

Risk Management in Technology Transfer

The Most Important Aspects of PDA Technical Report # 65

Overview

Nowadays technology transfer projects are a reality in the pharma markets. For several reasons, manufacturing process and related activities (i.e. analytical, development, quality, operation excellence) are moved intra companies and inter companies. Due to the high number of risks associated with the safe robust and in compliance manufacturing of a drug, an appropriate risk management approach and appropriate skills have to be in place in the transferring and receiving site.

Following the main international guidance, such as technical report 65 and ICH, this workshop will guide the attendees through a technology transfer process and its risk management and provide insights and practical guidance for developing internal robust procedures, skills and approaches.

Who Should Attend:

Subject matter experts coming from different areas such as

- Production
- QA
- Validation
- Engineering (involved in process/equipment design)
- RA
- QC (involved in analytical transfer)
- Project Managers and Technology Transfer Managers are key

Learning Objectives:

- Understand principles, main documents and main steps of a technology transfer process (internal and external)
- Identify risks in technology transfer processes
- Evaluate risks and put in place appropriate mitigation plan
- Understand main roles and responsibilities of the stakeholders of technology transfer process
- Create high level internal procedures for handle technology transfer



Mirko Gabriele, *Global Technology Transfer Senior Manager, Patheon*

Mirko joined Patheon in 2008 and has held various positions, including Technology Transfer Project Manager, Technical Business Manager and Manager of Technology Transfer Responsibility 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.

Thursday, 8 November 2018

9:00 – 17:30

9:00 Welcome & Attendees Introduction

9:00 Technology Transfer – Definition and Main Principles

- Opportunities along product lifecycle
- Regulatory guidance on technology transfer
- Planning and Social Intelligence
- Tool for planning

10:00 Technology Transfer – Definition and Main Principles (continued)

- Tool for Social Intelligence
- Role and responsibility
- General org chart in technology transfer

11:00 Coffee Break

11:30 Technology Transfer Project Management Tools

- Timelines
- Leadership
- Communication

12:30 Lunch Break

13:30 Technology Transfer Documentation

- Technology Transfer Plan
- Technology Transfer Report
- Feasibility batches Protocol and Report

14:30 Technology Transfer Procedures

15:30 Coffee Break

16:30 Analytical Transfer

- General approach (transfer vs validation)
- Analytical Master Plan

17:00 Recap of the Day

17:30 End of Day 1

Friday, 9 November 2018

9:00 – 16:30

9:00 Recap of the Main Concepts of Day 1

9:30 Introduction into Technical Report TR 65

- Project staging
- Risks in technology transfer
- Risk Management in technology transfer

10:30 Introduction into Technical Report TR 65 (continued)

- Severity/Occurrence/Detection in technology transfer
- FMEA

11:00 Coffee Break

11:30 TR 65 – Case Study 1 ‘Analytical Method Transfer (AMT)’

- Design of Comparative AMT Test Studies
- Selecting AMT Performance Characteristics
- AMT Documents

12:30 Lunch Break

13:30 TR 65 – Case Study 2 ‘Manufacturing Process Transfer’

- Overview of Manufacturing Process Transfer
- Development to Commercialization Technology Transfer Process
- Intracompany Technology Transfer Process

16:30 End of Course