BII WORLD
Engage • Enlighten • Empower

PHARMACEUTICAL TECH TRANSFER

2 Day (16 hours) of In-Person Learning Experience

27-28 February 2025

Amsteram, Netherlands

09:00 - 17:00 Central European Time (CET)

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 2 Day In-Person Course will shed light on the Technology Transfer application & tools, risk factors and how to measure, and reduce those risks. The Daily 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 2 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

09:00 - Pre-Course | Registration

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)

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

AM Coffee 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.

Lunch Break

Module 4: Knowledge Management in Technology Transfer

- Knowledge management and proper transfer:
- Knowledge assessment and maturity journey of the receiving unit
- How to use Technology Transfer to challenge and improve your knowledge management system & Lesson learnt

PM Coffee Break

Module 5: Project Documentation

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

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 – 1: Example of TT procedure in place in a manufacturing organization.

Exercise – 1:

Simulate audit to a third party focusing on a TT plan.

17:00 - End of Day 1

Break

Course Outline:

Day 2

09:00 – 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

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

AM Coffee 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

Lunch Break

Module 10: Analytical Transfer

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

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

PM Coffee Break

Module 12: Digital & 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

17:00 – End of Day 2

Upcoming Courses 2024

Pharmaceutical Technology Transfer

Facilitator : **Mirko Gabriele**
Date : **27 - 28 Febraury, 2025**
Timings : **09:00 - 17:00 Central European Time (CET)**

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Our Expert 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).

CLICK HERE To access this course agenda.

GXP - Good Practices

Facilitator : **Markus Roemer**
Date : **10 - 13 March, 2025**
Timings : **09:00 - 13:00 Central European Time (CET)**

This 12 hrs online expert course covers GXP aspects for Computer System Validation (CSV) and Data Integrity (DI). The 3 Day sessions also covers the baseline for digitalization projects, digital validation, qualification of cloud computing used in the GXP environment. It contains a full session about the validation of artificial intelligence (AI), deep learning and machine learning (ML). All applicable world-wide regulations will be introduced, including but not limited to EU GMP Annex 11 and US-FDA 21 CFR Part 11 – ERES and others.

Our Expert is an independent consultant, involved in a wide range of areas including the validation of computerised systems, auditing, quality management, project management and compliance management. Since 2008, he has been working as an ISPE ambassador for the DACH affiliate. He is a frequently invited speaker and trainer, more than 100 events passed by.

CLICK HERE To access this course agenda.

Pharmaceutical Dissolution Testing

Facilitator : **Mark Powell**
Date : **12 - 13 May 2025**
Timings : **09:00 - 17:00 Central European Time (CET)**

Pharmaceutical dissolution test results are influenced by a large number of physical and chemical parameters. Regulators expect that dissolution tests will be robust, adequately precise and, for poorly-soluble drugs, discriminating. This two-day in-person course is aimed at those developing or performing dissolution tests for solid oral dosage forms. It would also be useful for regulatory professionals who would like to understand more about reviewers' expectations. The 16 hrs face to face course incorporates relevant guidance from the recent ICH Q14 (Analytical Procedure Development) and the updated ICH Q2 (Validation of Analytical Procedures).

Our Expert is a Fellow of the Royal Society of Chemistry (RSC) with over thirty years' experience as an analytical chemist. He is an expert in sampling and sample preparation, chromatography (liquid and gas), spectroscopy (atomic and molecular) and pharmaceutical dissolution testing. Mark was Honorary Treasurer of the RSC's Analytical Division and led a working group on continuing professional development until July 2016.

CLICK HERE To access this course agenda.

Pharmaceutical Technology Transfer

27 - 28 February, 2025 | Amsterdam

BII World Limited
9616 45th Avenue
Northwest, Edmonton, AB
T6E 5Y9, **Canada**

Please complete this form and send it back to
tim.miles@biiworld.ca

Event Code: EU LS 03

Delegate Details

1. Name: Mr/Mrs/ Ms .....
.....
Job Title: .....
Email: .....
2. Name: Mr/Mrs/ Ms .....
.....
Job Title: .....
Email: .....
3. Name: Mr/Mrs/ Ms .....
.....
Job Title: .....
Email: .....

Company/Organisation Detail

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

PAYMENT METHOD:

CREDIT CARD OR ONLINE PAYMENT ☐
The secured payment link will be shared/sent

WIRE 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:

Name:.....

Date:.....

Signature:.....

Delegate Fee ☐ **€ 2299 per delegate**

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

TERMS & CONDITIONS:

1. 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 Ãme. The registraÃon fee includes: Training documentaÃon and admission to all training sessions.

2. CancellaÃon by client: The client has the right to cancel his/her parÃcipaÃon in the event. CancellaÃon must be received by BII World LTD in wriÃng either by mail or fax. If the client cancels the event, he/she will get two opÃons:

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 aÃend any of the training programs (valid 2 years).

B- NOMINATION: In this opÃon delegate can nominate/refer someone from his/her group/company to aÃend the parÃcular training program on behalf of the actual delegate.

3. CancellaÃon by BII World LTD : While every reasonable effort is made to adhere to the adverÃsed 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 condiÃons, compliance with government requests, orders and legal requirements, failure of third-party suppliers to Ãmely deliver, and failure to register the minimum target number of aÃendees 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 enÃrely 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 cancellaÃons.

4. CancellaÃon of the event: In case BII World LTD cancels an event, then client can choose any of the below menÃoned opÃons:

(a) BII World LTD will refund full payment to the client within 15 business days.
(b) Client can choose the credit opÃon for 2 years, for more details please read term no-2 part (a)

5. Postponement of the event : In case BII World Ltd postpones the event to a new date, then client can choose any of the below menÃoned opÃons.

(a) The client can aÃend the course on the postponed dates.
(b) Client can choose the credit opÃon for 2 years, for more details please read term no-2 part (a)

6. Client's idenÃficaÃon informaÃon. By signing of this sales contract and these terms and condiÃons the client gives full right to BII World LTD to share the client's idenÃficaÃon informaÃon, i.e. client's name, address, email addresses, phone numbers and names of representaÃves and website with other clients who parÃcipated in the same event. The client has the right to opt out of this clause by wriÃen noÃce to BII World LTD.

7. Governing law: This contract shall be governed by and construed in accordance with the laws of the Pr ovince of Alberta, Canada. Any disputes arising under or in connecÃon with this registr aÃon form shall be seÃled bef ore the competent court in Canada.

8. IndemnificaÃon: To the fullest extent permiÃed 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, penalÃes, and costs (including reasonable aÃorney's fees) (collecÃvely "the Claims"), in any way arising out of or relaÃng 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 intenÃonal misconduct of BII World LTD employees, agents, contractors, and aÃendees; provided, however, that nothing in this indemnificaÃon shall require you to indemnify BII World LTD Indemnified parÃes for that porÃon of any Claim arising out of the sole negligence, gross negligence or intenÃonal misconduct of the BII World LTD parÃes.

9. 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.

10. Other CondiÃons: Any terms or condiÃons contained in the client's acceptance which contradict or are different from the terms and condiÃons of this registraÃon document shall not become part of the contract unless individually negoÃated with BII World LTD and expressly accepted by BII World LTD.