

REGULATORY AFFAIRS *Certificate*

OVERVIEW

Compliance to federal regulations such as those established by the Food and Drug Administration (FDA) determine the basic working operations within regulated industries. North Hennepin Community College (NHCC) has recognized the need for all employers to have a basic understanding of these regulations and has initiated and developed a non-degree Regulatory Affairs program designed to make individuals aware of federal regulatory requirements and the impact of these requirements on their work environment and their work activities. NHCC's program ties together the many aspects of the regulatory process in order to provide an individual with a context for their daily activities. This approach benefits the company because employees better understand how their role helps the organization remain compliant with federal regulations. The course does not train individuals in any specific form or procedure. Rather, it trains employees in the generally accepted guidelines in order for them to have a well-rounded educational background necessary to work more productively and accurately in regulated industries.

OBJECTIVES

- To provide familiarity with the language and utilization of the Code of Federal Regulations through highlighted review and case studies from industry.
- To understand the impact of regulation during the life cycle of products from design to post market.
- To provide an understanding of the implications of non-compliance.

WHO SHOULD ATTEND

The program is intended for new and current employees at any level within an FDA regulated industry who want to play a larger role in regulatory affairs matters within their organizations.

KEY TOPICS

- Regulatory Affairs: An Introduction.
- History of the FDA and the creation of the Code of Federal Regulations for Medical Devices and Pharmaceuticals.
- Good Laboratory Practices.
- Good Manufacturing Practices.
- Good Clinical Practices.

PRESENTERS

- Harvey M. Arbit, PharmD, MBA. President, Arbit Consulting, LLC
- Megan Brandt, Design Assurance Engineer, Cardiovascular Systems, Inc
- Victoria Carmack, Consultant: Medical Device; Compliance & Audit; and Preclinical and Clinical
- Cari Dufner, QA Manager, Cargill Kitchen Solutions
- Samantha Haldeman, Senior Quality Assurance Specialist, Lifecore Biomedical
- Larry Hodgins, Consultant, IntegriPharm Consultants



North Hennepin
Community College

Adult Education & Training

7411 Eighty-Fifth Avenue North
Brooklyn Park, MN 55445-2299
www.nhcc.edu/cect

Email: cect@nhcc.edu
Phone: 763-424-0880
Fax: 763-424-0889

Member of the Minnesota State Colleges and Universities System. Equal Opportunity Educator and Employer.
To receive this information in an alternative format, call 763-493-0555 (V) or 763-493-0558 (TTY).



Presenters Continued...

- Roy Martin, DVM, Partner, The Integra Group
- Sharon Matson, FDA Field Investigator and Minneapolis District Office BioResearch Monitoring (BIMO) Specialist, U.S. Food and Drug Administration
- Kathy Mischke, Clinical Trial Monitor, University of Minnesota, Office of Clinical Research
- Timothy Philips, Compliance Officer/ BioMedical Engineer, U.S. Food and Drug Administration, Minneapolis District
- Lars Pekay, General Mills, Inc.
- Jack Risdahl, DVM, PhD, Partner, The Integra Group
- Alison Tetzloff, Food Safety Coordinator, Cargill Kitchen Solutions
- Catherine Vitols, Principal Regulatory Affairs Specialist, Medtronic Inc., Neuromodulation
- Patrice Webster, Assistant Director University Wide Research, Research Subject Protection Program, University of Minnesota

BENEFITS OF ATTENDANCE

- Course taught by leading professionals from pharmaceutical, medical device, biologics and food industries to include representatives from Medtronic, University of Minnesota, Boston Scientific, Integra Group, Cargill, General Mills, Lifecore, FDA and independent industry consultants.
- Use of relevant, real-life examples.
- Practical, immediately applicable information.
- Thirty-two hours of in-depth instruction delivered in eight four-hour evening sessions.

TUITION: \$1,495

QUANTITY DISCOUNT

Employers receive a fifteen percent (15%) discount when three (3) or more company employees register as a group.

COMMENTS FROM PAST PROGRAM PARTICIPANTS

"I really enjoyed the examples the instructor gave. I have a whole new appreciation of regulations."

"Excellent, very well thought program. Instructors were very experienced in their respective fields. I would really recommend the class to anybody."

ADDITIONAL INFORMATION

If you or your company would like more information on course specifics, as well as to discuss how this program might meet either your individual or company needs, please call 763-424-0880 or by email at cect@nhcc.com.

For additional program information and registration go to www.nhcc.edu/regaffairs.

** Prices, course, and certificate information are subject to change. Please refer to our website at www.nhcc.edu/cect for current information.*



North Hennepin
Community College

Adult Education & Training

7411 Eighty-Fifth Avenue North
Brooklyn Park, MN 55445-2299
www.nhcc.edu/cect

Email: cect@nhcc.edu
Phone: 763-424-0880
Fax: 763-424-0889

Member of the Minnesota State Colleges and Universities System. Equal Opportunity Educator and Employer.
To receive this information in an alternative format, call 763-493-0555 (V) or 763-493-0558 (TTY).

