BII WORLD
Engage • Enlighten • Empower

QBD | Quality by Design

A lifecycle approach for a successful program.

Join our global industry expert & instructor:
Emil W. Ciurczak, Ex. PAT committee member for FDA and is a member of the PAT Advisory Committee to the USP. Emil consults and gives courses on PAT/QbD in the US, Europe, South America, and Asia.

16 Hours Virtual Learning Experience

24- 27 June 2024

13:00 - 17:00 CET Standard Time

www.biiworld.com

COURSE OVERVIEW:

Quality by Design (QbD) has become a force in the pharmaceutical industry, both saving money and producing superior products. This online course will cover the various aspects (Guidances and laws that cover QbD) from ICH, EMA, and FDA as well as the benefits and tools used for a successful program. It will also concentrate on the lifecycle management portions of ICH Q-11and Q-12.

Topics will include Science and Risk-Based Approach to Product Lifecycle and Process Validation, ICH Q8-Q11guidances, QbD Terminology and their concepts (QTPP, CQA, CPP), and Quality Risk Management. We will discuss Process Qualification using EMA, FDA, and ASTM documents. Process Performance Validation will discuss Verification of Control Strategies and the Validation protocol and Validation Report(s)

The **4-Day QBD Online Course** will also cover some of the more important technologies used in QbD: Near-Infrared, Raman, and fluorescence spectroscopies, acoustics, LIBS (LASER-induced breakdown spectroscopy) and more. Examples of application or these technologies and suggestions of where and how to apply them will be covered. The course will show where and how these techniques are used to update and improve product quality over the lifetime of the product.

LEARNING OBJECTIVES:

- **Identify** :Where QbD would be cost-effective and which product(s) are best measured.
- **Understand** :The legal aspects of performing QbD and where to find assistance from the Agencies.
- **Key Learning:** Which tests on which products should be first and will give the greatest payback for effort and cost.
- **Lifecycle QbD:** Allows the manufacturer to follow the vision of the Agencies: as the product ages, it is made better and better by understanding the process and modifying it over time.
- **Operational**: How to determine the equipment, software, and strategies for control of the process.
- **Integration:** How to take disparate data from several monitors (physical and spectroscopic) and integrate the signals into data and control of the system.
- **Build:** Your team who is needed and from which department? Your system: which tools and software will give you a successful program.
- **Sampling**: How to sample in a statistically significant manner to generate the most data from the minimum samples.

TARGET AUDIENCE:

Job Titles :

- Production Manager
- R&D Personnel (tech and finance-minded)
- Quality Assurance (All)
- Quality Control Manager/Supervisor
- AR&D Method Development Personnel
- Product Design Personnel (formulators)
- IT Personnel (highly computer dependent effort)
- Statistics and Chemometric personnel (Highly dependent on both)
- Validation
- Regulators

Industries :

- Proprietary Pharma
- Generic Pharma
- Contract Pharma (manufacturing)
- Contract Pharma (R&D)

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Instructor:

Emil W. Ciurczak

… your EXPERT TRAINER for this Course.

Emil Ciurczak, has worked in the pharmaceutical industry since 1970,

Emil has been presenting short courses in the US, Europe, Asia, and South America on Near-Infrared, PAT/QbD, Process Validation, and Design of Experiments. He is currently working with the US FDA to train the scientists in CDER (Maryland) on the latest instrumentation and applications in PAT/QbD in the Pharma industry. He will be working with FDA staff at their new facility to show how to choose points of measurement and best technologies to implement QbD in commercial manufacturing sites.

Emil has worked with industrial clients, aiding them in choosing the most effective technologies for their process monitoring and control programs (PAT/QbD). He also interfaces between the Pharma companies and instrument companies, helping configure instrumentation for the PAT applications of the clients.

He has been teaching professional courses in Chemistry, Physics, and Process Analysis (in the US, South America, Europe, and Asia) since 1979, was a member of the PAT sub-committee (Validation) for the US-FDA (2002) and was a member of the PAT Expert Committee (Spectroscopy) for the USP; (he was also co-author of the USP chapter on NIRS <1119>, now <856>).

In 1983, he introduced NIRS for pharmaceutical applications (first qualitative application) ay Sandoz. Emil currently consults for numerous instrument and manufacturing companies, has published over 100 journal articles, over 750 magazine columns, holds 14 patents, and presented over 450 technical papers. He is a Contributing Editor for Pharmaceutical Manufacturing and Contract Pharma magazines

PRESENTATIONS:

Day 1

13:00 - Pre-Course Intro – Delegate Expectation Briefing

Session 1: Introduction to PAT/QbD

- USFDA's PAT Guidance
- EMA PAT Guidance
- 21st Century Initiative
- Overview of ICH Guidelines:
  Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), Q10 (Pharmaceutical Quality Systems), Q11 (Development and Manufacture of Drug Substances), Q12 (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle)

Session 2: The Science and Risk Based Approach to Product Lifecycle & Process Validation

- What is a science and risk-based approach?
- Why do we have to change the way we develop and manufacture products?
- Why do we validate?
- How do we validate?

