

# 2014 PDA Training & Research Institute Courses



Denotes Laboratory Courses



Dates	Course Name	Location	Type
2/3 - 2/7	<b>Aseptic Processing Training Program, Session 1 (Week 2, March 3-7, 2014)</b>   <a href="http://www.pda.org/2014aseptic1">www.pda.org/2014aseptic1</a>	Bethesda, Maryland	Lab
2/20 - 2/21	<b>An Introduction to Visual Inspection - Session 1</b>   <a href="http://www.pda.org/visual1">www.pda.org/visual1</a>	Bethesda, Maryland	Lab
3/11 - 3/12	<b>Recommended Practices for Manual Aseptic Processing - Session 1</b>   <a href="http://www.pda.org/map1">www.pda.org/map1</a>	Bethesda, Maryland	Lab
3/17 - 3/21	<b>Fundamentals of Aseptic Processing - Session 1</b>   <a href="http://www.pda.org/apfundamentals1">www.pda.org/apfundamentals1</a>	Bethesda, Maryland	Lab
3/31 - 4/4	<b>Aseptic Processing Training Program, Session 2 (Week 2, May 5-9, 2014)</b>   <a href="http://www.pda.org/2014aseptic2">www.pda.org/2014aseptic2</a>	Bethesda, Maryland	Lab
4/10 - 4/11	<b>2014 PDA Annual Meeting Course Series</b>   <a href="http://www.pdaannualmeeting.org/courses">www.pdaannualmeeting.org/courses</a> Biosimilars: Understanding the CMC Challenges of Meeting 'Similarity' - <i>New Course</i>	San Antonio, Texas	Lecture
4/10	Risk-Based, Product Development Basics for Combination Products: Harmonizing Design Controls and Quality-by-Design in Product Development and Market Authorization Documents - <i>New Course</i>	San Antonio, Texas	Lecture
4/11	Quality Control and Quality Assurance of Cell-Based Therapeutic Products	San Antonio, Texas	Lecture
4/11	Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Validation and Ongoing Control	San Antonio, Texas	Lecture
4/10-4/11	Implementation of Quality Risk Management for Commercial Pharmaceutical and Biotechnology Manufacturing Operations	San Antonio, Texas	Lecture
4/10-4/11	Process Validation and Verification: A Lifecycle Approach	San Antonio, Texas	Lecture
4/15 - 4/17	<b>Validation of Moist Heat Sterilization Processes</b>   <a href="http://www.pda.org/moistheat">www.pda.org/moistheat</a>	Bethesda, Maryland	Lab
4/21 - 4/25	<b>Biotechnology Week</b>   <a href="http://www.pda.org/biotechweek2014">www.pda.org/biotechweek2014</a> Biopharmaceutical Manufacturing under Regulatory Compliance: Process Strategies, CGMP Considerations and Facility Requirements	Bethesda, Maryland	Lecture
4/23	Biosimilars - Understanding the CMC Challenges of Meeting 'Similarity'	Bethesda, Maryland	Lecture
4/24-4/25	CMC Regulatory Compliance of Biopharmaceuticals	Bethesda, Maryland	Lecture
4/22 - 4/24	<b>Environmental Mycology Identification Workshop</b>   <a href="http://www.pda.org/mycology">www.pda.org/mycology</a>	Bethesda, Maryland	Lab
4/28 - 4/30	<b>Management of Aseptic Processing</b>   <a href="http://www.pda.org/apmanagement">www.pda.org/apmanagement</a>	Bethesda, Maryland	Lecture
5/21 - 5/22	<b>2014 PDA Knowledge Management Workshop - Enabler for ICH Q8 &amp; Q11, QRM and Continued Process Verification Course Series</b>   <a href="http://www.pda.org/KMcourses2014">www.pda.org/KMcourses2014</a> Integration of Risk Management into Quality Systems	Bethesda, Maryland	Lecture
5/21	Learning and Training as Contributors to Knowledge Management	Bethesda, Maryland	Lecture
5/21-5/22	Technology Transfer - <i>New Course</i>	Bethesda, Maryland	Lecture
5/22 - 5/23	<b>2014 PDA Packaging Course Series</b>   <a href="http://www.pda.org/packagingcourses2014">www.pda.org/packagingcourses2014</a> Implementing Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations: Case Studies in the Packaging and Labeling of Drug Products	Washington, D.C.	Lecture
5/22	Pharmaceutical Package Integrity Testing: Industry Challenges, Technology and Advancement - <i>New Course</i>	Washington, D.C.	Lecture
5/23			
6/2 - 6/6	<b>Aseptic Processing Training Program, Session 3 (Week 2, June 23-27, 2014)</b>   <a href="http://www.pda.org/2014aseptic3">www.pda.org/2014aseptic3</a>	Bethesda, Maryland	Lab
6/5 - 6/6	<b>PDA Pharmaceutical Supply Chain Course Series</b>   <a href="http://www.pda.org/supplychaincourses2014">www.pda.org/supplychaincourses2014</a> Developing a Robust Supplier Management Process	Bethesda, Maryland	Lecture
6/5	Good Distribution and Storage Practices (GDP/GSP) - Securing the Supply Chain - <i>New Course</i>	Bethesda, Maryland	Lecture
6/6			
6/12 - 6/13	<b>PDA Viral and TSE Safety Course Series</b>   <a href="http://www.pda.org/viruscourses2014">www.pda.org/viruscourses2014</a> Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness and Response	Bethesda, Maryland	Lecture
6/12	Introduction to Emerging Methods for Virus Detection	Bethesda, Maryland	Lecture
6/13			
6/19 - 6/20	<b>2014 PDA Aseptic Processing-Sterilization Course Series</b>   <a href="http://www.pda.org/sterilizationcourses2014">www.pda.org/sterilizationcourses2014</a> Recommended Practices for Manual Aseptic Processes	Chicago, Illinois	Lecture
6/19	Clean Room Design, Contamination Control and Environmental Monitoring for Controlled Environments	Chicago, Illinois	Lecture
6/19	Process Simulation Testing for Aseptically Filled Products	Chicago, Illinois	Lecture
6/20	Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Validation and Ongoing Control	Chicago, Illinois	Lecture
6/20			

