



Fall 2009 Course Schedule

The BioNetwork Pharmaceutical Center, part of the North Carolina Community College System, is a statewide resource promoting workforce development in North Carolina. The Center announces its new training facilities in the Richard Dean Biomedical Research Building in the Piedmont Triad Research Park in Winston-Salem. Housing classroom and meeting space, plus the Analytical Training Lab, the Center is poised to meet the training needs of North Carolina's life science companies and academic institutions. Our fall line up of courses was selected in response to industry demand and include topics in GMP, validation, analytical skills, and other skill-building courses for which training leaders have indicated a continuous need. To register, complete and fax the included registration form, or call 336.748.4670.

Analytical Training Lab



This state-of-the-art resource houses analytical testing equipment available to students seeking hands-on training and experience with the latest tools in analytical chemistry. This one-of-a-kind training facility offers both lecture and lab components and provides a skill set in analytical evaluation techniques that is unmatched in the state. Future courses include GC, HPLC, UPLC, LC/MS, Empower and MassLynx software.

Fundamentals of Gas Chromatography teaches new users the fundamentals of chromatography with an emphasis on capillary columns and gas-liquid chromatography. Students are introduced to the components of a typical chromatograph and will set up an instrument and run samples. Evaluations of separation parameters and column performance are discussed. Guidelines are provided to improve and develop analytical methods and for maintaining and troubleshooting GC systems. Software packages are not specifically covered. The course is divided into three sessions. Instructor: Leonard Ponder (Shimadzu) \$165 per session, or \$425 if registering for all three

Part I: Theory and Column Selection	8:30am - 4:30pm	Oct 20
Part II: Operation and Method Implementation	8:30am - 4:30pm	Nov 3
Part III: GC Solutions, Report Development & Data Assessment	8:30am - 4:30pm	Nov 12

The Validation Academy



Validation Academy courses, developed in association with ISPE and other reputable sources, provide training in the theory and skills of validation for employees in life science industries. Validation Academy Instructors are recognized subject matter experts in their fields with significant industry related experience and training expertise.

Validation Documentation addresses the different types of validation documentation, the purpose of each document type, and how the documents are utilized by the FDA for ensuring compliance to GMPs. The course will provide samples of document types and case study examples of how documents are developed and completed. Students will learn how to identify documents to be included in Validation Master Plans and execute a formal documentation review. Instructor: Cathy Middleton.

8am - 5pm, Sept 9. \$195

Basic Concepts of Validation details the use of a master validation plan, Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) protocols, and the relationship of validation to GMP. Participants will learn the fundamental requirements to prepare a validation protocol, analyze data, and prepare a final report. FDA inspection expectations for qualification and validation of facilities, equipment, and processes will also be discussed. Instructor: Mark Yates.

8am - 5pm, Sept 17. \$195

Integrated Commissioning and Qualification addresses the commissioning and qualification process including impact assessment, Good Engineering Practices (GEPs), commissioning vs. qualification, and methods of integrating commissioning and validation activities. Typical components of qualification protocols will be briefly covered: IQ, OQ, PQ, and Commissioning, Enhanced Design Review (EDR), failure mode analysis. Instructor: Michael Parks.
Two days: 8am - 5pm, Sept 30 - Oct 1. \$395

Introduction to Computer Validation provides participants with fundamental principles of Computer Validation. The course will address the cGMP requirements related to computer validation, phases/life cycle of computer validation and computer systems, along with documentation requirements. Instructor: Pat Griffin.
8am - 5pm, Nov 6. \$195

GMP Basics & Related Practices



GMP regulations require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take a quality approach to ensure that their products are safe, pure, and effective. These course modules stress the importance and benefits of a disciplined approach to GMP in an FDA regulated environment.

GMP Basics I: Two modules from the GMP Basics series in one day-long course.

GMP Orientation/Refresher is an introduction to Good Manufacturing Practice (GMP) designed for new employees of any GMP-regulated industry, especially pharmaceutical and medical device manufacturing, and can serve as an annual refresher course for incumbent workers. It is also the appropriate initial course for individuals not currently employed in a GMP setting but who are interested in working in these industries.

and

Deliberate Documentation is an overview of the documentation requirements of Good Manufacturing Practice (GMP) and stresses the importance and benefits of a disciplined approach to documentation in an FDA (Food and Drug Administration) regulated environment. Prior enrollment in GMP Orientation/Refresher or experience in an FDA regulated industry is recommended.

8:30am - 4:30pm Sept 24; repeats Oct 15. \$75

GMP Basics II: Two modules from the GMP Basics series in one day-long course.

