ISPE®

Connecting Pharmaceutical Knowledge

2021 PROFESSIONAL DEVELOPMENT

Learn how to lower production costs, improve process efficiency, increase production quality, and meet changing regulatory requirements.

Why ISPE?

The International Society for Pharmaceutical Engineering (ISPE) is a not-for-profit association serving its Members by leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle.

We are committed to advancing the educational and technical efficiency of our Members through forums for the exchange of ideas and practical experience. We lead and facilitate the development of next-generation process technologies and innovative technical solutions. On matters of regulation, our focus is on those requirements that impact—or will impact—the licensing of facilities, manufacturing processes and operations, and the sustainability of the supply chain over the product lifecycle. We provide a neutral environment where our Members and experts belonging to Regulatory Authorities can engage in open dialogue on issues that will ultimately benefit patients worldwide.

- Our training courses give professionals solutions for their needs and connect them with other professionals to share best practices.
- We take pride in delivering learning that is personalized to the individual in the context of the organization's situation and goals.
- Our approach to lifelong learning includes self-directed, ongoing, systematic, and outcomes-focused content that is easily and immediately applied to practice.
- Our blended learning involves active participation in formal and informal learning activities that assist individuals in developing and maintaining continuing competence.
- Instructors are selected based on their knowledge of the subject matter, experience and teaching ability, and their ability to meet the educational needs of the learners.
- Our training assets help organizations stay abreast of the latest advancements and strategies required to successfully bring biologics to market.
- In response to the industry's need for current and reliable information in this rapidly growing area of pharmaceutical manufacturing, we develop and deliver a highly relevant, high quality, customized educational experience for employees at every competence level and across a broad range of the pharmaceutical engineering continuum.
- ISPE designs and implements active learning exercises as a component of all educational offerings.
- We tailor training content that is engaging and interactive, using current problems and situations common to the industry.
- Our highly practical, structured courses are flexible and responsive to the needs of the individual learner.

Fundamental Courses

Refers to knowledge in a particular content area that most often correlates to entry-level or early work experience. Someone who has been working in pharma for 15 years could still seek fundamental knowledge in a subject new to him/her.

In Bloom's Taxonomy of Educational Objectives, this level would have knowledge and comprehension objectives starting with words such as: identify, recognize, distinguish, interpret, classify, etc.

Fundamental Courses

GMP Fundamentals for the Pharmaceutical Industry (G01)

Through hands-on exercises and lectures, you will discuss and explore GMP principles and approaches for active pharmaceutical ingredients (APIs), excipients, and finished pharmaceuticals. Learn easy-to-grasp basics of regulatory requirements, current issues, and trends in the pharmaceutical industry with an emphasis on applying GMP in day-to-day operations. After understanding the "whys" behind the GMP regulations, participants discuss the history of the GMP regulations, the regulatory process, and the concept of operating in a "state of control," with an emphasis on the regulation of pharmaceutical products.

CEUs 1.3

Applying the GMPs Training Course (G03)

The highly interactive classroom course uses extensive exercises to provide an intense examination and interpretation of the cGMP regulations with special emphasis on applying the "right dose" of GMP to various situations to assure that methods, facilities, and controls are used for the manufacture processing, packing, or holding of drug products to meet requirements for safety, identity, strength, quality, and purity. The regulation will be divided into six elements: materials, buildings, equipment, records, procedures, and people. Participants will focus on compliance strategies for interpreting the controls needed to continuously operate in a state-of-control, validation, cleaning, and training interpretations will be discussed throughout. Specific case studies will be evaluated by the participants while the concept of regulatory inspections is covered along with an examination of the USFDA's quality system inspection techniques and the European inspection practices. Special emphasis will be placed on both cGMP compliance cGMP performance issues. Note: We recommend attendees have a least two years of experience with the cGMPs to attend this course.

CEUs 1.3

GMP Auditing for the Pharmaceutical Industry (G07)

Auditing is a critical function within a pharmaceutical company. It provides management with information about how effectively the company controls the quality of their processes and products. Auditors must perform their jobs competently to ensure their company's compliance with pharmaceutical USFDA GMP regulations and other quality standards like ICH Q10. This Auditing for GMP course is specifically designed to address the challenges of GMP auditing for the pharmaceutical industry and present the basic competencies required to effectively perform the auditor's assigned responsibilities and contribute to the improvement of auditor performance within a regulated industry.

Available online. CEUs 1.3

Clean-in-Place (CIP) Fundamentals (T03)

This course will provide an overview of clean-in-place (CIP) systems including design, integration, and selection of cleaning chemicals. Participants will discuss engineering concepts, principles, and integration of CIP systems, clean-out-of-place (COP) systems, or immersion parts washers. While there will be some discussion of manual cleaning practices, cleaning principles will be primarily introduced as they relate to the dynamics of CIP and COP technologies, with an emphasis on selecting the right cleaning chemistries for specific soil residues. Additional topics covered include a CIP technology review including examples of various pharmaceutical processes that illustrate how CIP technologies and hygienic design can improve cleanability. Other topics for discussion include CIP spray device selection criteria and dynamics of integrating CIP process piping into a pharmaceutical process. A dynamic hands-on workshop will allow participants to work in groups to design, build, and implement a cleaning process for a pharmaceutical application. Participants will apply knowledge gained from the course to identify cleaning solutions to complex cleaning processes.

Available online. CEUs 1.3

"ISPE training is an excellent option when you need in-depth and current technical knowledge."

Fundamental Courses

Basic Principles of Computerized Systems Compliance: Applying the *GAMP® 5 Guide: A Risk-based Approach to Compliant GxP Computerized Systems* (T07)

This fundamental course introduces participants to regulatory requirements for computerized systems in the pharmaceutical industry and explores tried, tested, and internationally recognized methods of meeting those requirements. GAMP guidance provides a pragmatic and effective framework for achieving computerized systems that are fit for intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner.

The course does not aim to cover detailed and highly technical aspects of software and hardware engineering, but rather gives the principles and an overview of the overall computer systems compliance process, including a scaleable and efficient system lifecycle, Quality Risk Management applying ICH Q9, updated GAMP categories, supplier assessment, and the selection of appropriate specification and verification activities.

Available online. CEUs 1.3

ISPE GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems

Oral Solid Dosage Forms: Understanding the Unit Operations, Process, Equipment and Technology for OSD Manufacture (T10)

The course examines current technology and provides scenario-based exercises for system troubleshooting and investigational events for process deviations, discusses quality management and GMP inspection preparation, and provides guidance on advanced asset lifecycle management strategy.

Using a Process and Production Video Simulation for Unit Ops, including Mixing, Blending, Drying, Sizing, Tableting, Encapsulating and Coating provides participants with a visual demonstration of current manufacturing and engineering practices. The simulation will vividly present real-time experiences for identifying and analyzing the problem identify the root cause and present solutions. A case study for production related issues and concerns will also be utilized.

CEUs 1.3

ISPE Baseline® Guide Vol 2: Oral Solid Dosage Forms 3rd Edition

Biotechnology Basics (T18)

This fundamental course is ideal for professionals that are new to the biotechnology industry, professionals entering new work assignments encompassing biotechnology operations or individuals with previous pharmaceutical industry experience that want to learn the basics of biotechnology. This is a course that is ideal for individuals involved in human resources, economic development, and business and strategic planning efforts. Professionals in quality control, quality assurance, and technical management support will also find it beneficial.

Participants in this course will explore the history of the biotechnology industry and will learn the fundamental concepts of biotechnology science. Participants will also learn basic terminology and how it is applied in the industry. The course will identify basic process science and unit operations for the manufacture of products and will describe the regulatory foundation that makes biological products different from traditional pharmaceutical products. There will be discussions to evaluate emerging technologies and how they will impact the industry. The course will also classify validation issues surrounding compliance with GMP and define basic requirements for facilities that manufacture biological products.

CEUs 1.5

Basic Principles of Computerized Systems Compliance Using GAMP® 5, Including Revised Annex 11 and Part 11 Update (T45)

This two or three-day fundamental course introduces participants to regulatory requirements for computerized systems in the pharmaceutical industry and explores tried, tested, and internationally recognized methods of meeting those requirements. GAMP® guidance provides a pragmatic and effective framework for achieving computerized systems that are fit for intended use and meet current regulatory requirements. Please click the "Locations and Registrations" table to select the two or three-day sessions.

CEUs 2

ISPE GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems Guide

A GAMP® Approach to Data Integrity, Electronic Records and Signatures, and Operation of GxP Computerized Systems (T50)

Data integrity is currently one of the highest cited areas in regulatory observations and a topic of great interest within the industry and for regulatory agencies that are re-evaluating industry guidance and their enforcement strategies. This course will cover data integrity, electronic records and signatures, and the compliant operation of GxP Computerized Systems to provide the tools and techniques to implement proper controls for data.

CEUs 2

ISPE GAMP® Guide: Records and Data Integrity

"Course had right focus on content critical to the subject area. The instructor was able to provide both broad perspective as well as answer specific questions about current issues."

Customize Your Training

Online Live Courses

ISPE brings the intensity of Online Live Training to your computer by providing instructor led training in a virtual, online experience. With ISPE Online Courses, you can take ISPE's signature training, the type usually delivered over two to three days in a distant classroom, from your home or office.

Each interactive course includes

- A downloadable presentation for note-taking
- Engaging graphics
- Reference materials and links to regulatory information
- Assessments to measure your comprehension
- The ability to start and stop at any time, beginning where you left off

On Demand Training

Using the expertise of our global Membership we developed e-Learning modules to meet the needs of global pharmaceutical manufacturing professionals. Find case studies with in-depth knowledge and best practices from top-notch seminars and authors of ISPE Guidance Documents.

