IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Data-Driven Process Control: Statistical Process Control (SPC) Tools for Quality, Stability, and Performance

24-25 February 27
+ 27-28 September 27

A two-day course on applying Statistical Process Control to monitor manufacturing processes and meet regulatory expectations from the U.S. Food and Drug Administration, European Medicines Agency, and World Health Organization.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overveiw

Modern regulators increasingly expect manufacturers to demonstrate that processes remain in a continuous state of control throughout the full product lifecycle - not only during initial validation. Authorities such as the United States Food and Drug Administration, the European Medicines Agency, the Medicines and Healthcare products Regulatory Agency, and the World Health Organization now place strong emphasis on effective monitoring, trending, and proactive management of manufacturing processes.

This two-day training course is designed for life science professionals who need to apply Statistical Process Control confidently, even if they do not have a statistics background. All concepts are taught from first principles using clear explanations, visual interpretation, and step-by-step manufacturing examples.

The course links Statistical Process Control to continued and ongoing process verification expectations and aligns learning with international guidance and standards including:

- The United States Food and Drug Administration Process Validation Guidance (Stage 3: Continued Process Verification)
- European Union Good Manufacturing Practice Annex 15 requirements for ongoing monitoring and trend review
- International Council for Harmonisation guideline on Pharmaceutical Quality Systems (Product Quality Monitoring System expectations)
- World Health Organization expectations for quality monitoring and performance control
- International standard for medical device manufacturing quality management systems, including process monitoring and critical-to-quality trending

Delegates will learn how to create and interpret control charts, detect meaningful process shifts, distinguish normal variation from abnormal variation, and build a structured governance system that supports inspection readiness and continual improvement.

Every session includes interactive learning activities designed around inspection-style scenarios. This ensures delegates understand not only the tools, but also how to build evidence that can confidently answer inspector questions such as:

- How do you know your process remains in control?
- Where is your trend review evidence?
- What triggers an investigation and how is this documented?

By the end of the course, delegates will be equipped to apply Statistical Process Control as both a compliance tool and a continuous improvement tool, supporting stronger product quality assurance and improved operational performance.

Benefits of attending

- **Understand** what regulators expect for Statistical Process Control and continued process verification evidence
- **Discover** how to present control and trend monitoring evidence confidently during inspections
- **Improve** decision-making so investigations are triggered only when justified
- **Understand** how to choose the correct control chart for different manufacturing data types
- **Learn** to interpret charts correctly and identify early warning signs of process drift
- **Study** how to detect true abnormal signals while avoiding false alerts
- **Gain** a practical view of predictive analytics and future monitoring trends without requiring advanced mathematical knowledge
- **Learn** how Statistical Process Control supports maintenance of a validated state and how trending data feeds into quality review systems and continual improvement

Who should attend

This course is ideal for professionals involved in manufacturing, quality oversight, process monitoring, validation, or regulatory compliance across pharma, biologics, sterile manufacturing, and medical devices, including:

- Pharmaceutical manufacturing and operations: process engineers, production managers, supervisors
- Medical device manufacturing teams: ISO 13485 roles responsible for CTQ (Critical-To-Quality) monitoring, capability, and validation maintenance
- Quality assurance/quality control: QA specialists, QC analysts, data reviewers
- Validation and technical operations: Continued Process Verification (CPV) owners, validation managers, tech transfer leads
- Regulatory/compliance: Risk Assessment (RA) and compliance professionals

No statistics knowledge required - all concepts are taught with practical visuals and guided interpretation.

