IPI Academy

MANAGEMENT forum




*Presented by*
**Management Forum**

# Effective Technology Transfer

**8-9 December**
+ 7-8 June 27, 7-8 December 27

A practical, regulator-aligned course on pharmaceutical technology transfer, covering science- and risk-based methods, QbD, QRM, digitalization, and analytical method transfer to ensure compliant, reliable product supply.

**Format:**
Live online

**CPD:**
12 hours for your records

Certificate of completion

# Course overview

**As global operations grow more complex and outsourcing and accelerated launches become common, robust technology transfer process is essential to ensure product quality and supply continuity.**

This two-day training course provides a comprehensive understanding of technology transfer, aligned with international regulatory guidelines ((FDA, EMA, MHRA, WHO, ANVISA, ICH Q7-Q12, EU GMP Annex 15, WHO TT guidance) and current industry expectations.

Participants will learn how to plan, execute, and manage technology transfer activities using science and risk-based methodologies. and how TT fits within the product lifecycle and the PQMS. It integrates current hot topics - such as digitalization (Pharma 4.0 tools), data integrity, and advanced regulatory frameworks - into the foundational principles of effective tech transfer.

Emphasis will be placed on the co-ordination between Sending and Receiving Units, addressing facility and equipment differences, and integrating Quality by Design (QbD) and Quality Risk Management( QRM) principles into transfer strategies.

Participants will also learn how to create transfer protocols, perform detailed gap analyses, use knowledge transfer practices, and regulatory-aligned documentation to ensure GMP compliance throughout.

The course includes Analytical Method Transfer and is designed to support a variety of operational models including small molecules, biologics, combination products, and outsourced manufacturing and as a result provides a practical framework for executing reliable, compliant transfers across diverse settings.

## Benefits of attending

- **Understand** the lifecycle context of Tech Transfer and how it supports product development and quality systems
- **Apply** risk-based, science-driven principles to build transfer strategies based on data and risk assessment
- **Improve** cross-site collaboration and engage effectively between Sending and Receiving Units.
- **Master** analytical method transfer to ensure analytical methods are successfully transferred and performed at the new site
- **Identify** and mitigate common pitfalls through addressing issues like scale-up, equipment gaps, or knowledge loss early
- **Apply** regulatory expectations according to FDA, EMA, ICH, and WHO requirements
- **Strengthen** governance and knowledge management with the use of structured oversight and tools to manage documentation and decisions
- **Learn** from real-world case studies in practical sessions from successful transfer projects across product types

## Who should attend

This course is designed for professionals involved in developing, transferring, or manufacturing pharmaceutical and biopharmaceutical products including:

- Technology Transfer teams or MS&T (Manufacturing Science & Technology) professionals
- Production managers and Engineers
- R&D scientists and formulators
- Quality Assurance and Quality Control managers
- Regulatory Affairs specialists
- CMC Project managers
- Analytical Development scientists
- Supply Chain and Outsourcing/CMO Management specialists

# Programme

## Day 1

**Day 1: Foundations and regulatory framework**

**Module 1: Introduction of technology transfer**

- The Role of Pharmaceutical Quality System (ICH Q10)
- Digital Tools and Pharma 4.0™ Principles
- Digital twins (virtual process models) and remote transfers

**Module 2: Global regulatory expectations**

- FDA, EU GMP Annex 15, WHO Technology Transfer Guidelines
- ICH Q8, ICH Q9, ICH Q10, ICH Q11 and ICH Q12
- Regional Regulatory Compliance

**Module 3: Quality by design and risk management**

- QTPP,CQAs and CPPs
- TT linkage to QbD
- Integration of New updates of ICH Q9 (R1)

**Module 4: Planning and management of tech transfer project**

- Cross-functional Tech Transfer team roles (SU vs RU)
- Gap Analysis & Due Diligence
- Project transfer milestones, Governance & Communication

**Exercise 1: Design a tech transfer plan**

**Module 5: Transfer documentation & knowledge management**

- Transfer plans, protocols, reports
- Tacit Knowledge management
- Data Integrity & Cybersecurity

**Exercise 2: Create a transfer protocol**

**Module 6: Regulatory and GMP compliance in transfers**

- Change management & PACMPs
- Regulatory Filing Strategy
- GMP controls and inspection readiness

## Day 2

**Day 2: Execution, analytical transfer and lifecycle management**

**Module 7: Process execution at the receiving unit**

- Engineering runs and PPQ
- Scaling strategies and comparability
- Data monitoring and continued verification

**Module 8: Facility, equipment, and material adaptation**

- Equipment and facility
- Utilities and Environmental considerations
- Bridging studies and utilities qualification

**Module 9: Analytical method transfer (AMT)**

- AMT protocol design
- Alignment with new ICH Q2 and USP <1224>
- Mitigation of OOS and lab variability

**Exercise 3: Analytical method transfer protocol creation**

**Module 10: Training, knowledge transfer and troubleshooting**

- RU training strategies and knowledge continuity
- Problem-solving and root cause analysis

**Module 11: Post-transfer regulatory and lifecycle management**

- Regulatory Submission for Site Change
- Post Approval Change Management Protocol (PACMP)
- Continuous verification process

**Module 12: Case studies and emerging trends**

# Presenters



**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.



**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

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|---|---|---|
| **8-9 December** | **Live online**<br>09:30-17:00 **UK (London)** (UTC+00)<br>*Course code 16900* | GBP **1,499**<br>EUR **2,099**<br>USD **2,399** |
| **7-8 June 27** | **Live online**<br>09:30-17:00 **UK (London)** (UTC+01)<br>*Course code 17222* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 12 Apr** |
| **7-8 December 27** | **Live online**<br>09:30-17:00 **UK (London)** (UTC+00)<br>*Course code 17562* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 12 Oct** |

## How to book

**Online:**
ipi.academy/2375

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

★★★★★

**The theoretical part was interesting, but the practical excercises proposed during the course were so helpful for a better understanding, excercises challanged me to actively partecipate, and even sometime it was difficult because of my working background, I really appreciated.**

**Alessia Reitano**
Senior CMC Specialist
Sintetica SA
Feb 3 2025

★★★★★

**The training course exceeded my expectations.The course was well structured ,with a perfect balance of theory and practical applications. The speaker was knowledgeable, approachable, and provided clear detailed explanations.**

**Maria Galanou**
Quality Affairs for New Products Expert
Pharmathen
Oct 7 2024

★★★★★

**Bruce had an outstanding performance as speaker! I truly recommend everyone to have the chance to exchange knowledge with Bruce.**

**David Miguel Soares Dias**
Regulatory Affairs Team Lead
Generis Farmacêutica S.A.
Jul 16 2024

★★★★★

**Very good**

**Jeļena Gurko**
Leading Industrial Pharmacist
JSC
Jan 23 2024

## 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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