Our online content gives professionals an interactive learning experience

- A downloadable course presentation for note taking
- Learning reviews/assessments highlighting important points
- Links to regulatory and industry information
- An online resource handout as a quick reference for all the web links discussed
- ISPE CEUs for each course you take

Customized Onsite Training

ISPE's Professional Development Department, in collaboration with our instructors, will work with you to create a dynamic instructional program where your employees will have the opportunity to apply best practices and seek practical solutions. We can customize our content to your needs in a variety of ways. For example, adjusting our existing instructor-led courses, combining topics from multiple courses into one, or creating new course material specific to your business.

Some training courses utilize a complimentary guidance document as part of the curriculum, allowing participants to apply the course objectives immediately. Produced by pharmaceutical manufacturing industry professionals, ISPE Guidance Documents provide the practical, real-world information you need to help your organization build on current best practices that help you meet and exceed regulatory standards.

ISPE helps your staff prevent performance lapses and stretch your training budget by bringing our courses to you in a private session. This forum allows you to discuss the challenges of your business confidentially and receive guidance from ISPE's instructors, who are subject matter experts. By leveraging the combined knowledge of our global membership, our courses provide practical, real-world information to meet and exceed regulatory requirements—from instructors who work in the industry and face the same daily challenges you do. A well-trained staff is critical to meeting cGMP regulations. Training can also be the difference between successful operations and regulatory violations.

Intermediate Courses

Refers to content an individual regularly uses but at which they are not yet an expert. Content in this area is sought for deeper application and analysis.

In Bloom's Taxonomy of Educational Objectives, this level would lead with words such as: apply, examine, utilize, analyze, explain, construct, etc. Experience with the topic is recommended, but advanced expertise or specialty practice in the subject area is not necessary.

Intermediate Courses

Pharmaceutical Water Generation (T04)

Using the USP, EP, JP Monograph, USFDA Guide to Inspections of High Purity Water Systems, current FDA views and cGMP requirements, this course will provide a sound regulatory framework to understand common water system myths. A variety of practical system designs will be evaluated for compliance, as well as their advantages and disadvantages. Particular attention will be paid to microbial control, laboratory water, key design philosophies, systems and component sanitization procedures, operation, testing and maintenance of equipment and systems for water generation. Examine methods for proper water quality selection, information on compendial and non-compendial water, fundamentals of basic water chemistry and information on common unit operations (deionization, reverse osmosis and distillation). Pre-treatment systems, detailed guidance for selection of construction materials and operation issues related to pharmaceutical water generation systems will also be discussed.

ISPE Baseline® Guide: Water and Steam Systems (Second Edition)

ISPE Good Practice Guide: C&Q of Water and Steam Systems (Second Edition)

Complying with Part 11—Risk Management: Applying the GAMP® Good Practice Guide Electronic Records and Signatures Principles (T08)

Using the *GAMP® Guide: Records and Data Integrity* as a resource, this course will give participants a practical introduction to the 21 CFR Part 11 regulation, which affects all aspects of computerized systems in the pharmaceutical industry and up-to-the-minute information on current FDA interpretations. Taught through classroom presentations, workshop sessions, and team exercises, the course will present an overview of Part 11 including its objectives, benefits, and potential problems. This will be followed by a detailed analysis of Part 11 requirements, a discussion of electronic records and signatures, and key industry issues.

A central element of this course will be an explanation of the GAMP approach to 21 CFR Part 11 compliance, as well as compliance with other international regulations covering electronic records and signatures. The GAMP Records and Data Integrity Guide provides timely and much needed direction on meeting current regulatory expectations for compliant electronic records and signatures. The Guide describes how a risk management approach may be used to ensure the compliance of regulated electronic records and signatures, through the application of appropriate controls commensurate with the impact of records and the risks to those records.

Available online. CEUs 1.3

ISPE GAMP® Guide: Records and Data Integrity

Sterile Product Manufacturing Facilities: Applying the ISPE Baseline® Guide and FDA Guidance Principles to Design and Operation (T12)

Through lectures and group exercises the course will review regulatory philosophy; aseptic process and equipment considerations; aseptic clean room design and operation; differential pressure requirements; airlocks; basic utility system monitoring; US and European HVAC considerations; C&Q issues, and a brief introduction to barrier isolation technology. An exercise in the layout of an aseptic filling facility will be used to demonstrate how to use process flow diagrams and an accommodation schedule to thoroughly define facility requirements before advancing to the floor plan layout stage. Additional topics include the use of RABS and isolator systems, and methods for contamination control.

CEUs 1.3

ISPE Baseline® Guide: Sterile Product Manufacturing Facilities (Third Edition)

Clinical Trial Materials: Applying Production, Quality Assurance and Packaging Processes (T13)

In this course, you will receive a thorough overview of the clinical supply chain from beginning to end, including: designing appropriate packaging and labeling to match the study design, creating a plan of action to prepare the CTM and how to implement the plan and troubleshoot. The course will also cover the logistics of distribution of the CTM to the clinical sites globally. Important tools, such as outsourcing vendors for packaging and labeling and Interactive Response Technology will be covered to ensure familiarity with all the necessary concepts.

Participants will discuss the different roles of the Clinical Team and how they interact with the CTM group. We will also cover current Good Manufacturing Practices (cGMPs) and how they are implemented in the packaging process. The course will also provide a dictionary of terms used in the CTM industry and how they apply to our daily business. After taking this course, you will be better prepared to manage every aspect of CTM for your clinical trials.

Available online. CEUs 1.3

ISPE Good Practice Guide: Booklet Labels

Cleaning Validation Principles (T17)

With the USFDA's risk-based regulatory initiatives focusing new attention on the risks of cross-contamination, understanding lifecycle management techniques for an effective cleaning validation program is paramount. Course topics include: risk-based approach to cleaning development and verification; risk analysis, control, review and communication ; procedures and evaluation tools including FMEA/FEMCA; master planning; PAT; periodic assessment and monitoring; selection of analytical and sampling methods; determination of residues to be targeted and appropriate limits in various pharmaceutical and biotechnology processes, and establishment of scientific rationales acceptable to regulatory inspectors. For mature cleaning validation programs, concepts such as understanding process control, capability, learning to effectively self-audit a cleaning validation program and documentation will be essential takeaways.

CEUs 1.3

Practical Application of Technology Transfer (T19)

Technology transfer (TT) includes knowledge transfer, science and risk-based principles including ICH Q8, Q9, Q10, Q11 and efficient processes to meet evolving business needs. As the industry continues to experience changes, technology transfer for active pharmaceutical ingredients (APIs), finished dosage forms and analytical methods between development and manufacturing sites and contract manufacturing organizations (CMOs) has become increasingly important. This course identifies criteria for successful TT and provides 'how to' examples which can be individually tailored, depending on the type and scope of transfer. It takes into account current industry challenges and real-world examples as tools for industry and regulators to use when conducting and evaluating technology transfer activities.

CEUs 1.3

ISPE Good Practice Guide: Technology Transfer (Third Edition)

"The course had the right focus on content critical to the subject area. The instructor was able to provide both broad perspective as well as answer specific questions about current issues."

Intermediate Courses

Integrating Data Integrity within a Risk-Based approach to Compliant GxP Process Control Systems (T21)

This highly interactive classroom course describes how the *GAMP Good Practice Guide: A Risk-Based Approach to Compliant GxP Process Control Systems*, and *GAMP RDI Good Practice Guide: Data Integrity - Manufacturing Records* may be applied to achieve process control systems that are fit for intended use, incorporate data integrity and meet current regulatory requirements. The course covers recommended good practice based on a lifecycle approach for the development and management of process control systems and shows how the principles and concepts of GAMP 5 may be practically applied to process control systems. It looks at the data created by the process control system through the data lifecycle to understand how to protect against threats to data integrity. The course covers both regulated company and supplier quality management systems and the full system lifecycle from concept to retirement.

This course shows how appropriate quality risk management, planning, specification, implementation, verification and reporting activities should be an integral part of the normal system lifecycle. Many suppliers of systems now have mature quality management systems and the course promotes the leveraging of supplier documentation and activities to avoid unnecessary duplication, cost and waste.

CEUs 1.3

ISPE GAMP® Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems (Second Edition)

ISPE GAMP® RDI Good Practice Guide: Data Integrity – Manufacturing Records

An Overview of Biopharmaceutical Manufacturing Processes (T24)

This course provides a comprehensive understanding of biotech manufacturing processes - what makes biopharmaceutical processes different from small molecules. Course content explores the underlying principles of proteins and cells to provide the foundation for how and why processes manufacture therapeutic proteins. The course studies commonly used manufacturing process operations including: cell culture and fermentation; harvest and recovery; viral removal and inactivation; purification processes such as tangential flow filtration, centrifugation, size exclusion and adsorptive chromatography.

ISPE Guide: Biopharmaceutical Process Development and Manufacturing

Facility Project Management in the Regulated Pharmaceutical Industry (T26)

This interactive course provides more than the usual project basics. It develops the concept of project lifecycle from initiation through delivery of business benefits, along with tools to manage all project resources. It is specifically targeted to the needs of facility projects within the regulated pharmaceutical industry and demonstrates the value inherent in the use of ""good practice"" project management. Trends in regulatory compliance, environmental, health and safety legislations, project delivery methodologies, and product speed-to-market expectations all impact how pharmaceutical facility projects are managed. Each course module introduces key project management concepts and tools as well as methodologies that specifically support successful project delivery.

CEUs 1.3

PMI® PDUs 2

ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry

Applying the Biopharmaceutical Manufacturing Facilities Baseline® Guide Principles (T31)

Using case studies and exercises this course in facility design provides an overview of the concepts utilized in the development and renovation of sound designs for facilities that manufacture biopharmaceutical products. The course includes a review of facility design and regulatory issues important in the US and Europe that involve industry trends and changing regulatory policy. Participants will discuss current case studies on a wide array of facility topics, and complete class exercises that involve developing facility scope of work and deliverables to meet corporate economic goals and regulatory requirements.

