



BII WORLD
Engage • Enlighten • Empower



PHARMACEUTICAL TECH TRANSFER



16 hours of virtual learning experience

28 April - 01 May 2025

08:00 - 12:00 Eastern Standard Time (EST)

www.biiworld.com

Course Overview:

Significant changes in the pharmaceutical space need to be handled daily. More Technology Transfer Projects are expected to be executed to respond efficiently and rapidly. Alignment between the receiving and transferring sites is one of the most significant challenges of a technology transfer. “More than the technology or the knowledge itself, the alignment of systems and mentality, culture, and approaches to issues between these stakeholders are the most important factors for success,”

This 4 Day-Online Course will shed light on the Technology Transfer application & tools, risk factors and how to measure, and reduce those risks. The Daily 4-hrs varied sessions will have topics such as Project Management, example of Project Governance, Knowledge & Change Management, Risk Assessment & Management, Different approaches of Analytical Transfer, Application of Digital Tools in Tech Transfer among others. Case Studies and Exercises will be part of all the 4 Days to give this training a more interactive approach.

Learning Objectives:

- Application of Technology Transfer to Pharma Projects
- Adopting the main Tools and Best Practices available, how to raise the bar in your TT organization
- Main risks to count for during a Pharma Technology Transfer Project,
- How to measure, handle and mitigate those risks; converting some of those in real opportunities for your team/organization
- Knowledge Management during Technology Transfer, what does it mean and how to develop a smooth process to share knowledge within your organization

TARGET AUDIENCE (Who should attend):

Title/ Department:

1. Technology Transfer Leaders
2. Technology Scale-up and Transfer Managers
3. Process Validation Leaders/SPV
4. Quality Compliance Leaders/SPV
5. Quality Control Managers
6. Process Engineers
7. Manufacturing Leaders/SPV
8. Risk Management Specialists
9. Validation Specialist
10. Product Transfer Manager





Instructor:

MIRKO GABRIELE

... your **EXPERT TRAINER** for this Course.

Mirko is a passionate advocate of pharma and innovation, and a strong believer that new technology has a positive impact on people's quality of life. He has over 20 years of experience in the Pharma industry predominantly in Technology Transfer and Operations.

He has held several key roles in Technology Transfer from Project Leader to Program Manager, moving from technical feasibility assessment and tasks coordination to complex multi-sites multi-dosages project management to overall technology transfer company portfolio management (100+ active programs). These include team leading in an Agile framework, financial monitoring, performance management, overall risks management and mitigations, reporting to executive and development of strategy and relationship with key stakeholders (i.e Regulatory Agency, Sponsors, Suppliers, Executives).

As a result of his ability to successfully execute all stages of the technology transfer process, he was promoted from site roles to global roles, with the opportunity to work on Technology Transfer Policy harmonization and best practices improvement and sharing. He successfully covered several dosage forms projects, from Oral to Combination products with a strong expertise in Sterile.

Director roles in Business operations and innovation and strategy gave Mirko a full overview of the technology and pharma space, strengthen his ability to successfully lead complex team and organization (500+ reports). He is also part of the PDA (Parenteral Drug Association www.pda.org) since 2005 and is now member of the Board of Director. He led the writing task force who produced the Technical Report 65 (TR-65 Risk Management in Technology Transfer), and he is currently the PDA Europe Trainer for Technology Transfer. Mirko is leading the PDA Technology Transfer Interest Group (TT IG) for Europe which has the mission to define, share and implement best practices in the industry.



PRESENTATIONS:

Day 1

13:00 - Pre-Course Intro

Module 1: Technology Transfer

- History of Technology Transfer – Revolutionary changes in few years.
- Why and when Technology Transfer happens.
- Different types of Technology Transfer
- Regulations Journey: from WHO 2011 to the TR 65, PDA (2022)

Break:

Module 2: Technology Transfer Project Management - 1

- Roles and responsibilities in the Technology Transfer: Steps from planning to lesson learned to support process control during lifecycle management.
- Governance within sending and receiving team and governance among them including sponsors.

- Tools to reduce risks in decision making
- KO meeting and team definition

Break

Module 3: Technology Transfer Project Management - 2

- Project Leader Role.
- Project phases and challenges associated.
- Performance management and indications.

Case Study – 1: Example of project governance in place for a sterile TT

Exercise – 1:

- Define the stakeholder map in a typical TT project.
- Define the RACI for a typical TT project.

