



BII WORLD
Engage • Enlighten • Empower



Statistical Process Control & Quality Control (SPC/SQC)

Join our global industry expert, Tara Scherder,
and transform your learning experience.

25- 28 September 2023

16 Hours Virtual Learning
13:00 – 17:00 Central European Time (CET)

www.biiworld.com



The methods of Statistical Process Control/ Statistical Quality Control (SPC/SQC) are relatively simple, yet pay significant dividends across many industries. In addition to the business benefit drawn from the increased knowledge of process variability and early alerts of changes in process behavior, these methods are used to meet the ongoing monitoring expectations described in European Commission Annex 15: Qualification and Validation and the FDA Guidance on Process Validation.

In this 4 Day Online Course, you will learn details of various control charts and process capability metrics. Focus is not limited to the fundamentals of application; you will also gain an understanding of the influence of nuances of pharmaceutical data on interpretation. Design of an efficient ongoing process verification/continued process verification program is discussed.

The Daily 4 hrs Course includes many actual examples of various SPC/SQC tools across multiple product platforms, in addition to analytical applications. Days 1-3 include time for software application using both JMP and Minitab.

Learning Objectives:



- Describe the significant business and compliance benefit of SPC/SQC achievable from a small investment
- Define construction and appropriate application of various types of control charts for individual, sub grouped, proportion, count and multivariate data
- Recognize the influence of typical nuance of pharmaceutical process on interpretation of control charts
- Utilize process capability metrics as part of a Quality Risk Management Program and use resources wisely
- Design an efficient monitoring program
- Decipher the usefulness of statistical software to implement SPC/SQC





Instructor:

Tara Scherder

A statistician with over 20 years of experience in pharmaceutical and biopharmaceutical industries.

Tara Scherder has over 20 years of experience in the pharmaceutical and biopharmaceutical industries as a statistician, engineer, and master black belt.

Her passion is the powerful combination of science and statistics to increase knowledge, optimize both manufacturing and business processes, and reduce risk. She combines statistical expertise with extensive knowledge of manufacturing platforms and analytical sciences, in conjunction with business and regulatory acumen to achieve goals. She has functioned as both an in-house and external statistical consultant to drug substance and drug product teams from product development through commercial supply for the spectrum of product platforms.

She frequently speaks at industry forums and publishes on the practical incorporation of statistical methods for Lifecycle Process Validation.

Tara earned a BS degree in Chemical Engineering from the University of Pittsburgh and a MS degree in Statistics from Carnegie Mellon University. At SynoloStats, she passionately collaborates with teams to leverage statistical methods to accelerate timelines, design and develop robust processes, and assure ongoing quality to patients and consumers.



Key Focus:

- Leverage Statistical Process Control/Statistical Quality control methods to enable assurance of ongoing product and analytical quality and continual improvement
- Become alerted to changes in process performance as they occur
- Use process capability metrics to allocate resources to areas of highest risk
- Understand the various control charts and when and how to apply them
- Implement an efficient and effective monitoring program that accounts for the nuances of pharmaceutical manufacturing and measurement data.

Target Audience:

- Manufacturing Science and Technology Engineer
- Operational Excellence Engineer
- Process Engineer
- Quality Assurance
- Quality Control
- Statistician
- Data Scientist
- Data Analyst
- Operations Lead
- Process Validation
- CMO



Day 1

13:00 - Pre-Course Intro

Gain appreciation for the value of Statistical Process Control /Statistical Quality Control (SPC/SQC) methods over the lifecycle of a pharmaceutical product

Module 1: Regulatory Expectations for Ongoing Process Verification (OPV)

Recognize use of SPC/SQC methods to be compliant to EMA and FDA ongoing monitoring guidelines. How it fits into lifecycle process validation.

Module 2: Fundamentals of All Control Charts and Charts for Individual Measurements

Understand general details and goals of all control charts. Learn specific details and how to

choose the most appropriate chart for individual measurements. Use Nelson rules to identify patterns.

Exercise: JMP and Minitab Exercises

16:50 - Post-Session Q &A

17:00 – End of Day 1

Day 2

13:00 - Pre-Session Q & A

Module 4: Statistical Assumptions of Control Charts

Learn and understand the impact of independence & normality on control chart interpretation. Understand the effect on the “state of control”.

Module 5: Charts for Sub grouped Data and Proportions/Counts

Learn specific details and how to choose the most appropriate chart for sub grouped, proportion passing, or defects measurements.

Module 6: Establishing Sample Size

Recognize considerations of sample size and when to “fix” control limits for SQC. Define and recognize role of average run length for in-process-check (IPC) sampling.

Exercise: JMP and Minitab Exercises

Post-Session Q &A

17:00 – End of Day 2



Day 3

13:00 - Pre-Session Q & A

Module 7: Process Capability Fundamentals

Understand the connection of customer and process limits and the influence of derivation of pharmaceutical specification limits.

Module 8: Process Capability Metrics for Risk Management

Define process capabilities metrics and apply them in a Quality Risk Management paradigm, including special cases.

Module 9: Designing a Monitoring Plan

Understand the two substages of the third stage of lifecycle process validation and determine what attributes/parameters to monitor and the frequency. Create an efficient reporting process

Exercise: JMP and Minitab Exercises

Post-Session Q &A

17:00 – End of Day 3

Day 4

13:00 -Pre-Session Q & A

Module 10: Analytical Applications

Leverage SPC/SQC methods in the laboratory

Module 11: Using Control Charts for Investigations

Recognize the usefulness of control charts to speed root cause investigations

Module 12: Other Control Charts

Learn proper use and interpretation of EWMA, Multivariate, G Charts

Post-Session Q &A (Day 1- 4)

17:00 – End of Day 4 & 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.

Do I get a Certificate at the end?

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





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BII World Limited
9616 45th Avenue
Northwest, Edmonton, AB
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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:

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

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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

Company/Organisation Detail

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

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 € 1299* Per Delegate
- 2-3 Delegates Fee € 1199* Per Delegate
- 4 & more Delegates Fee € 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 Province of Alberta, Canada. Any disputes arising under or in connection with this registration 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.