ISPE Baseline® Guide Vol 6: Biopharmaceutical Manufacturing Facilities (Second Edition)

Science and Risk-based Commissioning and Qualification—Applying the ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification (T40)

Through interactive workshops, this course will explain and apply the science and risk-based approach to verification of systems, equipment and facilities in accordance with the ICH documents Q8 (R2), Q9, and Q10 and ASTM E2500. Topics covered include the principles and activities that constitute an efficient and acceptable approach to demonstrating facility and equipment fitness for use as required by major global regulatory authorities; improving the ability to meet documented process requirements; controlling risks within the manufacturing process; producing high quality products and consistent operation to meet product user requirements. Guidance on the transition of an organization's approach to Commissioning and Qualification to one that incorporates a science and risk-based approach will be discussed.

Baseline Guide Vol 5: Commissioning & Qualification (Second Edition)

Managing the Risk of Cross Contamination: Applying the Risk-MaPP Baseline® Guide (T41)

Know how to use quality risk management processes to determine the extent of technical measures required to control the risks for cross-contamination. This course outlines a method for preparing QRM plans based on ICH Q9 and use health-based exposure limits to provide manufacturers with effective tools to reap the benefits of lower costs and higher efficiency while maintaining product quality and patient safety. Course topics include: overview of ICH Q9 and Q10 and how Risk-MaPP fits in; using the Logic Diagram; risk assessment, analysis, evaluation control, tools and communication.

ISPE Baseline® Guide: Volume 7 Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP) (Download Only)

"This course is very comprehensive, and the knowledge gained after the course will be useful. Now I have more confidence in performing the test and meeting the regulatory requirements."

Intermediate Courses

Applying Quality Risk Management (QRM) (T42)

Through interactive workshops, this course will help you apply the key principles of QRM programs that need to include Quality System elements (ICH Q10) within the product/system lifecycle. Topics discussed include understanding the philosophy and application of a holistic QRM process through the development of a QRM plan; developing and implementing a risk decision tree and the appropriate use of risk assessment tools; applying risk management methodologies through design and verification phases; the importance, format and maintenance of a Risk Dashboard and a summary of the US/EU/CFDA and WHO regulatory requirements, citations and expectations that may influence the implementation.

ISPE PQLI® Guide: Part 1, Concepts and Principles

Turning QbD into a Practical Reality (T43)

This interactive course uses group exercises to provide examples of how products and processes can be developed, using QbD with special emphasis on the considerations for implementing these processes in manufacturing. Topics include: understanding the principles of a science-and-risk-based approach, product and process understanding and patient requirements; using tools and techniques provided to understand QRM; implications of relevant ICH, EMA, ASTM E2500, and USFDA Guidelines; QRM tools (FMEA, risk ranking); applying FMEA to Control Strategy selection; and relationship between PQS and GMP and how they link to Control Strategy; considerations when implementing a control strategy derived from enhanced, QbD approaches; and opportunities for continual improvement arising from application of statistical techniques.

ISPE PQLI® Guide Part 1, Product Realization Using Quality by Design (QbD): Concepts and Principles

ISPE PQLI® Guide Part 2, Product Realization Using Quality by Design (QbD): Illustrative Example

Practical Implementation of Process Validation Lifecycle Approach (T46)

This 3-day course will define the requirements for preparation, planning and execution of Validation/Process Validation and how to maintain a state of control. It explores the 3 Stages of the validation product lifecycle, including Process Design, Equipment and Utility Qualification, establishing and implementing Process Performance Qualification (US) or Process Validation (Europe) requirements, and putting in place an Ongoing/Continued Process Verification program. The course is applicable to all sectors of the pharmaceutical industry—small and large molecules, innovators and generics.

The content comprises a blend of presentation of concepts and details, followed by related practice application scenarios/exercises.

Available online. CEUs 2

ISPE PQLI® Guide Part 2-Product Realization using Quality by Design (QbD): Illustrative Example

Effective and Efficient Deployment of Operational Excellence—Striving for World Class Performance in Pharmaceutical Operations (T56)

Using the well-established architecture of the St. Gallen OPEX Benchmarking, this course also leverages this well-established industry-tested benchmarking approach. The combination of enablers, quantitative performance indicators and structural factors will allow you to develop a manufacturing strategy or establish an operational excellence program to improve effectiveness and efficiency. The course also defines a common language with which to discuss operations management, and introduces lean concepts. Additional content includes tools and techniques to help you identify appropriate solutions for specific problems to address issues in manufacturing and compliance.

CEUs 1.3

Quality Management Systems: Agile Approach for Product Realization & Lifecycle Management (T57)

The Pharmaceutical Quality System (PQS), supported by ICH Q10, is the key foundation on which product realization depend. Through lecture and group exercises this course illustrates how quality systems work, the purpose of the different elements, how they connect to each other and how to recognize and transfer knowledge/connectivity throughout the organization. The diagram below from ICH Q10, covers the product lifecycle for a PQS/QMS system and all aspects will be covered by this course. We will be using QMS and PQS terms interchangeably throughout this course to establish a holistic approach.

CEUs 1.3

ISPE PQLI® Guide Series: Part 3, Change Management System as a Key Element of a Pharmaceutical Quality System

ISPE PQLI® Guide Series: Part 4, Process Performance and Product Quality Monitoring System **(Electronic Download)**

Efficient, Effective Pharma Manufacturing Problem Solving Through the Use of Engineering First Principles (T60)

The implementation of Quality by Design (QbD) and Six Sigma within the pharmaceutical industry has led to an emphasis on the importance of companies developing a robust operational control strategy (OCS) to drive the management of product manufacturing processes. This course will show how First Principles-based approaches will provide a valuable tool to help create such control strategies. Drawing on examples from over 30 years' experience in the pharma industry, the attendees will see what First Principles are and how not using a First Principle approach can lead to poor problem solving and even significant disasters. Many activities and exercises will be used to demonstrate the application of First Principles to problem-solving in pharmaceutical manufacturing and engineering. A detailed process for implementing the First Principle approach will be presented, including an example of a complete application of this process.

At the completion of this course, attendees will understand how to identify areas of opportunity for applying the First Principle approach and how to present the results and benefits from such an approach. Many of the First Principle applications presented during the course will be made available to the attendees in macro-driven Microsoft Excel files that can be used to review the examples and discuss with colleagues within their own organizations. Attendees are encouraged to bring a laptop with Microsoft Excel to gain maximum benefit from this course.

CEUs 1.3

About ISPE Professional Development Programs

Classroom Professional Development

Instructor-led content including interactive sessions, hands-on activities, case studies and assessments.

On Demand Professional Development

Online Live Learning and On Demand courses help you expand your skills and knowledge from the comfort of your desk.

Customized On-site Professional Development

Tailored content based on competency and learning goals & objectives.

Guidance Documents

Guidance Documents offer practical advice on regulatory initiatives by providing effective, cost-efficient approaches.

CUSTOMIZED TECHNICAL AND OPERATIONAL SOLUTIONS

ISPE delivers technical and operational solutions to support pharmaceutical engineering professionals across the industry to improve performance in the manufacturing of quality medicines for patients.

CONTINUED IMPROVEMENT AND INDUSTRY TRANSFORMATION

ISPE offers increasing and unparalleled value for Members, companies, and stakeholders globally and across all constituent parts of the industry. The result will be the continued improvement and transformation of the pharmaceutical manufacturing industry to better ensure the availability of quality medicines to patients worldwide.

BEST PRACTICES AND INDUSTRY STANDARDS

ISPE's training, conferences, and Knowledge Networks give professionals solutions and connect them with other professionals to share best practices. We know how to design, build, qualify, license, operate, and maintain complex facilities, including those that manufacture active pharmaceutical ingredients, finished dosage forms, delivery systems, and packaging. Our Guides are relied on globally by industry and regulators to define the industry standards for design, construction, and operation of pharmaceutical manufacturing facilities.

FLEXIBLE AND PRACTICAL RESOURCES

ISPE has a wide variety of holistic and complementary training resources and learning assets to reach, engage, and develop high-potential employees effectively. Our training portfolio includes classroom training, customized on-site training, online training, and guidance documents developed by subject matter experts. The training opportunities allow participants to "put it all together" by attending classes, reading articles and guidance documents, interacting with industry experts, and applying new information learned.

Gain solutions to achieve your organization's short- and long-term goals, such as lowering production costs, improving process efficiency, increasing production quality, improving employee engagement, and meeting regulatory requirements.

- **Real World Practice:** Courses utilize exercises that use current problems and situations common to the pharmaceutical industry.
- **Experienced Instructors:** Subject matter experts and top leaders in the pharmaceutical industry who have years of experience in their field of study.
- **Global Training to Fit Your Needs:** With classroom, online, and custom training options available, ISPE pharmaceutical training courses adapt to any schedule or location.

Advanced Courses

Refers to content an individual fully understands and at which they are considered an expert. Content in this area could be described as in the areas of synthesis and evaluation and could be in the realm of moving the field forward into new possibilities.

In Bloom's Taxonomy of Educational Objectives, this level would lead with words such as construct, integrate, propose, critique, test, judge, etc. This study plan intends to expand and enhance an individual's current competencies who fully understand the concepts.

Advanced Courses

HVAC (T14)

This 3-day course focuses on common issues and problems in the operation of a facility and maintaining readiness for cGMP inspection. Topics include control system alarm management; common system construction deficiencies; cGMP documentation; how to maintain an ""inspection ready"" state; frequency of testing and balancing; airflow visualization and air change rate reduction. A thorough review of global cGMP regulations and their common interpretations and how they can apply to your facility. The course also examines the challenges and some accepted HVAC solutions for a variety of facility types, including: Laboratories, Bulk Pharmaceutical Chemicals (BPC), Bulk Biologics, Vaccines, Oral Dosage Forms (solid and liquid), Sterile fill/finish, Medical Devices and Combination Devices.