Programme

Day 1

Regulatory foundations for SPC

- Continued process verification expectations from global regulators
- EU requirements for ongoing verification and trend review
- PQS expectations for product quality monitoring
- Medical device process monitoring requirements
- Typical inspection findings linked to weak trend review or poor governance

SPC fundamentals in manufacturing processes

- Understanding variation and state of control
- Data quality and measurement readiness
- Variables data and attributes data
- Control chart selection principles
- Examples from pharmaceutical and medical device manufacturing
- Exercise: chart selection

Process capability and practical statistical interpretation

- Establishing baselines and subgrouping logic
- Capability indices for pharmaceutical and device processes
- Interpretation of capability results and risk implications
- Rules for detecting out-of-control signals
- Common mistakes that create false alarms
- Exercise: workshop with capability analysis and chart interpretation

Governance of continued process verification and data review

- Selection of critical process parameters and quality attributes
- Data review systems
- Trend identification and response
- Exercise: workshop reviewing and improving a mock continued process verification report

Day 2

Implementing SPC in Production

- Applying Statistical Process Control to high-risk process steps
- Integrating control monitoring into standard operating procedures
- Defining reactions: monitor, investigate, escalate
- Using control signals to support deviation handling and corrective and preventive actions
- Exercise: simulation exercise (teams interpret signals)

Modern monitoring tools for process control

- Monitoring multiple process parameters together (practical introduction)
- Process Analytical Technology monitoring principles
- Digital dashboards and automated alert systems
- Practical overview of predictive monitoring concepts
- Interactive: interpretation quiz using a dashboard-style dataset

Current challenges and industry trends

- Common inspection findings linked to poor Statistical Process Control governance
- Data integrity risks in trend systems and reporting tools
- Avoiding spreadsheet-driven compliance failures
- Medical device monitoring expectations for critical-to-quality characteristics
- How regulators expect decisions to be justified and documented
- Interactive: build an inspection-ready evidence pack in teams

Workshop: applying SPC to real cases

Interactive session with examples and discussions.

Topics (case scenarios):

- Oral solid dose manufacturing trend shift
- Sterile manufacturing attribute drift
- Biological process parameter shift
- Medical device critical-to-quality trend and capability problem
- Interactive: team presentation plus mock inspector questions and feedback

Presenters



Paul Palmer

Paul R Palmer is a Director / Pharmaceutical Consultant and a practicing EU / UK Qualified Person. He has over 35 years experience in the pharmaceutical industry in the development, manufacture and supply of medicinal products and medical devices.

Throughout his career, Paul has intentionally taken on all opportunities as they arose in order to develop a broad range of knowledge with an in-depth detailed understanding of manufacturing, storage, distribution, research, computerised systems, as well as the facilities and services to support each.

People and systems have always been a core focus, how to ensure best use, optimise and enhance efficiency. He has a level of curiosity rarely displayed in people taking on the qualified person role in pharmaceutical manufacturing. Culture, behaviour and psychology are all significant influences on the systems and processes we implement, but are often ignored.

Paul studied psychology as part of his MSc in 1993 and has always enjoyed observing the world around him with a curiosity that is rarely satisfied.



Farah Nadeem

Farah Nadeem is an Operations Manager at Paul R. Palmer Limited/ Pharmaceutical Consultant and a Trainee Qualified Person. Farah is a Pharmacist and recognised QA expert and has over 20 years of experience in the Pharmaceutical industry in the development, manufacture and supply of medicinal products.

Throughout her career, she has held various quality assurance roles and actively pursued new opportunities to expand her knowledge and expertise. As a result, she has gained a comprehensive understanding of manufacturing, storage, and distribution processes, as well as the facilities and services that support them. Involved in documentation management: writes, reviews, and audits SOPs and QMS implementations. Assists companies in meeting regulatory requirements.

In her current role as a QA Operations Manager for a Pharmaceutical Consultant Company, Farah Nadeem provides various solutions, including assistance in obtaining the first MIA(IMP) and MIA licenses, as well as preparation and hosting for regulatory inspections. Her work involves collaborating with Paul Palmer to offer services such as QP declarations for API manufacturers, regulatory inspection hosting, commercial and clinical batch release, compliance audits, and coaching and training in GxP.

Course dates

24-25 February 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 16935*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 30 Dec**
27-28 September 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17300*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 02 Aug**

How to book

Online:
ipi.academy/3354

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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