Break

Session 3: Building the Team

- Which departments need to be represented?
- Prioritizing the first PAT/QbD project
- Setting budgets and working with instrument/ software vendors
- Milestones and how to keep management in the loop
- Second through 100th project; building on success

Session 4: PAT/QbD Workflow Evolution

- Traditional (cGMP) workflow
- Workflow with Process Monitors
- Workflow with True PAT/QbD
- The difference between data and information
- Applying the information gathered: now and for future lots

Case Study – 1: Justifying a Pat/ QbD Project

Post-Session Q &A

17:00 – End of Day 1

Day 2

09:00 - Revision of day 1

Session 5: Process Validation Guidance: Drug Substance, Drug Product, Small & Large Molecule

- FDA's Process Validation approach and expectation, drug products
- EMA's Process Validation approach and expectation, drug products incl biological drug substances
- ICH Q7 – API Process Validation expectations

Session 6: Quality Risk Management

- QRM Tools
- Quality Risk Management
- QRM for Process Validation
- Finding Critical Attributes and how to use them
- Risk Management in updating products

Break

PRESENTATIONS:

Day 2

Session 7: Process Qualification

- EMA Annex 15
- FDA PV stage 2.1
- ASTM E2500
- Linking qualification to CQAs, CPPs, Critical Aspects

Session 8: Process Validation (Process Performance Qualification)

- Verification of the Control Strategy
- Readiness for PV
- Validation protocol & Validation Report

Case Study – 2: Following the Progress of a Fluid Bed Granulator vis NIRS

Post-Session Q &A

17:00 – End of Day 2

Day 3

09:00 - Revision of day 2

Session 9: Design Space and Appropriate Sources

- ICH Guidances 8-10
- Design of Experiments:
- What are Good or Desired attributes?
- Collection of correct data

Session 10: Building Design Space (DS)

- Mathematics used to build DS
- Preliminary design plans
- Expanded designs for final DS

Break

Session 11: Application of Design Space

- Maintaining and updating DS
- Adapting DS to a changing supply chain
- Known Space vs. Design Space vs. Operating Space

Session 12: Failure Nodes and Effects Analysis (FMEA)

- Model Predictive Control
- Chemometrics Used
- Multivariate Analysis
- Finding CQAs and CtQs

Case Study 3: Using Commercial DoE software for a tablet formulation study

Post-Session Q &A

17:00 – End of Day 3

PRESENTATIONS:

Day 4

09:00 - Revision of day 3

Session 13: Near-Infrared Spectroscopy

- Basic Theory & Instrumentation
- Small Molecule Applications
- Biopharma Applications
- Updating Models over product lifetime

Session 14: "Other" Spectroscopies

- Ultraviolet/Visible
- Mid-Range Infrared
- Far-Infrared (Terahertz)
- Raman
- LIBS [LASER-induced breakdown spectroscopy]
- Fluorescence (traditional and Light-Induced Fluorescence)

Break

Session 15: Physical Methodologies

- Acoustics
- Passive Acoustics
- Sound/Ultrasound
- Active Ultrasound
- Focused Beam Reflectance Measurement (FBRM)

Session 16: Other Methodologies

- Electrical Tomography
- EIT, Soft-Field Tomography
- Electrical Capacitance Tomography
- MFI Flow Microscopy Technique
- Chromatographic Methods
- Ion Mobility "Spectrometry"

Case Study:

4a: Aseptic Filling Line using PAT/ QbD

4b: Qualifying solid dosage forms in real time

Post-Session 7 Q & A (Day 1 – 4)

17:00 – End of Day 4 & Course

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

Quality by Design (QBD)

24 - 27 June 2024

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

Please complete this form and mail it back to
sarodh.panicker@biiworld.com

Event Code: OL LS 37

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 Details

METHOD: CREDIT CARD ☐ OR WIRE TRANSFER ☐

Please debit my

Visa ☐ Eurocard /Mastercard ☐ Amex ☐ Diners club ☐

Card Billing Address:.....
Street: .....City.....
Zip/Postal: .....
Card Holders Name: .....
Email Address: .....
Card Holders Signature: .....
Card Number

Credit Card CVV2/ CVC / CID Number:

Visa / Mastercard (3-digit code on the back) ☐☐☐ Amex (4-digit code on the front) ☐☐☐☐

Valid from: ☐☐ / ☐☐ Expiry Date: ☐☐ / ☐☐

I agree to BII debiting my card

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 ☐ EUR 1299 Per Delegate

Early Bird offer until 15th April ☐ EUR 1099 Per Delegate

EUR 20 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 time. The registration fee includes: Training documentation and admission to all training sessions.

2. 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.

3. 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.

4. 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)

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 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)

6. 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 written notice 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 connection with this registr ation form shall be settled before the competent court in Canada.

8. 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.

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 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.