CEUs 2

ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning

Implementing Process Analytical Technology (T29)

Process analytical technology (PAT) is becoming a very important tool for controlling pharmaceutical processes and when implementing Quality by Design. As defined by the USFDA, PAT is ""a system for designing, analyzing, and controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality."" As a scientific, risk-based framework, PAT is intended to support innovation and efficiency in pharmaceutical development, manufacturing, and quality assurance and is being seen as a very important tool for Quality by Design. The PAT framework is founded on process understanding to facilitate innovation and risk-based regulatory decisions by industry and the Agency.

This course is designed to help pharmaceutical manufacturing professionals chart a new course for innovation based on PAT. The course provides an overview to the tools and principles outlined in the FDA guidance, PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing and Quality Assurance. Concepts to help organizations meet regulatory requirements for validating and controlling the manufacturing process also are provided.

CEUs 1.3

ICH Q7A: Implementing Good Manufacturing Practices for Active Pharmaceutical Ingredients (T30)

This course provides you with the areas in which compliance requirements differ most from traditional pharmaceutical and biologics and will review common deficiencies and problem areas related to Q7A. Particular focus will be provided for equipment and engineering with recommended systems; controls and procedures to avoid pitfalls; knowing how to ask the right questions based on science and applicable regulations; buildings and facilities; cell culture and fermentation specifications; documentation; risk assessment; manufacturing controls; materials management; packaging; process equipment; in-process controls; qualification/verification and validation; quality management and specifics for clinical manufacturing.

CEUs 1.3

ISPE Baseline® Guide Volume 1, Active Pharmaceutical Ingredients

Process Validation in Biotechnology Manufacturing (T32)

The inherent complexity and uncertainty of biotechnology makes developing and validating bioprocesses for manufacturing proteins and biopharmaceuticals very difficult. Understanding and using USFDA's Process Validation Guideline is critical to establishing and maintaining control of complex processes, as well as achieving regulatory approval of new products. This course is designed to provide a clear understanding of the regulatory, scientific, and engineering tools required to successfully develop and validate bioprocesses. Course topics includes a long list of activities required to validate biopharmaceutical processes; a comprehensive strategy to process validation; a review of important biotechnology manufacturing processes, and the regulatory requirements for their validation. In addition to classroom lectures, participants will take part in several interactive exercises, solve group problems, and participate in class discussions to understand the underlying principles behind Process Validation. For this advanced course participants should have a basic understanding of C&Q, validation and basic familiarity with biotechnology manufacturing processes and unit operations.

"Professionalism and depth of knowledge. Instructors were genuinely interested and enthusiastic about the subject matter. The course was well organized and there was dense content delivered in the course."

Pharmaceutical Water Systems (T35)

This course has been substantially updated to feature the guiding principles of the ISPE Baseline Guide: Water and Steam Systems (Second Edition) with particular emphasis placed upon microbial control and laboratory water as well as key design philosophies. The principles of design and operation of water systems used directly in pharmaceutical manufacturing and laboratory applications, including the essential concepts and principles of systems used to generate USP, EP and non-compendial waters will be covered. These concepts include specification, design, operation, testing, and maintenance of equipment and systems for water generation.

Participants will examine methods for proper water quality selection and receive detailed guidance regarding the choice and use of appropriate construction materials and instrumentation. Particular attention will be paid to system and component sanitisation procedures and microbial control while participants will receive guidance regarding appropriate monitoring programmes during ongoing operation as well as during initial system qualification.

The course will also cover regulatory requirements including USP, EP, and JP Monographs, the USFDA Guide to Inspections of High Purity Water Systems, current FDA views, and current Good Manufacturing Practice (cGMP) requirements. Common water system myths will also be explored and a variety of practical system designs will be evaluated for EP, EMA, USP and FDA compliance, as well as their advantages and disadvantages. Particular attention will be paid to system and component sanitization procedures and microbial control.

Baseline Guide Vol 4: Water & Steam Systems (Third Edition)

Good Practice Guide: Sampling for Pharmaceutical Water, Steam, and Process Gases

Advanced Courses

Aseptic Processing and Annex I (T63)

Driven by biopharmaceuticals but also prominent in small molecules drug manufacturing as well as for APIs, aseptic processing will undergo a technology jump start driven by the new EC GMP Guide Annex 1. Globally supplying companies, which deliver drugs to Europe, must comply with this new regulatory requirement. There is an impact for all stakeholders of manufacturing, across hierarchy levels and various functions at manufacturers. Also, suppliers have to consider Annex 1 when supplying new equipment or installing new production facilities. This 2-day course will focus on aseptic processing and quality management around the most important pharmaceutical technology.

CEUs 1.3

"The knowledge, examples, and interactive Q&A are invaluable."

Instructors

Karen Ashworth
Director, Karen Ashworth Consulting Ltd.

Karen Ashworth has 23 of years experience in the pharmaceutical industry, initially as a control system supplier, and then as a validation consultant. Prior to that, she has experience as both a control systems designer and an operations manager within the nuclear industry. As a consultant, Ashworth has worked on control system projects for over 30 different end users, and has experience using GAMP® techniques over a full range of projects, from small data monitoring systems to large DCS systems, and embedded control systems for complex machines. She has been an ISPE member since 2001 and was a member of the editorial group within the SIG that produced the GAMP® Good Practice Guide: A Risk-Based Approach to Testing of GxP Systems (Second Edition), and led the team that updated the GAMP® Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems. (Second Edition). She is currently leading the team that is developing the process control systems chapter of the ISPE/GAMP® practical guide to data integrity.

Becky Brewer (Rebecca)
VP Strategic Practices, Quality Executive Partners, Inc.

Rebecca Brewer has more than 29 years of experience in validation and compliance within the pharmaceutical, biopharmaceutical, and medical device industries. In 2013 she began work with Quality Executive Partners, a boutique consultancy, to make a difference in pharmaceutical consulting.

Prior to working with Quality Executive Partners, Becky was Director of Consultancy and GMP Compliance with Dober, where she assisted customers with challenging validation and compliance problems, including Cleaning Validation. Prior to working with Dober, Becky was a senior consultant with Raytheon Engineers & Constructors' Validation Services Department (now Washington Group). As a consultant, Becky has had the opportunity to audit, develop, and provide training in validation and compliance programs for a large variety of companies and products. Becky's work has led to the development of procedures and policies in some of the most challenging environments, including: research and development, contract manufacturers, and suppliers. Becky frequently conducts site-specific validation and GMP compliance training for individual companies. Prior to joining Raytheon, Becky worked for Bristol-Myers Squibb in New Brunswick, New Jersey. Becky has specific expertise in cleanroom design and construction, aseptic processing, isolation technology, computer system validation, cleaning, and sterilization.

Cheryl Bondurant
Principle Consultant, CAI

Cheryl is a professional with 38 years of experience working in FDA and ISO regulated environments. She has implemented effective compliant quality systems for medical devices, biologics, in-vitro diagnostics and electronics. Cheryl is an instructor of FDA regulations and ISO standards and implementation for Quality Systems for Medical Devices and Current Good Manufacturing Practices for Finished Pharmaceuticals.

- 11 years serving as Director of Quality, Quality Management ensuring product quality through establishment, enforcement, monitoring, and reporting of Quality System compliance to 93/42/EEC, ISO 13485, and 21CFR Part 820.
- 7 years as lead assessor of quality systems and liaison for FDA and notified body registrar communications and inspections.
- 3 years as professor for Portland Community College. Planned, created, and taught course content for the understanding and implementation of Quality Management Systems and quality product in a regulated environment.

Winnie Cappucci
Associate Director Product Supply IT Systems Compliance, North America, Bayer HealthCare (Retired)

Winnie Cappucci is currently retired. She was the Associate Director Product Supply IT Systems Compliance, North America for Bayer HealthCare. She has worked in the pharmaceutical industry for 44 years and in global roles for the last 15 years. Ms. Cappucci has worked as a business process owner, an IT professional and lastly as a quality and compliance specialist in a highly regulated environment. Ms. Cappucci was responsible for developing and implementing Bayer's global standards for computer systems compliance. She was a member of the ISPE International Board of Directors, GAMP America Steering Committee, the GAMP Editorial Board, and past Chair of the GAMP. She was also a member of the PDA Industry Advisory Board for Technical Report 32 (Auditing of Suppliers Providing Computer Products and Services for Regulated Operations).

Jack Chu
Senior Consultant, Special Products, Commissioning Agents, Merck & Co., Inc. (Retired)

Jack has more than 35 years experience in Bio-pharm and Medical Device R&D and Manufacture Operations. Jack was assigned to high level roles and responsibilities for Facility, Utility, Process, and Production System Management. Jack has held various managerial positions in his professional career: VP of Life Sciences Engineering, Director of Engineering, Manager of Tech Services and CQV, Manager of Site Operation Supports, Project Manager, and Senior Process Engineer. Jack leads a number of medically significant projects for large and small Biopharmaceutical companies in the US and abroad. Jack has extensive knowledge in Manufacturing Operation that includes quality systems, production systems, facility and utility systems, and process control systems. In addition, he has hand-on experiences in M&U Operation, Asset Lifecycle Management, and Production Optimization. Jack teaches graduate school PME (Pharmaceutical Manufacturing Engineering) courses and undergraduate BME (Bio-Medical Engineering) courses. He is a certified Instructor for ISPE's OSD (Oral Solid Dosage Form), API (Active Pharmaceutical Ingredients), cGMP, and Manufacturing Operations courses.

Andrew Collentro
President, WCSI

Andrew Collentro is the President of WCSI, a water treatment firm primarily serving the pharmaceutical and biotechnology industries. He has over 25 years experience in the design, commissioning, and qualification of pharmaceutical water purification systems; specializing in process design and regulatory compliance of USP/EP Purified Water, WFI, and Pure Steam Systems. Andrew is a member of the ISPE Training Instructors and has taught educational courses for PDA and several other industry organizations. He is a frequent lecturer and author on pharmaceutical water topics and holds several patents on various water treatment processes. Collentro is a Past Chair of the ISPE Critical Utilities Community of Practice (CoP), a chapter author for the *ISPE Baseline® Guide: Water and Steam Systems*, and co-developer for ISPE and PDA educational courses for pharmaceutical water.

