

Senior Director of Biotechnology at Catalent To Lead Workshop on Immunogenicity for Biologics 2009



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Ana T. Menendez, Ph.D., Senior Director of Biotechnology at Catalent Pharma Solutions, will be teaching a pre-conference workshop titled "Detection and Characterization of Immunogenicity of Therapeutic Biologics" on Monday, September 7, 2009 in Prague, Czech Republic. The course will focus on the practical technologies used to measure antibody responses to biologic drugs. The pre-conference begins at 10:00 a.m. The Immunogenicity for Biologics 2009 conference will be held on September 8-9, and will include additional discussion on outstanding technical issues, such as standardization and validation of assays as well as the interpretation and application of regulatory guidelines.

As part of Catalent's Respiratory, Analytical and Biotechnology group, 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.

The Immunogenicity for Biologics 2009 conference will cover case studies on assay challenges, FDA and European submissions IgG4 and IgE, pre-clinical and clinical strategies and aggregation. Participants will benefit from practical advice on the design and validation of neutralizing assays.

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 more than 30 facilities worldwide and in fiscal 2008 generated more than \$1.8 billion in annual revenue. For more information, visit <http://www.catalent.com>.

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