Post-Session Q&A

17:00 – End of Day 1

Day 2

13:00 - Review of Day 1

Module 4: Knowledge Management in Technology Transfer

- Knowledge management and proper transfer:
 - o Information from the sending to the receiving unit
 - o Including control checklist and risk assessment on documentation
- Knowledge assessment and maturity journey of the receiving unit
- How to use Technology Transfer to challenge and improve your knowledge management system

- Lesson learnt

Break

Module 5: Project Documentation

- Technology Transfer plan description and minimum requirements
- Technology Transfer report description and minimum requirements
- Technology Transfer procedures and documentation handling

Break



Course Outline:

Day 2

Module 6: Change Management

- Project Change
- • Change Management: How to convert from static to dynamic organization leveraging Technology Transfer projects
- Change management tools

Case Study 2: Example of Technology Transfer procedure

in place in a manufacturing organization

Exercise – 1:

- Simulate audit to a third party focusing on a Technology Transfer plan.

Post-Session Q&A

17:00 – End of Day 2

Day 3

13:00 – Review of Day 2

Module 7: Risk Management in Technology Transfer - 1

- The role of the risk management in Technology Transfer
- Challenges and opportunities in Technology Transfer
- Regulatory Framework

Break

Module 8: Risk Management in Technology Transfer - 2

- ICH Q9 and Q10
- Risk assessment tool
- Selection of the most appropriate tool based on project stage

Break

Module 9: Risk Management in Technology Transfer - 3

- Post-approval change management (PACMP)
- Risk prioritization
- Solid Oxide Fuel Cells

Case Study 3: Example of CQA and CPP of a sterile product

Exercise – 3:

- o Perform as a team an assessment on the main risks associated with a Technology Transfer

Post-Session Q &A

17:00 – End of Day 3



Day 4

13:00 – Review of Day3

Module 10: Analytical Transfer

- Regulatory framework
- Different approaches
- Documentation minimum requirements
- API, quality control standards, packaging components/operations

Break

Module 11: QBD, Scale-Up and Process Validation

- From the bench to the market
- Design the Technology Transfer roadmap
- Challenges and opportunities
- SUPAC (Scale-up and post approval changes)

Break

Module 12: Digital and Innovation in Technology Transfer

- Technology assessment and profiling
- Technology Transfer and strategy fit
- Application of digital tools in Technology Transfer

Case Study 4: Assessment of new technology before transferring in

Exercise -4:

- o Define the Technology Transfer mission and strategy for a CDMO

Post-Session Q &A (Day 1 – 4)

17:00– End of Day4 & Course



Does BII Online Virtual Training have the same value as traditional classroom training?

Yes, BII Online Virtual Training offers participants; same training system as in-person, i.e face-to-face engagement with instructors, course material, interactive participation of all delegates, and personal support that they would expect to find in a traditional classroom.

What are main features of your online courses? Are they on-demand? Is it different content from the in-person offering?

The content of the virtual training is similar to the in-person sessions and customized presentation makes it a richer online learning experience. As always, we will share presentation materials with attendees for later reference.

The online courses are not on-demand and recordings cannot be purchased. They are set on scheduled dates, live with an instructor and co-host via webinar software. While the day is shorter than an in-person session (4hrs vs 8hrs), timing are adjusted to accommodate attendees in different time zones and allow more time for one-on-one conversations via the Q & A.

What are the technical requirements for participation in a virtual course?

All you need to participate in virtual training are:

- Desktop or Laptop or Tablet Computer, and Internet connection
- Webcam
- Headset with built-in microphone

Can I attend an online training session if I have a Macintosh computer?

Yes, Our Online training systems does allow Macintosh computers, PCs, and computers running Linux to easily enter any of our online training sessions.

What type and version of browser will I need for online classes?

It is recommended that you use the latest version of Firefox, Chrome or Internet Explorer for Windows and Firefox or Safari for Mac. Each of these is available for free download and also suggested you have the PDF Reader

How do I have access to the trainer for questions?

As in the classroom, you will see the trainer in front of you and have the opportunity to ask questions at any time - all via audio and video transmission.

Is there a mute option within an online training session to minimize background noise from my audio connection?

Yes, the Mute button will display to the right of your name as you hover your mouse over your name shown in the Participants panel on the top, right side of the Web conferencing screen.

What if I miss few sessions of the online training program?

The training will be simultaneously recorded which will be provided to you as per request & requirement

Do I get a Certificate at the end?