Instructors

Bruce Davis

Principal, Global Consulting

Bruce Davis trains for ISPE in several topics including Process Validation, Technology Transfer, and Quality Systems. He is passionate about ensuring that each trainee's individual learning experience is as high a quality as it can be. Bruce is based in the UK and runs his own consultancy, covering science- and risk-based applications, including the topics above, plus Quality by Design and Risk Management.

He is a professional engineer and has many years experience in the pharmaceutical industry and a wide international knowledge. Bruce previously worked at AstraZeneca. He is Past Chair of ISPE International Board of Directors, and has contributed to many ISPE events and Guides, most recently co-chairing the team updating ISPE's Technology Transfer Guide.

Jean Francois Dulliere

Jean Francois has spent more than 20 years in the pharmaceutical industry in various positions: quality control, oral solid dosage forms manufacturing (tablets, capsules), packaging, raw materials production from bacteria growth, industrial development (scaling up, equipment qualification, process validation, cleaning validation), dual compartments syringes aseptic filling. Jean-François was involved in the conceptual design phases for oral solid dosage forms facilities and in the conceptual design phases for sterile products facilities aseptic filling, freeze drying.

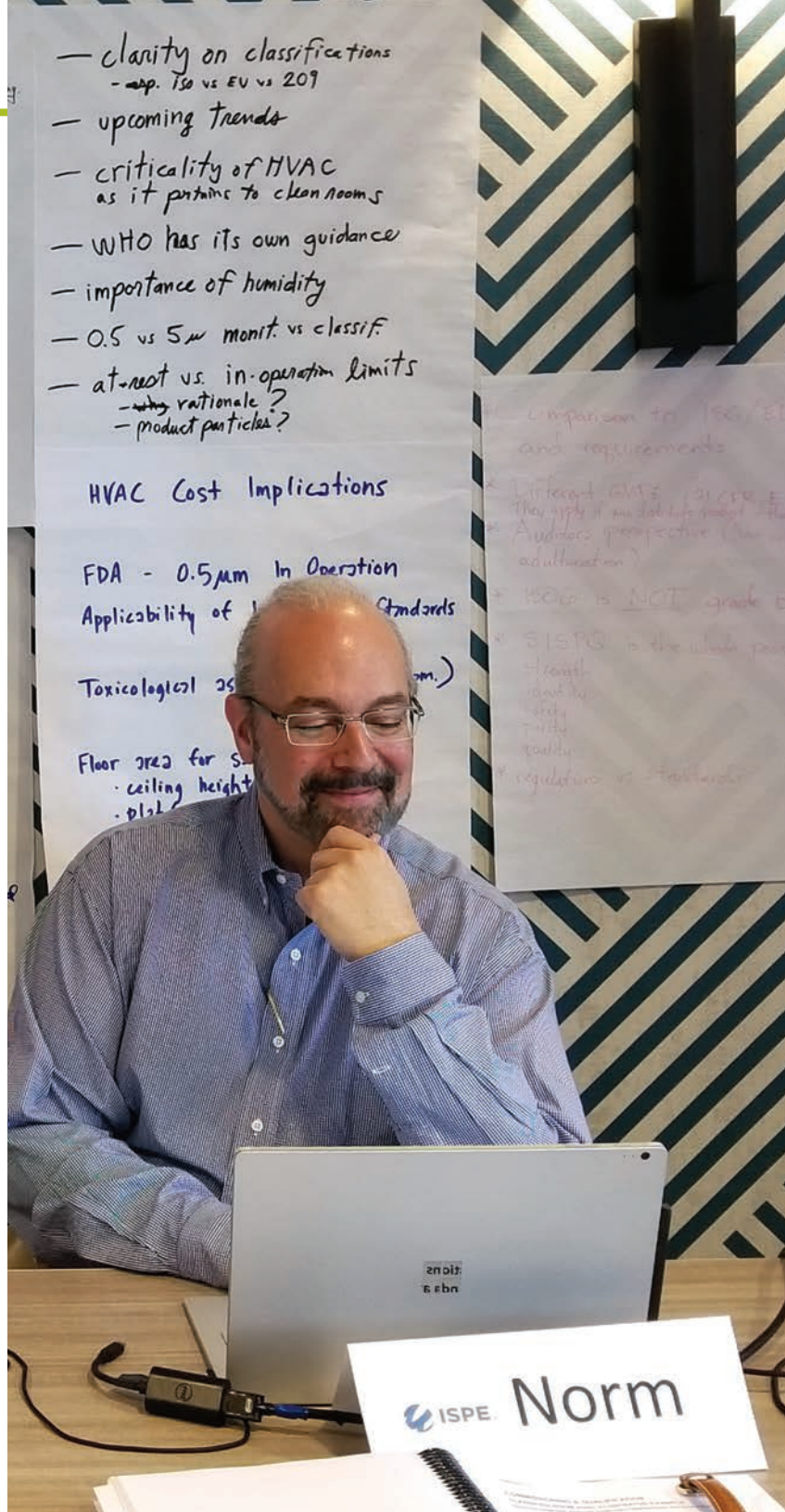
Gordon Farquharson

Principal and Managing Director, Critical Systems Ltd.

Gordon Farquharson is a Chartered Consulting Engineer with more than 35 years experience of quality and safety critical processes and facilities used by industries such as Healthcare, Life Science, Micro-electronics, etc. He is Principal and Managing Director of Critical Systems Ltd, an international consultancy firm with partnerships with PharmOut Pty Ltd (Australia), FactoryTalk (Thailand), Airex (Japan), CM-Plus Corporation (Japan), and Pharma Solutions (Japan).

He has focused on technologies such as isolators, barrier technology, mini-environments, critical utility systems and bio-containment applications. He has been responsible for the development of technical solutions in product development, primary manufacturing and device and dosage form manufacturing.

Standards and regulatory compliance issues in the Pharma/Life Science sectors are a major interest and responsibility. In this context he has a high degree of expertise in the practical interpretation & application of EU/PIC-S/WHO GMPs and US FDA cGMP requirements. Experience with the variation in expectations gives him an ability to dovetail the differing regulatory requirements. In recent years, he has been heavily involved in the development of the new regulatory guidance and standards. In particular, he is active working on CEN/ISO Cleanroom & Contamination Control Standards, WHO GMP guidance and ISPE Baseline Guides. He is Chairman of BSI's LBI 30 Committee and of CEN Technical Committee 243, and was Convenor of WG1 and a UK expert working on the ISO TC209 and CEN TC243 family of contamination control standards that provide the platform for contamination control standardisation and practice in this millennium. He has worked with the EMA in London to help update and improve the cleanroom classification and monitoring requirements in Annex 1 of the EU and PIC/S GMPs and has contributed writing WHO's Pharmaceutical water GMP Guidance and the revision of the WHO GMP guidance on sterile products.



Instructors

Dan Franklin
Manager of Compliance Service, IPS

Dan Franklin, CIRM, CxA is the Regional Manager of Integrated Project Services' Midwest US Commissioning and Qualification operations based in Indianapolis, Indiana. Current responsibilities include consulting and program planning, delivery and execution support for capital projects, and risk-based verification programs.

Mr. Franklin has over 30 years of project delivery and operations support experience. Graduated from Lewis University with a BS in Aviation Maintenance Management, Mr. Franklin has also earned an MBA from National University, and holds many industry certifications and licenses.

Mr. Franklin supports the ISPE Commissioning and Qualification CoP as a Steering Committee Member, and has served as a contributing author to the ISPE FE Guide, the ISPE Good Practice Guide: C&Q Applied Risk Management, and the *ISPE Good Practice Guide: Decommissioning.*

Stephanie Gaulding
Executive Director, Regulatory Compliance for Pharmatech Associates

Ms. Stephanie Gaulding is the Executive Director, Regulatory Compliance for Pharmatech Associates and is based in the Boston area. As a Quality Systems professional with over 25 years' experience in Pharma, Biotech and Medical Device industries, she draws on her experience to develop, redesign and implement efficient and sustainable quality systems for her clients resulting in compliance with global regulatory requirements and industry best practices. Ms. Gaulding is an ASQ Certified Quality Auditor and ASQ Certified Pharmaceutical GMP Professional and has previously worked for companies such as Boehringer Ingelheim, Eli Lilly and Company, and Human Genome Sciences in variety of quality assurance, quality control and validation roles.

Ms. Gaulding holds a M.Sc. in Biotechnology from Johns Hopkins and a B.Sc. in Biology from Virginia Tech. She is an active member of PDA, ISPE, and ASQ including serving as member of the PDA Letter Editorial Committee (2018-19), co-teaching the ISPE "Applying Quality Risk Management" course, serving as an ASQ technical community member leader, and participating in the Certified Pharmaceutical GMP Professional Exam development process.

Katherine Giacoletti
Partner, SynoloStats LLC

Katherine Giacoletti has worked as a statistician in the pharmaceutical industry for over 20 years, and has expertise across the product lifecycle, from non-clinical product and process development, through validation and commercial supply, as well as all stages of clinical development from First in Human through licensure and beyond. Katherine is highly skilled in a wide range of statistical methodologies, and has the expertise to choose the best methodology to meet both scientific and business demands. She applies modern statistics to biologics (including biosimilars) development and manufacturing, with expertise in complex, modern statistical tools, but always chooses the simplest statistical approach that protects the patient, based on the context of the application.

Norm Goldschmidt
President, Genesis Architects, Engineers & Constructor

Norman Goldschmidt has almost 30 years of experience leading teams through concept, design, and delivery of efficient facilities and processes. Prior to joining Genesis Architects, Engineers & Constructor, Norman served in numerous capacities during 20 years with Bristol-Myers Squibb. Starting as a Mechanical Engineer/Project Manager, and culminating as Executive Director of Global Engineering, leading the Strategy and Design teams. His industry experience is vast, from facilities and processes necessary to bring a product to market, to R&D through manufacturing for pharmaceuticals, biologics, and medical devices.

