IPI Academy

MANAGEMENT forum



Presented by
Management Forum

ICH Q12: Advanced Pharmaceutical Product Lifecycle Management in Practice

18-19 January 27
+ 7-8 July 27

A practical course on implementing ICH Q12, covering risk-based management of post-approval CMC changes, Established Conditions (ECs), PACMPs, and lifecycle documentation to ensure efficient and compliant product lifecycle management.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

ICH Q12 provides a harmonised framework for management of post approval CMC changes more predictably and efficiently across the commercial lifecycle, using risk and science-based approaches and an effective Pharmaceutical Quality System (PQS).

The guideline introduces a set of practical tools and enablers, including risk-based categorisation of changes, Established Conditions (ECs), Post Approval Change Management Protocols (PACMPs), and the Product Lifecycle Management (PLCM) document, and explains how these connect to regulatory assessment and inspection expectations.

This course translates Q12 into real-world execution for the delegates and explains to them how to define ECs without 'over locking' the dossier, how to set reporting categories based on risk and knowledge, how to design PACMPs that regulators can approve, and how to keep lifecycle documentation inspection ready while enabling continual improvement.

Benefits of attending

Delegates will be able to:

- **Apply** ICH Q12 lifecycle tools to accelerate post-approval CMC change implementation while maintaining compliance and product quality
- **Define** and justify Established Conditions (ECs) to enable regulatory flexibility without over-locking the dossier
- **Develop** PACMPs with clear scope, studies, and acceptance criteria to improve predictability and reduce regulatory rework
- **Use** science- and risk-based approaches to categorise CMC changes and align reporting pathways across global regions (EU vs FDA)
- **Build** and govern the PLCM document as a living lifecycle tool linked to internal change control, ECs, and PACMP strategy
- **Integrate** ICH Q12 into the PQS (ICH Q10) using knowledge management, QRM, and change control to strengthen inspection readiness
- **Apply** Q12 through practical case studies and workshops covering site transfers, process optimisation, analytical changes, and frequent post-approval updates
- **Understand** Q12 implementation across FDA, EMA, MHRA, PMDA, Health Canada, and WHO, including legal and procedural differences by region
- **Strengthen** regulatory decision-making by recognising how assessors and inspectors interpret lifecycle data and apply 'flexibilities' in practice.

Who should attend

- Regulatory affairs and submission authors
- Quality assurance and pharmaceutical quality system owners
- Change control leads and QRM specialists
- MS&T, tech transfer, process development teams
- Analytical development, quality control, method lifecycle owners
- Supply chain, external manufacturing management specialist
- Quality agreements owners
- Program lifecycle management leads for marketed products

Programme

Day 1

Why ICH Q12 matters: mindset for marketed products

- Q12 relationship to ICH Q8, Q9, Q10, Q11
- Regional adoption overview: FDA, EMA, PMDA, MHRA, Health Canada, WHO influence
- Regional legal framework constraints (e.g., EU Variations model alignment)
- Case study discussion: delayed global change implementation

ICH Q12 overview and key concepts

- Scope of Q12 (DS vs DP; small molecules; biologics; combinations)
- Regulatory tools and enablers: ECs, PACMPs, PLCM
- Categorisation of post-approval CMC changes
- Dossier vs PQS responsibilities
- Drug - device combination products: where ICHQ12 applies and where device regulation take over

Risk-based categorisation of post-approval CMC changes

- Risk-based change categorisation principles
- Role of product/process knowledge (development, validation, prior knowledge)
- Group exercise: multi-region change classification scenarios
- Apply Q9(R1) formality and subjectivity principles to change categorization decision

Established conditions (ECs): defining the flexible regulatory controls

- Writing EC statements in CTD Module 3 (key sections)
- Linking ECs to reporting categories
- Lifecycle management of ECs (variations/supplements/PACMP routes)
- Workshop: identifying ECs and drafting EC statements (mock dossier)

ECs in manufacturing: process performance and lifecycle controls

- PAT and real-time monitoring as lifecycle enablers
- Maintaining overall control strategy with fewer ECs
- Lifecycle control of process EC changes (PLCM updates, PACMP alignment)
- Case study: manufacturing change strategy using Q12 tools
- Biologics manufacturing ECs - Annex IB and the role of Q5E comparability
- Continuous manufacturing under ICHQ13 - interaction of EC concept with CM control strategies

ECs for analytical procedures

- Analytical performance
- Development knowledge impact on EC
- Analytical change strategy
- The Q14 interface - minimal vs enhanced approach to analytical procedures development in EC footprint

Day 2

Post-approval change management protocols (PACMPs) - designing effective protocols

- PACMP maturity
- Acceptance criteria
- Selection of PACMP
- Workshop: design a PACMP package
- Design PACMP for biologic products - role of ICHQ5E comparability data

PACMP: execution, reporting, and common pitfalls and knowledge management

- PACMP execution planning and internal readiness
- Repeatable PACMPs
- Multi use/repeatable PACMPs
- Case study: PLCM document review and improvement

Product lifecycle management (PCLM) document

- PLCM content strategy
- Lifecycle governance
- Regional trends

Managing frequent changes and 'immediate notification' scenarios

- Structured approaches to recurring change
- Designing internal playbooks: data packages, decision trees, and success criteria
- Inspection readiness for high change volumes

Supply chain strategy and regulatory communication

- Knowledge management across complex supply chains
- PQS–RA interface roles and governance model
- CMO management and quality agreement considerations
- Case examples: site transfer/CMO change management

Stability data and post approval changes

- Stability expectations for post-approval changes
- Predictive stability tools and modelling concepts
- Commitments vs prior data (regional differences)
- Biologics specific stability considerations

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.



Farah Nadeem

Farah Nadeem is an Operations Manager at Paul R. Palmer Limited/ Pharmaceutical Consultant and a Trainee Qualified Person. Farah is a Pharmacist and recognised QA expert and has over 20 years of experience in the Pharmaceutical industry in the development, manufacture and supply of medicinal products.

Throughout her career, she has held various quality assurance roles and actively pursued new opportunities to expand her knowledge and expertise. As a result, she has gained a comprehensive understanding of manufacturing, storage, and distribution processes, as well as the facilities and services that support them. Involved in documentation management: writes, reviews, and audits SOPs and QMS implementations. Assists companies in meeting regulatory requirements.

In her current role as a QA Operations Manager for a Pharmaceutical Consultant Company, Farah Nadeem provides various solutions, including assistance in obtaining the first MIA(IMP) and MIA licenses, as well as preparation and hosting for regulatory inspections. Her work involves collaborating with Paul Palmer to offer services such as QP declarations for API manufacturers, regulatory inspection hosting, commercial and clinical batch release, compliance audits, and coaching and training in GxP.

Course dates

18-19 January 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 16937*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 23 Nov**
7-8 July 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17295*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 12 May**

How to book

Online:
ipi.academy/3353

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.

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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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