BII WORLD
Engage • Enlighten • Empower

GXP – Good Practices

digitalization of projects, validation, qualification in the GXP environment

Join our global industry expert & instructor:
Markus Roemer, trainer, independent pharmaceutical consultant.

12 Hours Virtual Learning Experience

10 – 12 March 2025

09:00 - 13:00 Central European Time (CET)

www.biiworld.com

COURSE OVERVIEW:

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.

Learn about the background, effects and details regarding the current changes and extensions of the ISPE GAMP®5 – Second Edition – which was released in August 2022.

In 2008, ISPE set GAMP®5 as the recognized state of science and technology regarding so-called computer system validation (CSV) in the GxP environment. The volume ISPE GAMP®5 – Second Edition, published in August, is a deliberate extension of the proven standard.

With the expansion in the form of a second edition, current topics are to be presented even more clearly, pragmatically and purposefully. Validation should be based more on process, data and system knowledge and these should be even more in the foreground of agile system development and the validation approach.

LEARNING OBJECTIVES:

- **Identify** CSV and DI Requirements
- **Understand** validation projects and goals
- **Lifecycle** data and system lifecycle
- **Operational** understand what and how to do it – and why
- **Integration** use it in your daily business
- **Build** a landscape and roadmap to compliance

TARGET AUDIENCE:

Job Titles:

- Senior Management / CEO
- Qualified Person / Responsible Person
- Head of QA, Production and QC
- Validation and Qualification Teams
- Inspectors and Investigators
- Validation Experts
- People willing to be a game changer in the company

Job Industries:

- GMP
- GDP
- GCP – sponsors and CMOs
- GLP
- CGMP
- GVP
- Medical Devices
- Suppliers
- Consulting

tim.miles@biiworld.ca

www.biiworld.com

Instructor:

MARKUS ROEMER

… your EXPERT TRAINER for this Course.

Markus Roemer 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.

An Engineering Graduate, Mr. Roemer started his professional career as a team member in computer validation at Vetter Pharma in Ravensburg. He then worked for the MES system provider Propack Data GmbH in Karlsruhe where he worked as quality manager for EBR projects.

In 2003, Mr. Roemer took on the role of Senior Validation Consultant at Invensys Validation Technologies in Montreal, Canada where he supported global IT and validation projects abroad. In his role as Head of Compliance Services and Quality Management at Systec & Services, he was in a position to use his knowledge of customers and suppliers.

Markus Roemer is a frequently invited speaker and trainer by organizations such as PTS (pharmaceutical training services), ISPE, European Compliance Academy and the European QP Association at more than 100 events or training. In his current position as Managing Director at comes compliance services he is in charge of consultancy services for IT and PQS compliance. Mr. Roemer has written widely on the subject of computer system validation and the use of electronic systems (eDMS, EBR, ERP) and is also the author of several books on validation, IT compliance, GMP documentation and processes.

PRESENTATIONS:

Day 1:

09:00 - Pre-Course Intro – Delegate Expectation Briefing

Session 1: Regulations – Regulatory Baseline for Computer System Validation (CSV) and Data Integrity

- Roadmap: GXPGLP – GCP – GMP – GDP - GLP
- Medicinal Products and Medical Devices
- US-FDA CGMP and EU GMP and GMP ROW
- PIC/S, ICH, WHO, OECD and others
- CSA vs. CSV – what is it really about?

Session 2: Standards ISPE GAMP®5 SE

- History and Background of ISPE GAMP®5 – second edition - 2022
- Overview of all Good Practice Guides
- Key messages ISPE GAMP®5 SE – Enabling Innovation
- OECD Guidelines for CSV, Cloud Computing and Data Integrity (GLP)

Break

Session 3: Understanding regulations and validation concepts

- EU Annex 11 and Annex 15, US-FDA 21 CFR Part 11
- Other Qualification and Validation activities: Process Validation, Cleaning
- Validation, Transport Verification, Qualification of equipment etc.
- Using electronic signatures (signature regulations)

Session 4: Validation Planning and data literacy

- Validation Planning, Design Phase
- From Process and Data Mapping to URS and User Acceptance Testing
- How to use process-based risk management (FMEA)?
- Process Mapping with SIPOC followed by FMEA

Post-Session Q &A

13:00 – End of Day 1 Good Documentation Practices (GDocP)

PRESENTATIONS:

Day 2:

09:00 - Review of Day 1

Session 5: Standards for Data Integrity / Data Management

- Global requirements for good practice for data management and integrity
- MHRA, US-FDA, EU, PIC/S requirements
- Data Integrity Assessment Programs incl. Data Flow Diagrams
- Approach for existing systems and new systems (validation)

Session 6: Validation and Compliance Planning

- Writing URS – get what you want and really need
- Project Management for compliance projects
- What is software development? What is agile and scrum?
- Tracking status
- Preparation for digital validation solutions

Break

Session 7: Suppliers and Service Providers incl. Cloud Service Provider

- Audit Planning, Execution and Reporting
- Quality Systems for Pharma – PQS
- Quality System of suppliers – QMS
- Quality System of providers – SMS
- What are IT standards – ISO 20000, ISO 27001, ITIL
- How does IT work (tools)?

Session 8: Digital Validation Approaches and Validation of Artificial Intelligence

- Requirements management
- Test management
- Examples with Atlassian Confluence and Jira
- Other tools

Post-Session Q &A

13:00 – End of Day 2

PRESENTATIONS:

Day 3:

09:00 - Review of Day 2

Session 9: Test Plan and Test Execution

- Supplier testing verification
- Test Phases and Strategies
- Test Readiness Checks and Test Scripts
- Handling of test errors and test runs

Session 10: Verification and Testing

- Scripted testing vs. unscripted
- Release Management
- Verification of validation status
- Preparation for Go-Live and Hyper-Care Phase

Break

Session 11: Keep it validated

- Procedures for operational phase
- Training
- How to write SOPs
- Periodic Evaluation

Session 12: Validation Summary Report

- How to write a final report
- Content
- Regulatory requirements
- Final conclusion and lessons learned

Post-Session Q &A

13:00 – End of Day 3

FAQs

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

Upcoming Courses 2024

Pharmaceutical Technology Transfer

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

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.

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.

GXP - Good Practices

10 - 12 March, 2025

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: OL LS 42

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 ☐

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:

Name:.....

Date:.....

Signature:.....

Delegate Fee ☐ USD **1099 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.