Mr. Goldschmidt studied Mechanical Engineering at the University of Buffalo, and Engineering Management at the State University of New York. He holds four patents for innovations in HVAC and Pharmaceutical Processing, is an International Standards Organization (ISO) US TAG Delegate, and US Expert Delegate to ISO 14644 Cleanroom Standards WG 13 and 4. Norman provides consulting and training support to Genesis' many clients and to regulatory bodies around the world.

Norman was Lead Author of the *ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC)* and has authored chapters in the ISPE Guidance Documents for biopharmaceutical manufacturing facilities, oral solid dosage forms, sterile and laboratory facilities, and risk MaPP. He is dedicated to developing the next generation of pharmaceutical professionals, serving as an Adjunct Professor at NJIT, an instructor for ISPE training classes, and a trainer for NSF, ASHRAE, and several regulatory agencies.

Shawn Gould
Director of Regulatory Compliance, Johnson & Johnson

Shawn Gould is Director of Regulatory Compliance with Johnson & Johnson's Regulatory Compliance group. He currently holds responsibilities in the Pharma Segment overseeing compliance issues regarding large molecule and gene therapy products. Shawn also served in the US Food and Drug Administration's Office of Compliance where he worked on the pre-approval process for new and generic drugs with special emphasis on applications involving QbD and PAT concepts. In his 20+ years in industry, Gould has held roles in development, manufacturing, quality, and validation for several companies within the industry including pharmaceutical, biopharmaceutical, blood plasma fractionation, and topical/medical device firms. Gould graduated from the University of Toledo with a BS in Chemical Engineering followed by his MS in Chemical Engineering from Washington University in St. Louis, Missouri.

John Hannon
Principal for IT and Automation Global Business, Commissioning Agents, Inc.

With over 27 years in the pharmaceutical, IT, and process automation fields, John Hannon has been instrumental in starting up cutting-edge biotech facilities for companies such as Baxter, Monsanto, Amgen, Genentech, Wyeth, and Cook. He has managed multi-million dollar projects along with dozens of client managers across the Southeastern US, responsible for delivering hundreds of high-profile, mission-critical projects for biotech, pharmaceutical, and medical device customers. In his current role he is co-leading CAI's IT and Automation business area, responsible for soup to nuts automation, MES, and other IT system business with the international client base.

With a demonstrated knowledge of quality assurance and regulatory compliance across the pharmaceutical industry, John has led national and international seminars with ISPE, contributed to several publications, and has led speaking venues related to risk-based approaches to smarter integrated system delivery compliant to the FDA, USDA, and EU regulatory agencies. He is an active and sought-after consultant for complex IT and automation problems in the pharmaceutical industry.

Instructors

James John (Jim)
Sr. Project Manager, JWJ Consulting LLC

James W. (Jim) John, PMP, has worked with clients in the areas of pharmaceutical project management, validation, and Part 11 remediation in the manufacturing and laboratory environments for the past fifteen years. Prior to ProPharma John worked for Rockwell Automation and several compliance consulting companies dealing in the FDA regulated industries. John began his career working in plant operations and engineering in the chemical industry with BASF, followed by several years in the Manufacturing IT Group at Nabisco. He has served as a featured speaker at conferences in the US, Canada, Europe, and Japan. John has been a member of ISPE and the ISPE Midwest Chapter for 22 years. His other professional affiliations include: Chairman of the JETT Consortium (a special interest group of ISPE's GAMP® CoP), member of the GAMP® Americas Steering Committee, member of ISPE's North American Education Committee, and training developer and presenter of FDA in-house training for CSV. John has served on guideline development committees for ISPE (including GAMP®) and PDA, and has had papers published by ISA, Pharmaceutical Online, and ISPE's *Pharmaceutical Engineering®* magazine.

Jeff Jones
Executive Director of Quality, Humacyte

Jefferey Jones has over 20 years of experience with development-stage and commercial biopharmaceutical process technology transfer. In his current role, Jefferey oversees quality aspects of facility, process, and instrumentation design and scale-up for a novel biologic process manufacturing bioengineered blood vessels. Prior to his work at Humacyte, Jefferey was responsible for Manufacturing Operations, Quality Assurance/Control, and Validation at Emergent Biodefense in Lansing, Michigan. Jefferey previously held positions overseeing quality assurance, quality control, and product development activities at MedImmune, Inc. and Human Genome Sciences. Jefferey earned a BS in biology from Virginia Polytechnic Institute and State University, and a MS in biotechnology from Johns Hopkins University.

Neil Lloyd
CQV Consultant, Gallo Engineering Ltd

Neil Lloyd has more than 20 years of experience working in laboratory, manufacturing, design, and CQV cGMP environments. The majority of his time has been spent in CQV teams, working hands-on and in a lead capacity on start-up biopharmaceutical facilities. He has extensive experience with upstream and downstream processing equipment and systems, process support equipment and clean utility generation, storage and distribution systems, and has been involved in the development of and implementation of CQV strategies for fast track projects compliant with the requirements of regulatory bodies, ensuring fitness for intended purpose. Neil has been involved in projects from the design stage to build in quality to the CQV lifecycle. Neil has prepared VMPs for projects with a science and risk-based approach, using different CQV strategies to achieve this, such as the traditional leveraged commissioning approach and ASTME2500. He has generated the underlying plans and procedures that support and control the CQV strategy, such as risk assessment procedures, change management, and verification plans. Neil understands the pressures fast track projects put on the safety, quality, efficiency, and effectiveness of a CQV Project and what practices need to be put in place to ensure compliance throughout.

Line Lundsberg-Nielsen
Global Technology Partner, NNE

Line is a Global Technology Partner in GMP and Regulatory aspects, working for NNE and run her own consulting business, Lundsberg Consulting Ltd. She has been working in the pharmaceutical Industry for the last 20+ years. Her background is in physics and she holds a PhD in PAT. Line's main consulting areas are Regulatory Expectations, Future Pharma trends in smart manufacturing and control (Pharma 4.0 and the Manufacturing Control Strategy), QbD, PAT including Real Time Release Testing, Process Validation, and GMP combined with science- and risk-based innovative development and manufacturing.

Line is active in ISPE, currently the chair of the Global Process Analytical Technology and Lifecycle Control Strategy CoP, delivering training in Quality by Design, Process Analytical Technology, and Process Validation, and is co-author of several Good Practice Guides.

David Margetts
CEO of Factorytalk

Dave Margetts is the CEO and co-founder of Factorytalk and focuses his advice, consulting and technical experience for clients in the Pharmaceutical and Biotech industries on quality, technology capability and process performance.

Dave's background spans shop floor integration and control through manufacturing execution and quality management systems up to corporate operational improvement and regulatory compliance initiatives. He is responsible for leading the company and developing it's vision and key people and he remains an active resource for our clients in both technical solutions and consulting roles.

Before moving to Asia in 2004 to start Factorytalk, he worked in systems and validation roles across one of Europe's largest pharmaceutical production sites for AstraZeneca. His assignments covered manufacturing (OSD/Sterile injectables/Biotech), R&D and clinical trials manufacturing facilities for FDA regulated environments. From 2016 to 2019, he led the succesful and rapid start-up to operation of a new Asian business unit for Werum IT Soutions as the Managing Director for the region.

Kevin C. Martin
Managing Partner, Azzur Group LLC

Kevin has over 40 years of FDA-regulated industry experience that includes management positions at Wyeth and McNeil Pharmaceutical. He is currently a General Manager for Azzur IT, helping life science customers with technology and compliance solutions, and is a member of the Board of Directors for Azzur Group LLC. He is considered a subject matter expert on risk-based systems selection, implementation, and validation conducted within QA, IT, Manufacturing, Operations, Clinical, and R&D in FDA-regulated environments.

He was a member of the PhRMA Computer Systems Validation Sub-Committee (responding to the FDA's issuance of the 1983 *Blue Book*), was the Core Team Secretary for the PDA Part 11 Task Group (working alongside FDA's Paul Motise to develop industry guidance), and is a former Chair of the GAMP Americas and GAMP Global Steering Committees, and a contributor to several GAMP Good Practice Guides and Special Interest Groups.

He received his BS in Chemistry from Delaware Valley University (formerly Delaware Valley College of Science and Agriculture) and his ME from Penn State University.

Instructors

Bernard McGarvey

Engineering Fellow, Eli Lilly and Company (Retired)

Retired at the end of 2017, Bernard McGarvey has a BE and PhD in Chemical Engineering from University College Dublin, Ireland. He spent 34 years working for Eli Lilly and Company at various locations in Ireland and the United States. He has held a variety of roles in process control and process engineering over this time, as well as time in corporate manufacturing. His main interest is in the application of First Principles thinking to improve engineering decision-making and problem-solving at Eli Lilly, covering both process development and manufacturing. Recently he has applied this approach to pharmaceutical cold chain distribution leading to improvements in both the speed and quality of decision-making in this area.

Chris McNaulty

Director of Bio-Pharm Sales, Sani-Matic, Inc.

Chris McNulty is responsible for leading Sani-Matic's sales team and their customers through the complex BioPharm regulatory landscape, and generating detailed system cleaning approaches to meet industry standards and customer-specific processes. He is driven by the desire to "solve problems for our customers and ensure they meet regulatory requirements." His experience spans more than 30 years, including field commissioning and program development, while also serving as an electrical project engineer and technical services manager. Chris is an instructor for the ISPE Clean-In-Place course, and has co-instructed with Becky Brewer on numerous occasions.

Instructors

Trish Melton

Managing Director, Mime Solutions Ltd.

