

Senior Director of Biotechnology at Catalent To Present Course on Bioassays



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Industry: [Pharmaceuticals](#)

Ana T. Menendez, Ph.D., Senior Director of Biotechnology at Catalent Pharma Solutions, will be leading a course in [Bioassay](#) Method Development and Validation. The course is being offered through IBC Life Science on November 12-13, 2009 in Boston, MA.

Menendez will present a lecture outlining sensible approaches to developing reproducible bioassays using live systems and/or biologically derived reagents. Additionally, Menendez will conduct a workshop on writing validation protocols, and will give participants hands-on experience and case studies, which will add relevance to lecture material as well as create a point of discussion. Targeted audiences are bio-analytical scientists, validation specialists, project management leaders and bioassay scientists involved in bioassay execution. Upon completion of the course, participants will receive a certificate of attendance.

Bioassays are necessary components of the biopharmaceutical development process as functional potency assays during release, stability and formulation studies. The course expands on the importance of the appropriate use of non-analytical techniques that are critical during PK/PD evaluation and measurement of systematic responses to drugs, such as immunogenicity. Also included are immunological and enzymatic methods that are widely used in the detection of biological impurities due to their increased sensitivity and specificity over analytical methods.

As part of Catalent's Development and Clinical Services segment, Dr. Menendez is responsible for the release tests required to verify the functionality and purity of biotechnology products and the complex processes involved in their manufacture. Menendez implemented biotesting at Catalent and currently leads the following laboratories at the North Carolina Research Triangle Park facility: Cellular Technologies, Molecular Technologies, Virology and Analytical Biosafety. The expertise of the department ranges from proteins (i.e., monoclonal antibodies, enzymes, growth factors) to therapeutic viruses, bacterial vaccines and aptamers. Menendez is an international instructor on bioassay development and validation and a frequent speaker at biopharmaceutical conferences.

For more information on Catalent's broad range of drug and biologic development services, go to www.catalent.com/development.

About

Catalent

Headquartered in Somerset, New Jersey, Catalent Pharma Solutions is a leading provider of advanced dose form and packaging technologies, and development, manufacturing and packaging services for [pharmaceutical](#), [biotechnology](#) and consumer healthcare companies in nearly 100 countries. Catalent applies its local market expertise and technical creativity to advance treatments, change markets and enhance patient outcomes. Catalent employs approximately 9,500 at 30 facilities worldwide and in fiscal 2009 generated more than \$1.6 billion of annual revenue. For more information, visit www.catalent.com.

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