Dates	Course Name	Location	Type
7/14 – 7/18	<b>DoE Week for Process Design and Process Optimization</b>   <a href="http://www.pda.org/DoEweek2014">www.pda.org/DoEweek2014</a>		
7/14 – 7/15	Pharmaceutical Statistics: DoE Basics for Validation by Design – <i>New Course</i>	Bethesda, Maryland	Lecture
7/16	Assay Validation by Design – <i>New Course</i>	Bethesda, Maryland	Lecture
7/17 – 7/18	Pharmaceutical Statistics: Process Optimization by Design – <i>New Course</i>	Bethesda, Maryland	Lecture
8/4 – 8/8	<b>Fundamentals of Aseptic Processing – Session 2</b>   <a href="http://www.pda.org/apfundamentals2">www.pda.org/apfundamentals2</a>	Bethesda, Maryland	Lab
8/12 – 8/14	<b>Dry Heat Processes Used for Sterilization and Depyrogenation</b>   <a href="http://www.pda.org/dryheat">www.pda.org/dryheat</a>	Bethesda, Maryland	Lab
8/18 – 8/22	<b>Aseptic Processing Training Program, Session 4 (Week 2, September 22-26, 2014)</b>   <a href="http://www.pda.org/2014aseptic4">www.pda.org/2014aseptic4</a>	Bethesda, Maryland	Lab
8/27 – 8/28	<b>An Introduction to Visual Inspection – Session 2</b>   <a href="http://www.pda.org/visual2">www.pda.org/visual2</a>	Bethesda, Maryland	Lab
9/11 – 9/12	<b>2014 PDA Joint Regulatory Conference Course Series</b>   <a href="http://www.pda.org/pdacourses2014">www.pda.org/pdacourses2014</a>		
9/11	GMPs for Manufacturers of Sterile and/or Biotechnology Products	Washington, D.C.	Lecture
9/11 – 9/12	Role of the Quality Professional in the 21st Century	Washington, D.C.	Lecture
9/11 – 9/12	Application of a Quality Systems Approach to Pharmaceutical CGMPs	Washington, D.C.	Lecture
9/11 – 9/12	Preparing for Regulatory Inspections for FDA and EMA	Washington, D.C.	Lecture
9/12	Managing the QC and R+D Laboratory in a GMP Compliant Manner – <i>New Course</i>	Washington, D.C.	Lecture
9/12	Quality by Design for Biologics: A Practical Approach – <i>New Course</i>	Washington, D.C.	Lecture
9/16 – 9/17	<b>Fundamentals of an Environmental Monitoring Program</b>   <a href="http://www.pda.org/EMfundamentals">www.pda.org/EMfundamentals</a>	Bethesda, Maryland	Lab
10/1 – 10/2	<b>Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities</b>   <a href="http://www.pda.org/disinfection">www.pda.org/disinfection</a>	Bethesda, Maryland	Lab
10/9 – 10/10	<b>2014 Universe of Prefilled Syringes and Injection Devices Course Series</b>   <a href="http://www.pda.org/PFScourses2014">www.pda.org/PFScourses2014</a>		
10/9	Prefilled Syringe User Requirements – <i>New Course</i>	Huntington Beach, California	Lecture
10/9	Syringes and Elastomers: Understanding the Effects on Quality and Demonstrating the Production Process, Influences and Needs	Huntington Beach, California	Lecture
10/10	Technical and Regulatory Challenges of Combination Drug Delivery Products – Prefilled Syringes, Autoinjectors and Injection Pens – <i>New Course</i>	Huntington Beach, California	Lecture