Yes, you will get a PDF version of your certificate of completion



Please complete this form and send it back to
mithun.siddartha@biworld.com

Event Code: OL LS 43

Delegate Details

- Name: Mr/Mrs/ Ms
.....
Job Title:
Email:
- Name: Mr/Mrs/ Ms
.....
Job Title:
Email:
- Name: Mr/Mrs/ Ms
.....
Job Title:
Email:

PAYMENT METHOD:

CREDIT CARD

The secured payment link will be shared/sent

WIRE TRANSFER OR BANK TRANSFER

Authorization and Acceptance of Sales Contract & Terms & Conditions

I hereby declare I am authorised to sign this contract and terms & conditions in the name of the company/organisation:

Company/Organisation Detail

Name:
Person to Contact:.....
Email:
Address:
.....
City:
Country:
Contact No:
Type of Business:
Website:

Name:.....

Date:.....

Signature:.....

1 Delegate Fee **USD 1299 per delegate**

20 USD administration charge and any applicable withholding or any other tax or fee will be applied

TERMS & CONDITIONS:

- Payment terms: BII World LTD requires the full payment of the invoiced amount within 7 working days from the issue date of the invoice. BII World LTD reserves the right to refuse entry to any client who does not pay the invoice in full and on time. The registration fee includes: Training documentation and admission to all training sessions.
- Cancellation by client: The client has the right to cancel his/her participation in the event. Cancellation must be received by BII World LTD in writing either by mail or fax. If the client cancels the event, he/she will get two options:
A. CREDIT NOTE: Choose 2-year credit note, BII World LTD will send all the schedule training event details throughout the year. Delegate has the right to choose and attend any of the training programs (valid 2 years).
B. NOMINATION: In this option delegate can nominate/refer someone from his/her group/company to attend the particular training program on behalf of the actual delegate.
- Cancellation by BII World LTD : While every reasonable effort is made to adhere to the advertised program, circumstances can arise which may cause changes in the program, including but not limited to changes in the content, date(s), or special features of the planned event. Such circumstances include but are not limited to acts of terrorism, war, extreme weather conditions, compliance with government requests, orders and legal requirements, failure of third-party suppliers to timely deliver, and failure to register the minimum target number of attendees for a given event. BII World LTD reserves the right to change the content, date(s), and/ or special features of an event, to merge the event with another event, or to postpone it or cancel it entirely as appropriate under the circumstances. Client agrees that BII World LTD shall not be liable for any cost, damage or expense which may be incurred by client as a consequence of the event being so changed, merged, postponed or cancelled and client agrees to hold BII World LTD harmless and to indemnify BII World LTD in case of liability caused by any such changes, mergers, postponements or cancellations.
- Cancellation of the event: In case BII World LTD cancels an event, then client can choose any of the below mentioned options:
(a) BII World LTD will refund full payment to the client within 15 business days.
(b) Client can choose the credit option for 2 years, for more details please read term no-2 part (a)

- Postponement of the event : In case BII World Ltd postpones the event to a new date, then client can choose any of the below mentioned options.
(a) The client can attend the course on the postponed dates.
(b) Client can choose the credit option for 2 years, for more details please read term no-2 part (a)
- Client's identification information. By signing of this sales contract and these terms and conditions the client gives full right to BII World LTD to share the client's identification information, i.e. client's name, address, email addresses, phone numbers and names of representatives and website with other clients who participated in the same event. The client has the right to opt out of this clause by writing notice to BII World LTD.
- Governing law: This contract shall be governed by and construed in accordance with the laws of the Province of Alberta, Canada. Any disputes arising under or in connection with this registration form shall be settled before the competent court in Canada.
- Indemnification: To the fullest extent permitted by the law, you agree to protect, indemnify, defend and hold harmless BII World LTD, its owners, managers, partners, subsidiaries, affiliates, officers, directors, employees and agents, from and against any and all claims, losses or damages to persons or property, governmental charges or fines, penalties, and costs (including reasonable attorney's fees) (collectively "the Claims"), in any way arising out of or relating to the event that is the subject of this contract, and regardless of negligence, included but not limited to, Claims arising out of the negligence, gross negligence or intentional misconduct of BII World LTD employees, agents, contractors, and attendees; provided, however, that nothing in this indemnification shall require you to indemnify BII World LTD indemnified parties for that portion of any Claim arising out of the sole negligence, gross negligence or intentional misconduct of the BII World LTD parties.
- Other currencies. In case that client requests payment in other than official currency (USD), BII World LTD reserves the right to apply 5% currency risk surcharge to the actual exchange rate.
- Other Conditions: Any terms or conditions contained in the client's acceptance which contradict or are different from the terms and conditions of this registration document shall not become part of the contract unless individually negotiated with BII World LTD and expressly accepted by BII World LTD.