

# 2017 ISPE Training by Topic

## ◆ Auditing

- 13 - 14 March, Tampa, FL

## ◆ Basic GAMP® 5, Annex II/Part II

- 12 - 14 June, Lilly MQ Learning Center, Indianapolis, IN

## ◆ Bio Manufacturing Facilities\*

- 8 - 9 May, San Diego, CA

## ◆ Bio Manufacturing Overview

- 3 - 4 April, Tampa, FL
- May, Copenhagen, Denmark

## ◆ Bio Manufacturing Process Validation

- 27 - 28 March, Tampa, FL

## ◆ Commissioning and Qualification

- 16 - 17 May, NIBRT, Dublin, Ireland

## ◆ Commissioning and Qualification Risk Management

- 23 - 24 February, Tampa, FL

## ◆ Clean in Place

- 13 - 14 February, Tampa, FL

## ◆ Cleaning Validation

- 6 - 7 April, Tampa, FL
- May, Copenhagen, Denmark

## ◆ Cross Contamination (Risk-MaPP)

- 13 - 14 March, Tampa, FL

## ◆ Effective and Efficient Deployment of Operational Excellence

- 8 - 9 May, St Gallen, Switzerland

## ◆ Facilities, Systems, and Equipment Verification

- 27 - 28 March, Tampa, FL
- 12 - 13 June, Tampa, FL

## ◆ Facility Project Management\*

- 6 - 7 March, Tampa, FL
- May, Copenhagen, Denmark

## ◆ GAMP® 5, Annex II/Part II

- 23 - 25 January, Tampa, FL
- 26 - 28 April, Tampa, FL
- March, Manchester, UK
- June, Indianapolis, IN

## ◆ GAMP® 5 Data Integrity

- 6 - 7 February, Tampa, FL
- 8 - 9 May, San Diego, CA
- May, Copenhagen, Denmark

## ◆ GAMP® 5 Process Control

- 9 - 10 March, Tampa, FL
- 8 - 9 June, Tampa, FL

## ◆ HVAC

- 8 - 10 February, Tampa, FL
- 9 - 11 May, San Diego, CA
- May, Copenhagen, Denmark

## ◆ Oral Solid Dosage

- 3 - 4 April, Tampa, FL
- May, Copenhagen, Denmark

## ◆ Process Validation

- 1 - 3 February, Tampa, FL
- May, Copenhagen, Denmark

## ◆ Q7A

- 5 - 6 April, Tampa, FL

## ◆ Quality by Design

- 1 - 2 June, Tampa, FL

## ◆ Quality Risk Management System

- 30 - 31 January, Tampa, FL

## ◆ Sterile Facilities

- 10 - 11 May, San Diego, CA

## ◆ Technology Transfer

- 30 - 31 March, Tampa, FL

## ◆ Water Generation

- 6 - 7 February, Tampa, FL
- 8 - 9 May San Diego, CA

## ◆ Water Storage, Delivery, and Qualification

- 8 - 9 February, Tampa, FL
- 10 - 11 May, San Diego, CA



# 2017 TRAINING

*A well-trained staff is critical to meeting global cGMP regulations. Training can mean the difference between successful operations and regulatory violations.*

## **Our Courses:**

- Have Measurable Learning Objectives
- Provide an In-Depth Understanding of “How” and “Why”
- Use Lectures, Group Exercises, Case Studies, and ISPE’s Guidance Documents
- Provide You With Tangible “Take-A-Ways” For Immediate Application on the Job
- Leverage the Expertise of ISPE’s Global Subject Matter Experts

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# 2017 ISPE Training Schedule

## JANUARY

### ISPE Training Institute, Tampa, FL

- Basic GAMP® 5, Annex II/Part II, 23 – 25 Jan.
- Quality Risk Management , 30 – 31 Jan.

## FEBRUARY

### ISPE Training Institute, Tampa, FL

- Process Validation, 1 – 3 Feb.
- GAMP® 5 Data Integrity, 6 – 7 Feb.
- Water Generation, 6 – 7 Feb.
- Water Storage, Delivery, and Qualification, 8 – 9 Feb.
- HVAC, 8 – 10 Feb.
- Clean In Place, 13 – 14 Feb.
- Science and Risk-based Commissioning and Qualification, 23 – 24 Feb.

## MARCH

### ISPE Training Institute, Tampa, FL

- Facility Project Management, 6 – 7 Mar.\*
- GAMP® 5 Process Control Systems, 9 – 10 Mar.
- Cross Contamination (Risk-MaPP), 13 – 14 Mar.
- Bio Manufacturing Process Validation, 27 – 28 Mar.
- Verification of Facilities, Systems, and Equipment Workshop, 27 – 28 Mar.
- Technology Transfer, 30 – 31 Mar.

### Manchester, UK

- Basic GAMP® 5, Annex II/Part II, Dates TBD

## APRIL

### ISPE Training Institute, Tampa, FL

- Bio Manufacturing Overview, 3 – 4 Apr.
- Oral Solid Dosage, 3 – 4 Apr. – **Updated!**
- Q7A, 5 – 6 Apr.
- Cleaning Validation, 6 – 7 Apr.
- Basic GAMP® 5, Annex II/Part II, 26 – 28 Apr.

Online Courses and Webinars are also Available!  
Visit [www.ISPE.org/Elearning](http://www.ISPE.org/Elearning)

*I Like the emphasis of efficiency, with drawbacks of overdoing clearly explained. The instructor had lots of relevant experience and was able to give useful real-world examples. – Attendee*

## San Diego, CA

- Bio Manufacturing Facilities, 8 – 9 May\*
- GAMP® 5 Data Integrity, 8 – 9 May
- Water Generation, 8 – 9 May
- HVAC, 9 – 11 May
- Sterile Facilities, 10 – 11 May
- Water Storage, Delivery, and Qualification, 10 – 11 May

## St Gallen, Switzerland

- Operational Excellence, 8 – 9 May – **New!**

## NIBRT, Dublin, Ireland

- Commissioning and Qualification, 16 – 17 May – **New!**

## Copenhagen, Denmark

- Bio Manufacturing Overview, Dates TBD
- Cleaning Validation, Dates TBD
- Facility Project Management\*, Dates TBD
- GAMP Data Integrity, Dates TBD
- HVAC, Dates TBD
- Oral Solid Dosage, Dates TBD – **Updated!**
- Process Validation, Dates TBD
- Technology Transfer, Dates TBD

## ISPE Training Institute, Tampa, FL

- Quality by Design, 1 – 2 June
- GAMP® 5 Process Control Systems, 8 – 9 June
- Verification of Facilities, Systems, and Equipment Workshop, 12 – 13 June

## Lilly MQ Learning Center, Indianapolis, IN

- Basic GAMP® 5, Annex II/Part II, 12 – 14 June



GAMP® is a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry and a registered ISPE trademark.



\*ISPE has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI®)