Dr. Trish Melton is Managing Director of MIME Solutions Ltd., an engineering and management consultancy providing project, program and risk management, business change and improvement management, regulatory, validation, and GMP consulting for pharmaceutical, chemical, and healthcare clients. She has previously worked for Eli Lilly and GSK, amongst others.

Trish has worked as a project manager and project management consultant on engineering and non-engineering projects worldwide, predominantly within the global pharmaceutical and biopharmaceutical industry. She is a chartered chemical engineer, and a Fellow of the Institution of Chemical Engineers (IChemE) where she was the founding Chair of the IChemE Project Management Subject Group, and authored a series of IChemE publications–the Project Management Toolkit.

As an ISPE Member, Trish serves as the chair of the steering group in charge of launching and now maintaining ISPE's Project Management Good Practice Guide. She was both an author and editor on this guide. She has presented on various subjects at ISPE conferences including project management, quality risk management, and lean manufacturing. She is also a member of the ISPE Global Documents Committee, and serves as chair of the RID (Rapid Information Delivery) sub-team.

Hilary Mills-Baker, CEng, BSc, MEng

European Quality and Validation Manager, Emerson Automation Solutions

Hilary is the European Quality and Validation Manager for Emerson Automation Solutions where she oversees all Life Science projects being supplied with Syncade or DeltaV from a Quality and Validation stance.

She is a member of the ISPE Special Interest Group for Process Control Systems, and co-lead the update of the PCS guide following the publication of GAMP5. She now delivers the training on this topic for ISPE with Karen Ashworth. She has recently been involved in the team writing the PCS practical guidance for Data Integrity, which will be published next year.

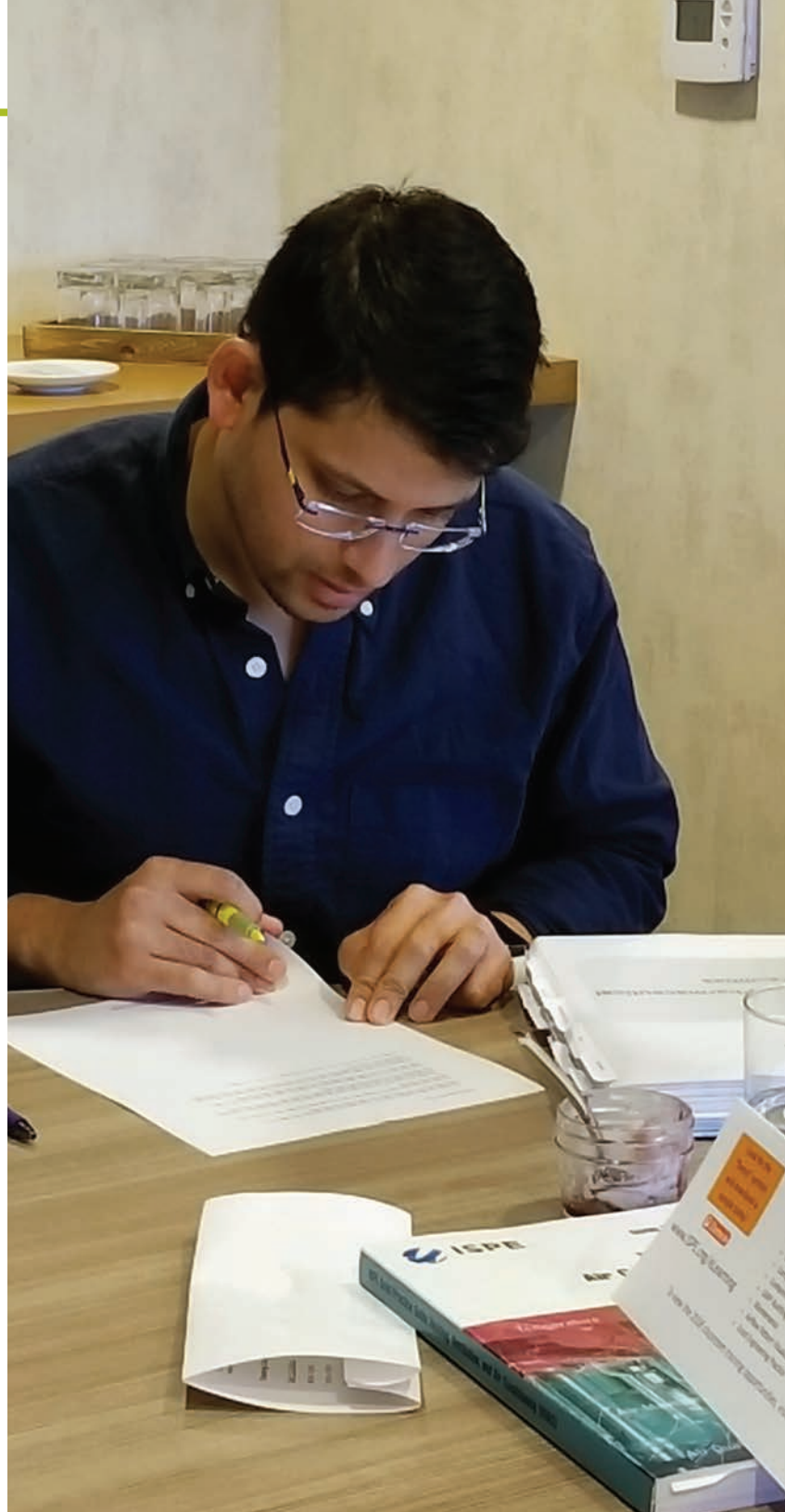
Jeff Odum

VP of Biopharma Life Sciences, Exyte

Jeff brings over twenty-five years of management experience in the design, construction, and commissioning/qualification of facilities in the biotechnology, and pharmaceutical industries. These facilities represent a global capital investment of over $3 billion (US). A recognized expert in biopharmaceutical manufacturing, Jeff has authored over eighty articles and four Industry reference books on subjects related to project management, GMP compliance, process improvement, and the design and construction of biopharmaceutical manufacturing facilities. He is a welcomed speaker at numerous international industry forums and conferences, presenting on topics relating to next generation facility design, bioprocess manufacturing, project management and GMP compliance. Jeff is a Certified Pharmaceutical Industry Professional (CPIP)), is the Chair of the ISPE global Biotechnology Community of Practice, and the Lead of the new ATMP Good Practice Guide for ISPE.

He is a member of the ISPE technical training faculty and is a Teaching Fellow in North Carolina State University's BTEC graduate program in biomanufacturing and has led training efforts in fifteen countries in over 100 sessions.

Jeff holds a Master Degree in Engineering from the University of Tennessee – Knoxville.



Instructors

Maurice Bruce Parlane

Director and Partner, CBE Pty Ltd (Australia)
Principal, New Wayz Consulting Ltd (New Zealand)

Mr. Parlane is a professional engineer and technical manager with over 30 years experience in manufacturing management, operational, and consulting roles within the human and animal health, biotechnology, medical device, and complementary medicines sectors. He has been involved with and managed numerous projects of varying scale related to compliance improvement and manufacturing effectiveness for clients nationally and internationally for NZ, Australian, US, and EU markets.

Maurice has extensive experience in design and operation of technical operations under GMP regulations specializing in biopharmaceutical process scale-up, optimization, and validation. He is an active participant and presenter for a number of national and international industry associations, and serves as a subject matter expert on GMP compliance, Qualification and Process Validation, Quality Risk Management, and QbD in a number of international committees.

Arthur (Randy) Perez

Retired, Director Information Governance and Management, Novartis Pharmaceuticals

Dr. Perez retired at the end of 2015 from the position of Director, Information Governance and Management for Novartis Pharmaceuticals. His responsibilities at Novartis included a wide range of IT compliance issues, such as GxP, Sarbanes-Oxley, and data privacy. He served on several global Novartis teams dealing with computer systems compliance issues, and authored many of the firm's global GxP compliance policies. During his 32-year tenure at Novartis, he developed a broad range of experience. Prior to joining IT, he worked as a chemistry group leader in process research, managed a chemical manufacturing process validation initiative, and ran both a GMP training program and a QA validation group for pharmaceutical operations.

Dr. Perez was a member of the PhRMA Computer Systems Validation Committee from 1995-1999, and was instrumental in the formation of GAMP® Americas when that group started in 2000. From 2002-2008 he was Chairman of GAMP® Americas, and has been a member of the global GAMP® Steering Committee since 2002, Chairing it from 2012-2015. He was part of the core team that led the development of GAMP® 5, published in 2008. In addition, he initiated and led the Global Information Systems SIG, who wrote a GAMP® Good Practice Guide that was published in 2005, and he led the team that developed the second edition of this guide that was published in 2017. He was the lead author of the 2014 *ISPE GAMP® Good Practice Guide: A Risk-Based Approach to Regulated Mobile Apps*, and was part of the core author team for the 2017 *ISPE GAMP® Guide to Record and Data Integrity.*

Dr. Perez has been a speaker and a course leader at numerous conferences in the US and Europe, and has been published in industry journals and textbooks. In 2005, he was elected to the ISPE International Board of Directors, and served as ISPE Chairman in 2011-2012. He continues to serve in a variety of ISPE volunteer leadership roles.

Robert Perry

Project Manager/Assistant Director OPM,
Commissioning Agents, Inc.

Robert Perry is a senior project professional with over thirty years of facilities project and construction management experience in the commercial, industrial, and municipal markets. He has extensive experience in program and project management in the life sciences and microelectronics industries. Bob has managed several expansion and capacity upgrade projects, from conception/programming, through turnover, to operations and maintenance. He has managed several planned shutdowns for GMP and clinical manufacturing plants. He is a licensed Master Plumber and pipefitter and possesses undergraduate degrees in mechanical engineering and computer science from Wentworth Institute of Technology, and a MBA in management information systems from Western New England University.

Veronica Power

Principal Consultant, VCD Validation Services Ltd.