Conducting Investigations introduces tools utilized in incident investigations and instructs how to properly conduct these investigations in a Good Manufacturing Practice (GMP) environment. Primarily intended for incumbent pharmaceutical manufacturing personnel, this course module is applicable to employees of any FDA (Food and Drug Administration) regulated industry.

and

QC Lab Operations outlines key principles that insure the validity of quality control systems in the laboratory and how a disciplined approach to meeting the requirements of GMP are beneficial. Experience in a GMP regulated industry and a familiarity with the QC Lab environment is recommended.

8:30am - 4:30pm Sept 25; repeats Oct 16. \$75

Offered by demand, these Special Interest courses are applicable across disciplines and departments, and provide general skills in areas of need as indicated by industry leaders.

System Based Inspections: Surviving an FDA Audit details how to integrate project management and risk management, and how to prepare for and manage an inspection as it occurs. Students will also understand the link between CAPA and good documentation/ validation practices and quality control, and understand FDA's focus on these systems. Organizational benefits include learning how to interact effectively with the FDA both in-person and post-inspection, learning how to reduce site risk potential and establish a history of compliance, and understanding that time and money will be saved by focusing attention on site's own critical risk areas.

Two Days: 8:30am - 4:30pm, Oct 5 - 6. \$195

Train-The-Trainer gives a foundation in training skills to those individuals who are new to the training situation, though any person wishing a thorough foundation in technical training skills would benefit from the course. The session is an interactive lecture discussion which includes individual and small group activities as well as a short individual presentation. The workshop will carry a heavy focus on those trainer skills typically associated with On-the-Job training.

8:30am - 4:30pm, Oct 30. \$75

Technical Writing is the process of creating, designing, and transmitting technical information so that people can understand it easily and use it effectively and efficiently. This course will teach students the established basics for effective written composition in industry and introduce them to such types of communication as processes, description of mechanisms, and reports.

8:30am - 4:30pm, Oct 28. \$95

To Register:

Complete the registration form and fax to 336.748.4661 to pay by credit/debit card, or send form and check by mail. You will be sent a confirmation packet by email, including directions and parking information. If no email address is given, information will be mailed to the address provided.

For questions or additional information, please email BioNetworkCourses@ncbionetwork.org, or call 336.748.4670.



To be added to our mailing list for upcoming classes, send contact information to BioNetworkCourses@ncbionetwork.org.

BioNetwork Pharmaceutical Center

Print and complete course registration form:

Fall 2009 Course Registration

Fax 336.748.4661
Mail BioNetwork Pharmaceutical Center
 391 Technology Way, Ste 162
 Winston-Salem NC 27101
Call 336.748.4670 to register by phone

For questions or additional information:

Call 336.748.4670
Email BioNetworkCourses@ncbionetwork.org

Name _____ **Phone** _____
Address _____ **Company** _____

eMail _____ **Title/Area** _____
(registration confirmation will be sent by email unless otherwise specified)

Date	Course Title	Fee	<input checked="" type="checkbox"/>
9/9	Validation Documentation	\$195	<input type="checkbox"/>
9/17	Basic Concepts of Validation	\$195	<input type="checkbox"/>
9/24	GMP Basics I: Orientation/Refresher; Deliberate Documentation	\$75	<input type="checkbox"/>
9/25	GMP Bascs II: Conducting Investigations; QC Lab Operations	\$75	<input type="checkbox"/>
9/30 - 10/1	Integrated Commissioning and Qualification	\$395	<input type="checkbox"/>
10/5 - 10/6	System Based Inspections: Surviving an FDA Audit	\$225	<input type="checkbox"/>
10/15	GMP Basics I: Orientation/Refresher; Deliberate Documentation	\$75	<input type="checkbox"/>
10/16	GMP Bascs II: Conducting Investigations; QC Lab Operations	\$75	<input type="checkbox"/>
10/20	Fundamentals of Gas Chromatography I	\$165	<input type="checkbox"/>
10/28	Technical Writing	\$95	<input type="checkbox"/>
10/30	Train-the-Trainer	\$75	<input type="checkbox"/>
11/3	Fundamentals of Gas Chromatography II	\$165	<input type="checkbox"/>
11/6	Introduction to Computer Validation	\$195	<input type="checkbox"/>
11/12	Fundamentals of Gas Chromatography III	\$165	<input type="checkbox"/>
10/20, 11/3 11/12	Fundamentals of Gas Chromatography I, II, and III <small>(Reflects tuition discount for all three courses)</small>	\$425	<input type="checkbox"/>

Payment Information

Visa or Mastercard # _____ **Exp Date** _____
Name on Card _____ **Amount** \$ _____

Make Checks Payable to: Forsyth Technical Community College