

Training Course Agenda

PDA EU00160 Managing Technology Projects Transfer in Pharma

Day 1, Thursday, 26 September 2024		
9:00	Welcome and Introduction of Trainer and Participants	
9:15	PDA Overview, Course Introduction and Expectations	Angela Molaschi, <i>Pharmatex</i>
09:45	<p>Technology Transfer in Pharma Part I</p> <ul style="list-style-type: none"> • Introduction to Technology Transfer • What is a Technology Transfer project in pharma? Main principles & final scope • Terminology • Types of TTs • Main aspects of Technology Transfer and success key factors: technical and organizational aspects <p><i>Breakout:</i> Provide the framework where pharma technology transfer takes place with reference to most common used terms and TT aspects.</p>	Angela Molaschi, <i>Pharmatex</i>
10:50	<i>Coffee Break</i>	
11:05	<p>Technology Transfer in Pharma Part II</p> <ul style="list-style-type: none"> • Regulatory & quality framework • Pharma project lifecycle and main steps and activities • GMP aspects of Technology Transfer 	Angela Molaschi, <i>Pharmatex</i>
12:00	<p>Team Role in Pharma</p> <ul style="list-style-type: none"> • Team setting and organizational aspects • Org Chart approaches • Functions RACI in each single step <p>Stakeholders Analysis Part I</p> <ul style="list-style-type: none"> • Stakeholders map analysis and main team dynamic principles <p><i>Breakout:</i> We will learn how to navigate in a pharma technology transfer space, focusing on the key actors and how they interact to succeed.</p>	Angela Molaschi, <i>Pharmatex</i>
13:00	<i>Lunch Break</i>	
14:00	<p>Stakeholders Analysis Part II</p> <ul style="list-style-type: none"> • Exercise <p>Project Management Technology Transfer Projects</p> <ul style="list-style-type: none"> • PM role in Technology Transfer • TT Team RACI 	Angela Molaschi, <i>Pharmatex</i>

	<ul style="list-style-type: none"> • Skills • Leadership styles <p><i>Breakout:</i> In Pharma TT people have a crucial role. We will understand better stakeholders' roles, behaviors and management and role of the PM.</p>	
15:45	<i>Coffee Break</i>	
16:00	<p>Pharma Tech Transfer Projects Governance</p> <ul style="list-style-type: none"> • Governance standard approach in pharma • Project governance tools • Timelines definition • Planning and execution control tools • Resources allocation main principles • Lesson learnt • Project closure • Focus on CDMO Technology Transfer <p>Pharma Tech Transfer Projects Risk Management</p> <ul style="list-style-type: none"> • Risk Management in pharma principles • Risk Management tools <p><i>Breakout:</i> Pharma TT project clearly is a complex project; we will learn the fundamental tools to be used to govern it and boost it.</p>	Angela Molaschi, <i>Pharmatex</i>
17:15	Q&A	
18:00	<i>End of Training Course Day 1</i>	
Day 2, Friday, 27 September 2024		
9:00	<p>Pharma Tech Transfer Projects Risk Management</p> <ul style="list-style-type: none"> • Exercise <p>Change Management</p> <ul style="list-style-type: none"> • Project change • Change management process • Change management plan • Knowledge transfer assessment <p><i>Breakout:</i> Risk and changes management are fundamental aspects of Technology Transfer. In this session we will learn how to handle them in a structured and effective way.</p>	Angela Molaschi, <i>Pharmatex</i>
10:45	<i>Coffee Break</i>	
11:00	<p>Management of Technology Transfer Projects In Pharmaceutical Environment</p> <ul style="list-style-type: none"> • Tools and documents 	Angela Molaschi, <i>Pharmatex</i>

	<ul style="list-style-type: none"> • Case studies • Examples from real life <p><i>Breakout: Real examples of Technology Transfers</i></p>	
12:30	Lunch Break	
13:30	<p>Technology Transfer Workshops</p> <ul style="list-style-type: none"> • Project chart creation • Stakeholder map definition • Costs and business case evaluation • Technology Transfer timeline principles and Gantt definition <p>Focused A: Technology Transfer from Development to Commercial</p> <p>Focused B: Technology Transfer from Commercial to Commercial</p> <p>Conclusions and Take Away</p> <p><i>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.</i></p>	<p>Angela Molaschi, <i>Pharmatex</i></p>
14:30	Coffee Break	
15:30	Wrap-up Discussion / Q&A	Angela Molaschi, <i>Pharmatex</i>
16:00	End of Training Course	