

Managing Technology Transfer Projects in Pharma

In the dynamic world of pharma significant changes need to be handled on a daily basis. A continuous improvement of regulatory and quality frameworks is only one of many reasons. More than 160BN US Dollars will be invested in R&D until 2020 according to most recent trends. Novel active compounds need to be identified and an increased activity in M&A is foreseen with a few big players sharing the market. More Technology Transfer Projects are expected to be executed to respond efficiently and rapidly to the needs of "process mobility" in the field of R&D and manufacturing. Moreover, matrix organization is becoming a key approach to provide agility and scalability to the organization and to ensure efficacy. The combination of the above aspects draws the conclusion that project managements skills, tools and expertise are a must-have and key drivers for success. Project management needs to be customized to the unique environment of the pharmaceutical industry!

The PDA Europe Managing of Tech Transfer Projects in Pharma course will help you to understand the opportunities project management in pharma can offer and how to apply these skills and tools most efficiently.

Who Should Attend

- Project Managers and Technology Transfer Managers
- Subject matter experts coming from different areas such as
 - Qualification/Validation Engineers
 - Qualified Persons
 - Responsible Persons
 - Security Specialists
 - Regulatory Affairs Specialists

Learning Objectives

Upon completion of the course participants

- Understand principles, main documents and main steps of a technology transfer process (internal and external)
- Understand Project Management tools specific for pharma technology transfer projects
- Identify and mitigate risks in technology transfer processes
- Understand main roles and responsibilities of the stakeholders of technology transfer process
- Manage project changes



Mirko Gabriele, *Production Director, Thermo Fisher Scientific*

Mirko joined Patheon, now part of Thermo Fisher Scientific, in 2008 and has held various positions, including Technology Transfer Project Manager, Technical Business Manager, Manager of Technology Transfer Responsibility and Global TT Sr. Manager for commercial unit for the Ferentino team. He also has experience in Quality Control and Research and Development, both in Finished Products and API companies. Mirko led the Parenteral Drug Association (PDA) Group issuing the Technical Report 65 on Risk Management during Technology Transfer and is currently leading the PDA Global Technology Transfer Interest Group. He is member of the PDA Regulatory Affairs and Quality Advisory Board since 2014. Mirko received a Master Degree in Chemical and Pharmaceutical Technologies in 2004 at the University of Rome and in 2012 and Executive MBA in Pharma Administration at the Luiss Business School of Rome. Mirko is Qualified Person for the Italian Health Authority since July 2014.

Tuesday, 3 September 2019 9:00 – 18:00

- 9:00 Attendees Introduction and Course Expectations**
- 9:15 Course Introduction**
- 9:30 Pharma Management**
- What is a project in pharma? Main principles & final scope
 - Regulatory & Quality Framework
 - Pharma project lifecycle and main steps (Project Matrix)
 - Terminology
- 10:30 Coffee Break**
- 11:00 Team Role in Pharma**
- Org Chart approaches
 - Stakeholders map analysis and main team dynamic principles
 - Functions RACI in each single step
- 12:00 Project Management Role in Pharma Technology Transfer Projects**
- Technology Transfer as key example of a pharma project
 - PM RACI
 - Skills
 - Leadership styles
- 13:00 Lunch Break**
- 14:00 Pharma Tech Transfer Projects Governance**
- Governance standard approach in pharma
 - Project Governance Tools
 - Timelines definition
 - Planning and execution control tools
 - Resources allocation main principles
 - Performance indicators
 - Lesson Learnt
 - Project Closure
- 15:30 Coffee Break**
- 16:00 Pharma Tech Transfer Projects Risk Management**
- Risk Management in pharma principles
 - Risk Management Tools
- 16:45 Change Management**
- Project Change
 - Change Management Process
 - Change Management Plan
- 17:15 Q&A**
- 18:00 End of Day 1**

Wednesday, 4 September 2019 9:00 – 16:00

- 9:00 Case Study 1 (Technology Transfer from Development to Commercial)**
- Project Chart Creation
 - Stakeholder Map Ddefinition
 - Costs and Business Case Evaluation
 - Technology Transfer Timelines Principles and Gantt Definition
- 10:30 Coffee Break**
- 9:00 Case Study 1 (Technology Transfer from Development to Commercial) (Continued)**
- 12:30 Lunch Break**
- 13:30 Case Study 2 (Technology Transfer from Commercial to Commercial)**
- Performance KPI Examples
 - Resources Allocation
 - Technology Transfer Governance Principles
 - Project Closure and Lesson Learnt Analysis
- 15:30 Q&A**
- 16:00 End of Training Course**