Veronica is an experienced Validation/CQV/CSV consultant with 25 years relevant pharmaceutical experience. She has many years' experience in the pharma, biopharma, and medical device industries, most of which were in a management/consultancy capacity. She has worked in many pharmaceutical companies as both an employee and consultant, including IVAX, Genzyme, Mylan, Gilead, and AbbVIe, to name a few. Veronica is a founding and long-standing committee member of the ISPE GAMP Ireland Community of Practice.

Andrew Provan

Process Consultant, MSc, MIChemE, EXmoor Pharma Concepts Ltd.

Andrew Provan is a Process Consultant and engineer at eXmoor Pharma Concepts, a technical and strategic consultancy company in biopharmaceuticals and regenerative medicine. Andrew has over 30 years of experience within the biopharmaceutical industry in a variety of roles, including process development, scale-up, process design, production management, project management, procurement, installation commissioning, and validation. He has had significant involvement in over 90 major capital projects, both green field and retrofitting/updating existing facilities. Most of these projects involve specification and procurement of process utilities, including purified water, WFI, and pure steam. He therefore has extensive knowledge of what works (cost/quality/time) and more importantly, what doesn't work, and where the problems are likely to arise. He holds a BS in microbiology and biochemistry from Kings College in London, and a MS in biochemical engineering from University College in London.

Tara Scherder

Partner, SynoloStats LLC

Tara Scherder has over 30 years of experience in the chemical and pharmaceutical industries as a statistician, process engineer, master black belt, and educator. She has functioned as both an in-house and external statistical consultant to drug substance and drug product teams across the product lifecycle for small and large molecule platforms.

Tara's formal education includes a BS in chemical engineering from the University of Pittsburgh, and a MS in statistics from Carnegie Mellon University.

Her current passion as Partner at SynoloStats is the implementation of statistical methods for lifecycle process validation, with a keen focus on business context and value.

Bob Tribe

AP Regulatory Affairs Advisor, ISPE

Bob Tribe joined the Therapeutic Goods Administration (TGA), Australia in 1971 as a GMP inspector after having worked in the pharmaceutical industry in a senior quality assurance position. He became Chief GMP Inspector in 1980, a position he held until his retirement in 2004. While at TGA he was elected Chairman of PIC/S in 2000-2001. After retiring from TGA he established Bob Tribe Consulting and has assisted many GMP regulatory authorities around the world reach the PIC/S level of regulatory control. Of the 17 regulatory authorities that he has assisted to date, 12 have obtained PIC/S membership. He also consults to pharmaceutical manufacturers wishing to achieve compliance with PIC/S GMP requirements.

Bob is a member of the WHO Expert Committee on Specifications for Pharmaceutical Preparations and undertakes GMP inspections for the WHO under its Pre-qualification Program. He is also the ISPE Regulatory Affairs Consultant for the Asia-Pacific region.

Instructors

Stephen Tyler
Director of Quality Assurance, AbbVie (retired)

Stephen Tyler was a Director of Technical Operations for Operations' Quality Assurance at AbbVie, a biopharmaceutical company in North Chicago, Illinois. Stephen holds a BS in applied biology and chemical engineering, and a MS in microbiology. Stephen joined AbbVie (Abbott) in 1984, and the Quality Assurance organization in 2008. He is a former international board member for ISPE, former Co-chair of the ISPE PQLI® Technical Committee, and current Chair for the ISPE PQLI® Steering Committee. Stephen was the recipient of the 2013 ISPE Richard B. Purdy Distinguished Achievement Award, that recognizes an ISPE member who has made significant, long-term contributions to the society.

Mark von Stwolinski
Vice President of Facility Integration, Clark Richardson & Biskup Consulting (CRB)

Mark von Stwolinski has over 20 years of experience in the design and construction of biopharmaceutical facilities worldwide. His experience with ISPE guidance documents includes: Steering Committee member and contributing author for three ISPE Guides; chair and contributing author for the ISPE Baseline® Guide: Biopharmaceutical Manufacturing Facilities, issued in 2013; member of the ISPE Guidance Document Executive Committee (GDEC); and Lead Process Architect for CRB.

Robert Warn (Rob)
Principal, Operational Readiness Partners Inc., (ORP)

Robert Warn has over 17 years in the biotechnology industry. He has extensive project management, process engineering, CQV and process validation experience on biotechnology manufacturing systems and equipment. His expertise are focused on operational readiness and support of process tech-transfer and manufacturing equipment implementation. As well, Robert is frequently relied on to support implementation of PPQ and C&Q programs for his clients. Robert has a mechanical engineering background and is a current member of the ASME Bioprocessing Equipment (BPE) Standards Committee.

Bruce Williams
Director, Williams Process Limited

Bruce Williams is a consulting chemical and process engineer, fellow of the Institution of Chemical Engineers, and past chair of ISPE's United Kingdom Affiliate. He specialises in industrial and pharmaceutical biotechnology, having spent 10 years in contract manufacturing with AstraZeneca and Avecia where he was responsible for process engineering and technology transfer activities. In 2008, he founded Williams Process Limited to help companies achieve efficient, effective and compliant processes. Bruce is also an industrial lecturer at the Newcastle University Biopharmaceutical Bioprocessing Technology Centre.

Steve Wisniewski
Principals Compliance Consultant, Commissioning Agents, Inc.

Steven Wisniewski is Principal Consultant for CAI Consulting, a highly respected provider of consulting and technical services for biotech and pharmaceutical manufacturers worldwide. He has more than 35 years of experience in the pharmaceutical, biotech, and device industries. Prior to joining CAI he was Senior Associate and Director of Compliance for IPS. Steve was senior consultant for Drug and Device Associates, and has served in manufacturing facility and corporate senior management roles at Sterling Drug and Bausch & Lomb. He has completed a wide variety of pharmaceutical manufacturing, filling, and critical support operations to major R&D laboratories, facilities, and upgrades. He holds a BSME from Rensselaer Polytechnic Institute, is an active Member of PDA, and has participated on a Technical Report draft team.

Steve is an active member of ISPE, serving on the ISPE Board of Directors beginning in 1982, and was chairman of the board in 1991. Steve served four years as chairman of the ISPE Community of Practice for Commissioning and Qualification, and was on the ISPE task team that developed the ASTM E2500 Verification Standard. In addition, he served as a leader of the Task Team that produced the ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment, and was a leader of the Task team that developed the ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification. Most recently he is a member of the leadership for a Task Team developing the second edition of Baseline Guide 5 for C&Q to incorporate QRM approaches.

Sion Wyn
Director, Conformity Ltd.

Sion Wyn is an acknowledged expert in computer system validation and compliance, and international regulations. He assisted the FDA as a consultant with its re-examination of 21 CFR Part 11, and was a member of the core team that produced the FDA Guidance on 21 CFR Part 11 Scope and Application. He was the technical content expert for the FDA's ORA Virtual University on-line training modules on computerized systems validation and compliance. He received the FDA Group Recognition Award for his work on Part 11.

Wyn was the editor of the *ISPE GAMP®5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems*, and is a member of the ISPE GAMP® Global Steering Committee, GAMP® Editorial Board, and the GAMP® Europe Steering Committee. He is lead trainer for GAMP® and Computer Systems Validation and Compliance, Part 11, and Data Integrity and a course developer for ISPE. He has extensive experience in all aspects of computer systems validation and compliance, including validation planning, specification and testing of systems, quality risk management, site and system compliance audits, risk assessments, policies and procedures writing, 21 CFR Part 11 assessments, Data Integrity assessments, and supplier audits.

At Conformity Ltd., Wyn provides computer validation and compliance consultancy to the pharmaceutical and other regulated life-science industries. Wyn received the 2006 ISPE Professional Achievement Award, which honors an ISPE Member who has made a significant contribution to the pharmaceutical manufacturing industry. He also received the 2016 ISPE UK Fellow Award.

Jörg Zimmermann

Vice President Vetter Development Service, External Affairs" of Vetter Pharma-Fertigung GmbH & Co.

Jörg Zimmermann is currently Vice President of Vetter Development Services for Vetter Pharma Fertigung GmbH&Co KG, Ravensburg, Germany. In this role, he is responsible for manufacturing science & process development, technology & process transfers, project & service analytics and drug delivery systems. Within Vetter, Jörg has held various positions in process implementation, new product introduction, lyophilisation process development and as production manager before becoming Director of Production of Vetter's production site at Lake Constance in 2000. There he managed 5 production lines for aseptically prefilled injection systems. Jörg has volunteered as track leader and speaker at conferences by ISPE, PDA, and Concept Heidelberg for over 15 years and served as the PDA-representative at the "interested parties meeting" at the EMA on the revision of Annex 1 in 2006.

Gary Zoccolante

President, Plymouth Rock Water Consultants

Gary has over 45 years experience in the design, operation and trouble-shooting of pharmaceutical water systems. He has been involved in the development of equipment for pretreatment, reverse osmosis, deionization, ultrafiltration and distillation.

Zoccolante was a committee member of the original *ISPE Baseline® Guide: Water and Steam Systems.* He was a member of the revised Edition 2 Guide, and is a co-chairman of the Edition 3 Guide in current revision. He is a member of the ISPE Critical Utilities Community of Practice Steering Committee. He has worked on the development of the *ISPE Good Practice Guide: Commissioning and Qualification of Pharmaceutical Water and Steam Systems* Editions 1 and 2.

Zoccolante is a frequent lecturer and has presented for ISPE, Interphex, American Institute of Chemical Engineers, American Society of Mechanical Engineers, Institute for International Research, Center for Professional Advancement, PDA, Pharmtec, Barnett International and many others. He has authored and co-authored many papers on pharmaceutical water production and system operation and maintenance. He holds several patents for pharmaceutical water processes. He holds a B.S. degree in Mechanical Engineering from Northeastern University.

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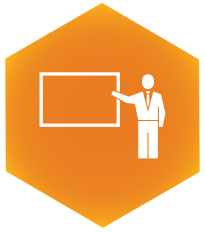

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