CONCEPT

Pharmaceutical Technology Transfer and Scale-Up Training: Site Transfers, Method Transfer and PPQ

19 – 23 April 2027
Barcelona - Eixample district four-star



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Ref: 1655_26127 **Date:** 19 – 23 April 2027 **Location:** Barcelona - Eixample district four-star **Fees:** 23500 SAR

Introduction:

Pharmaceutical technology transfer and scale-up, covering site transfers, method transfer and PPQ, is a 1-week course for MSAT, development, analytical, validation and quality staff at sending and receiving sites, ending with a Technology Transfer Master Plan for a case product. Transfers to partner plants stall when knowledge packages omit the control strategy, equipment differences are ignored, analytical methods fail comparative testing and PPQ batches start before the receiving unit is ready. Nominees already develop, make, test or release medicines and analyse transfer documents and batch data in case studies. CoreConcept Training Center delivers this pharmaceutical technology transfer course.

Course Objectives:

- Structure a transfer project with a sending unit and receiving unit charter, gap assessment and technology transfer protocol
- Assemble a knowledge transfer package that carries ICH Q8 design space, critical quality attributes, critical process parameters and the control strategy to the receiving site
- Translate solid oral and liquid manufacturing steps to larger or different equipment using equipment equivalence and scale-up rules
- Plan and execute analytical method transfer by comparative testing, co-validation, revalidation or justified waiver with acceptance criteria
- Design engineering and PPQ batch campaigns at the receiving site and define the continued process verification that follows
- Classify post-transfer changes with ICH Q12 established conditions and a post-approval change management protocol

Target Audience:

- Manufacturing science and technology staff responsible for moving processes between development, commercial and partner sites
- Formulation and process development staff responsible for writing process descriptions and scale-up rationales
- Analytical development and quality control staff responsible for transferring and verifying test methods
- Validation staff responsible for engineering runs, PPQ protocols and transfer reports at receiving sites
- Quality assurance staff responsible for approving transfer protocols, change controls and batch disposition
- Technical project staff responsible for contract manufacturer and licensee onboarding in localisation agreements

Course Outline:

Day 1: Technology Transfer Landscape, Roles and Feasibility Review

- ICH Q10 Lifecycle Stages Placing Technology Transfer in Context
- Sending Unit and Receiving Unit Responsibility Matrix
- Transfer Types From Development, Inter-Site, CMO and Licensee Routes
- Receiving Site Feasibility Checklist for Equipment, Skills and Capacity
- Technology Readiness Gap Register for a Candidate Product

Day 2: QbD Foundations, Design Space and the Knowledge Package

- ICH Q8 Quality Target Product Profile and Critical Quality Attributes
- ICH Q9 Risk Ranking Linking Material Attributes to Process Parameters
- Design Space and Proven Acceptable Ranges From Development Data
- ICH Q11 Drug Substance Starting Material and Impurity Fate Summary
- Knowledge Transfer Package Contents With Control Strategy Table

Day 3: Process Scale-Up and Analytical Method Transfer

- Equipment Equivalence Assessment by Design and Operating Principle
- High-Shear and Fluid-Bed Granulation Endpoint Scale-Up Rules
- Blending, Compression and Coating Parameter Translation Worksheets
- Liquid Mixing, Hold Time and Filling Scale-Up Considerations
- Analytical Method Transfer Protocol With Comparative Testing Criteria

Day 4: PPQ Readiness, Transfer Failures and Lifecycle Change

- Engineering and Demonstration Batch Plan Before PPQ Execution
- PPQ Protocol Sampling Intensity and Acceptance Criteria Rationale
- Transfer Failure Patterns From Dissolution, Content Uniformity and Yield
- ICH Q12 Established Conditions and Reporting Category Mapping
- Post-Approval Change Management Protocol for a Second Site

Day 5: Case Study and Technology Transfer Master Plan

- Case Oral Tablet Brief for a Licensee Site Transfer
- Case Gap Assessment and Equipment Comparison Review
- Case Analytical Transfer and PPQ Campaign Schedule
- Case Continued Process Verification and Change Strategy Review
- Technology Transfer Master Plan Completion and Peer Challenge

Skills You Will Gain:

- Transfer Feasibility Assessment
- Knowledge Package Assembly
- Design Space Interpretation
- Equipment Equivalence Analysis
- Granulation Scale-Up Translation
- Comparative Method Testing
- PPQ Campaign Design
- Established Conditions Mapping

Why Attend This Course:

- Deliver a Technology Transfer Master Plan to the head of manufacturing science, the site quality head and the partner steering committee for approval
- Judge whether a receiving site, its equipment and its laboratory are ready for engineering runs and PPQ batches
- Avoid failed PPQ campaigns, repeated method transfers and launch delays caused by incomplete knowledge packages
- Coach process, laboratory and quality colleagues in transfer protocols, scale-up worksheets and comparative testing templates

Conclusion:

Back at work, the participant presents the Technology Transfer Master Plan to the head of manufacturing science, the receiving site quality head and the steering committee that governs a contract or licensing agreement. They use it to decide when the receiving unit is ready for engineering batches, which methods need comparative testing and how many PPQ batches to schedule. After the first transfer campaign closes, the unit should compare actual batch results, method transfer outcomes and timelines against the plan and update its templates and equivalence rules.

Frequently Asked Questions FAQ:

What should participants know before a pharmaceutical technology transfer and scale-up course?

Participants should already work in development, manufacturing, laboratory, validation or quality roles and read batch records and process descriptions. Bringing an anonymised process description, method or equipment list helps them apply the case study to their own transfer.

How does pharmaceutical technology transfer and scale-up training differ from a general GMP and process validation course?

It follows one product from sending to receiving site: feasibility, knowledge package, scale-up, method transfer, PPQ and lifecycle change. General GMP and validation courses cover facilities, cleanrooms, equipment qualification and quality events, which appear here only as background.

Why does pharmaceutical technology transfer need PPQ batches at the receiving site?

A process proven at the sending site has not been proven on the receiving site's equipment, materials and people. PPQ batches give documented evidence that the transferred process, run at commercial scale, consistently meets its critical quality attributes.

What do participants take back from the pharmaceutical technology transfer and scale-up course?

Participants take back a Technology Transfer Master Plan for a case oral tablet, with a gap assessment, equipment comparison, method transfer plan, PPQ schedule and change strategy, ready to adapt to their next site transfer.