

PDA EU00160 Managing Technology Transfer Projects in Pharma

Thursd	lay, 14 September 2023
09:00	Attendee's Introduction
09:15	PDA Overview, Course Introduction and Expectations
09:45	 Technology Transfer in Pharma Part I What is a project in pharma? Main principles & final scope Terminology Types of TTs Main aspects of Technology Transfer and success key factors: technical and organizational aspects Breakout: Provide the framework where pharma technology transfer takes place with reference to most common used terms and TT aspects
10:50	Coffee Break
11:05	Technology Transfer in Pharma Part II Regulatory & quality framework Pharma project lifecycle and main steps GMP aspects of Technology Transfer
12:00	 Team Role in Pharma Team setting and organizational aspects Org Chart approaches Functions RACI in each single step Stakeholders' Analysis Part I Stakeholders map analysis and main team dynamic principles Breakout: We will learn how to navigate in a pharma technology transfer space, focusing on the key actors and how they interact to succeed
13:00	Lunch Break
14:00	Stakeholders' Analysis Part II • Exercise Project Management Technology Transfer Projects • PM role in Technology Transfer • TT Team RACI • Skills • Leadership styles Breakout: In Pharma TT people have a crucial role. We will understand better
	stakeholders' roles, behaviors and management and role of the PM
15:45	Coffee Break
16:00	 Pharma Tech Transfer Projects Governance Governance standard approach in pharma Project governance tools



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	Timelines definition
	Planning and execution control tools
	Resources allocation main principles Leasen Leasent
	Lesson learnt Design to all a support
	Project closure Focus on CDMO Technology Transfer
	Focus on CDMO Technology Transfer
	Pharma Tech Transfer Projects Risk Management
	Risk Management in pharma principles
	Risk Management tools
	Breakout: Pharma TT project clearly is a complex project; we will learn the fundamental
	tools to be used to govern it and boost it.
17:15	Q&A
18:00	End of Training Course Day 1



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Friday,	15 September 2023
09:00	Pharma Tech Transfer Projects Risk Management
	• Exercise
	Change Management Project change Change management process Change management plan Knowledge transfer assessment Breakout: Risk and changes management are fundamental aspects of the Technology
	Transfer. In this session we will learn how to handle them in a structured and effective way
10:45	Coffee Break
11:00	Case Studies
	Breakout: Real examples of Technology Transfers
12:30	Lunch Break
13:30	 Technology Transfer Workshops Project chart creation Stakeholder map definition Costs and business case evaluation Technology Transfer timeline principles and Gantt definition
	Focused A: Technology Transfer from Development to Commercial
	Focused B: Technology Transfer from Commercial to Commercial
	Conclusions and take away Breakout: At the end of this second day, we will have applied tools and concepts explained in day 1 in a real technology transfer project. We will start together defining the framework and as a team we will define timelines, assign roles, calculate allocation of resources, identify, and quantify risks and build a contingency plan to mitigate those risks.
15:30	Q&A
16:00	End of Training Course