

Catalent Scientist's Article Featured by Biotechnology Industry Organization



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Author: Dan Dunlop / Jennings
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Research Triangle Park, N.C., April 2, 2009 – An article written by Ana T. Menendez, Ph.D., Senior Director of Biotechnology at Catalent Pharma Solutions, was featured in the Biotechnology Industry Organization's (BIO) March 2009 e-Newsletter. The article, titled "A Guide to Accelerating Bioassay Transfer in the GMP Environment," highlights important questions and steps to set timelines and prepare for a successful bioassay transfer. Dr. Menendez's work, along with a number of articles written by industry leaders, is being offered for free download on BIO's website - www.bio.org.

According to Dr. Menendez, "Setting realistic timetables, creating thorough documentation to transfer bioassays between organizations, and working with a highly qualified CRO are the keys to streamlining the production of biologics and accelerating their time to market." Her article goes on to provide guidelines to help increase clarity in setting timelines, along with illustrative case studies where delays could have been avoided.

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. Dr. 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. Dr. Menendez is an international instructor on Bioassay Development and Validation and a frequent speaker at biopharmaceutical conferences.

About

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 9,100 at more than 30 facilities worldwide and in fiscal 2008 generated more than \$1.8 billion of annual revenue. For more information, visit www.catalent.com.

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Contact Details: Dan Dunlop, President
Jennings PR
104-A North Elliott Road
Chapel Hill, NC 27514
Ph: 919-929-0225
Fx: 919-968-8278
email: ddunlop@jenningsco.com