile plants, biologics production, and advanced therapy (ATMP) is at its peak, so any missed step, a schedule overrun, budget escalation, or compliance gap, can result in serious operational and financial risks.

This intensive two-day course offers delegates training on planning and executing pharmaceutical facility projects under strict GMP requirements. The programme follows the entire project lifecycle, where participants will learn how to develop realistic project scopes, build integrated project schedules, and embed regulatory compliance and Quality by Design (QbD) principles into every phase of the project.

This course also examines industry best practices in scope management, cost control, risk management (aligned with ICH Q9 guidelines), and change control. Case studies and interactive exercises allow delegates to apply these concepts and meet new regulatory guidelines (from FDA, EMA, MHRA, PIC/S, and WHO).

By blending both the technical and managerial aspects of project delivery, this course equips delegates with the skills to lead cross-functional teams (engineering, QA/QC, validation, operations) and deliver facilities right-first-time on time, while ensuring they are inspection-ready for regulatory approval.

Benefits of attending

- **Learn** to integrate Compliance into Projects
- **Apply** a structured lifecycle approach (from concept to C&Q and close-out
- **Implement** risk management and change control practices (aligned with ICH Q9 and PMI frameworks)
- **Understand** how to plan and oversee commissioning and qualification activities (IQ/OQ/PQ) as part of the project
- **Develop** strategies to coordinate engineers, contractors, QA/QC, validation, and operations teams, clarifying roles and communication to keep complex projects on track
- **Adapt** to Emerging Challenges
- **Master** techniques to keep projects within schedule and budget
- **Ensure** the facility and documentation will pass pre-approval inspections (e.g. FDA/MHRA site inspections) on the first

Who should attend

- Project managers and project engineers
- Engineering and Facility managers
- Validation professionals
- Quality assurance and compliance specialists
- Manufacturing and operations managers
- Consultants, EPCM contractors, and engineering service providers

Programme

Day 1

Introduction to pharma projects and industry standards

- Project planning: scope, URS, and concept design (Right-First-Time)
- Business case development
- Quality integration in project foundations

Project lifecycle and quality by design

- Optimisation of layouts and flows
- Incorporation of QbD principles
- Quality assurance in design reviews
- Case study: Identification of GMP compliance issues

Risk and change management

- Application of QRM
- Change control integration
- Tracking of Key Performance Indicators (KPIs) and project health
- Case study: how to conduct risk assessment

Procurement and construction management

- Oversight of vendors and contractors
- GMP during construction
- Schedule tracking and progress monitoring
- Construction-phase problem

Day 2

Commissioning and qualification (C&Q) strategies

- Commissioning of systems
- Risk-based qualification approaches
- Formal project handover
- Interactive exercise: developing high-level C&Q plan

Facility delivery by modality: sterile/biologics/ATMP/potent OSD

- Strategy changes by product type and risk profile
- Regulatory compliance by design
- GEP in construction and installation
- Interactive activity: what inspectors challenge

Regulatory and quality compliance

- Project deliverables and documentation
- Regulatory strategy ad approvals
- Interactive discussion: inspection readiness

Innovation and acceleration in projects

- Modular construction and fast-track strategies
- Digital tools - BIM, 3D modeling, digital twins
- Parallelizing activities and remote collaboration

Project close-out and post-project

- Readiness for process validation
- Final inspection and turnover to operations
- Interactive exercise: project close-out checklist - facilitation of knowledge transfer

Case Study

- Real-world project scenario from initiation to close-out

Presenters



Paul Palmer

Paul R Palmer is a Director / Pharmaceutical Consultant and a practicing EU / UK Qualified Person. He has over 35 years experience in the pharmaceutical industry in the development, manufacture and supply of medicinal products and medical devices.

Throughout his career, Paul has intentionally taken on all opportunities as they arose in order to develop a broad range of knowledge with an in-depth detailed understanding of manufacturing, storage, distribution, research, computerised systems, as well as the facilities and services to support each.

People and systems have always been a core focus, how to ensure best use, optimise and enhance efficiency. He has a level of curiosity rarely displayed in people taking on the qualified person role in pharmaceutical manufacturing. Culture, behaviour and psychology are all significant influences on the systems and processes we implement, but are often ignored.

Paul studied psychology as part of his MSc in 1993 and has always enjoyed observing the world around him with a curiosity that is rarely satisfied.



Aneta Jell

Aneta Jell is a seasoned Quality Assurance professional with over 20 years of experience across manufacturing, contract operations, and quality leadership in the pharmaceutical industry. Currently serving as Quality and training manager at PaulPalmer limited she oversees global contract manufacturing quality, ensuring GxP compliance, regulatory alignment, and supply chain integrity. Her expertise spans GMP, ISO 9001, ISO 17025, and QMS administration, with proven strength in audits, CAPA, deviations, and technical agreements. A qualified QMS lead auditor with bilingual proficiency in English and Slovak, Aneta is recognised for driving continuous improvement, fostering compliance culture, and leading high-performing quality and HSE teams.

Course dates

8-9 February 27	**Live online** 09:30-16:30 **UK (London)** (UTC+00) *Course code 16933*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 14 Dec**
15-16 September 27	**Live online** 09:30-16:30 **UK (London)** (UTC+01) *Course code 17273*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 21 Jul**

How to book

Online:
ipi.academy/3355

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

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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