

Catalent to Present at TIDES® 2009 Conference



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Industry: [Pharmaceuticals](#)

San Diego, CA – May 14, 2009 – Dr. Hans Westenburg, a senior scientist of structural characterization and analysis at Catalent Pharma Solutions, will present this month at the TIDES 2009 Conference to be held in Las Vegas, NV, May 17-20, 2009. The conference agenda was put together by leaders in oligonucleotide and peptide development and manufacturing, and features a program full of novel, in-depth scientific presentations related to oligonucleotide and peptide drug development and manufacturing. The TIDES conference is produced by IBC Life Sciences.

Dr. Westenburg's poster presentation is titled "Teriparatide Degradation Products Identified by Accurate Measured Mass LCMS." Presentation abstract: The human parathyroid hormone (PTH) contains 84 amino acids. The biologically active region is 34 N-terminal amino acids (teriparatide) from the recombinant human PTH. Teriparatide is the first FDA approved agent for the treatment of osteoporosis that stimulates new bone formation. The safety of the drug product is dependent not only on the toxicological properties of the active drug substance, but also on the impurities that it contains. Therefore, identification of impurities in the drug product is an important part of drug development and regulatory assessment. Accurate measured mass liquid chromatography/mass spectrometry (LCMS) is a rapid technique to identify impurities at levels as low as 0.02% in the drug product. LCMS enabled the identification of fifteen low level impurities in teriparatide.

Based in Catalent's Trade Place facility in San Diego, CA, part of the organization's Respiratory, Analytical and Biotechnology group, Dr. Westenburg works to structurally identify impurities for virtual, generic, small-, and mid-size pharmaceutical companies. In his current capacity, he has been able to identify impurities belonging to a large number of structural classes. The identification of these impurities supports the client to enable greater reporting thresholds or, in some instances, identify an impurity causing discoloration of a drug substance or product. During the past two years, Dr. Westenburg has routinely monitored low level genotoxic impurities by QTOF LCMS in a drug product. Overall, the majority of his work is impurity identification for companies concerning impurities in drug substances [Q3A(R2)] and impurities in drug products [Q3B(R2)], in compliance with the International Conference on Harmonization (ICH) guidelines.

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.

Catalent

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