10/10	Risk Management for Temperature Controlled Distribution	Huntington Beach, California	
10/13 – 10/17	<b>Aseptic Processing Training Program, Session 5 (Week 2, November 3-7, 2014)</b>   <a href="http://www.pda.org/2014aseptic5">www.pda.org/2014aseptic5</a>	Bethesda, Maryland	Lab
10/22 – 10/23	<b>Single Use Systems for the Manufacturing of Parenteral Products</b>   <a href="http://www.pda.org/SUS">www.pda.org/SUS</a>	Bethesda, Maryland	Lab
10/23 – 10/24	<b>PDA 9th Annual Global Conference on Pharmaceutical Microbiology Course Series</b>   <a href="http://www.pda.org/microcourses2014">www.pda.org/microcourses2014</a>		
10/23	A Risk-Based Approach to Global Environmental Compliance – <i>New Course</i>	Bethesda, Maryland	Lecture
10/23	Regulatory Aspects of Microbiology in a Non-Sterile Environment – <i>New Course</i>	Bethesda, Maryland	Lecture
10/24	Exclusion of Objectionable Microorganisms from Pharmaceutical and OTC Drug Products – <i>New Course</i>	Bethesda, Maryland	Lecture
10/24	Microbiological Risk Assessment of a Pharmaceutical Manufacturing Process – <i>New Course</i>	Bethesda, Maryland	Lecture
10/28 – 10/30	<b>Validation of Biotechnology-related Cleaning Processes</b>   <a href="http://www.pda.org/biotechcleaning">www.pda.org/biotechcleaning</a>	Bethesda, Maryland	Lab
11/10 – 11/11	<b>Quality Metrics: Performance Indicators</b>   <a href="http://www.pda.org/qualitymetrics">www.pda.org/qualitymetrics</a>	Bethesda, Maryland	Lecture
11/12 – 11/13	<b>Recommended Practices for Manual Aseptic Processing – Session 2</b>   <a href="http://www.pda.org/map2">www.pda.org/map2</a>	Bethesda, Maryland	Lab
11/17 – 11/21	<b>Quality Systems for Aseptic Processing</b>   <a href="http://www.pda.org/quality">www.pda.org/quality</a>	Bethesda, Maryland	Lab
12/1 – 12/4	<b>Lyophilization Week</b>   <a href="http://www.pda.org/lyoweeek2014">www.pda.org/lyoweeek2014</a>		
12/1 – 12/2	Fundamentals of Lyophilization	Bethesda, Maryland	Lecture
12/3 – 12/4	Validation of Lyophilization	Bethesda, Maryland	Lecture
12/8 – 12/10	<b>Risk-Based Qualification of Sterile Drug Product Manufacturing Systems</b>   <a href="http://www.pda.org/risk">www.pda.org/risk</a>	Bethesda, Maryland	Lab

### Registration Information:

You can register for PDA TRI courses one of three ways: online, fax or mail. To register online, please visit [www.pda.org/courses](http://www.pda.org/courses), find your course of choice and click the Register Now button. You may also submit a registration form along with payment information by fax or postal mail. Please visit [www.pda.org/triregistration](http://www.pda.org/triregistration) for more information. If you have any questions, please contact the registrar at 301-656-5900 ext. 115.