

## VENDOR SEMINARS

Symposium registrants who wish to participate in the free seminars must pre-register on-site at the booth of the seminar sponsor located in the Exhibit area or the Symposium Registration Desk. A complimentary small lunch will be included for all seminars.

**Monday, October 26: 12:00 pm – 1:00 pm**

### **Bruker Daltonics:**

**Location: Palm Breeze Salon I**

### **Use of Mass Spectrometry to Efficiently and Accurately Monitor the Properties of Biotherapeutics**

*Shannon Cornett, Product Specialist, Bruker Daltonics*

With the ever increasing numbers of protein and peptide therapeutics moving through the Drug Development process at many companies, the need for fast, robust, effective, and powerful methods for detailed analysis of biotherapeutics has become acute. Current methods for protein analysis are often very slow, labor intensive, (PAGE Gels, ELISAs, Western Blots, etc.) and provide limited information.

Monitoring and efficiently analyzing therapeutic proteins/peptides typically involves confirmation of the correct protein sequence and necessary structural elements of the biotherapeutic. Key to the release of a biotherapeutic is analyzing the molecule in question to determine that any of a number of improper protein processing events (mutations, truncations, misglycosylation, etc.) have not occurred during production of the biotherapeutic.

In addition, methods are needed to follow the metabolism of a biotherapeutic by proteolytic cleavage and to monitor changes in protein size and composition as well as protein modifications once the drug has been delivered. Many of these requirements can be met by the application of a high resolution qTOF and/or MALDI-TOF/TOF Mass Spectrometry.

In this presentation, the capabilities of MALDI-TOF/TOF Mass Spectrometry for the “Top Down” analysis of intact proteins will be detailed. This type of analysis allows researchers to simultaneously sequence and monitor the N- and C-Termini of proteins for any changes. Dozens of amino acids can be sequenced and monitored from either termini. Furthermore, this type of approach can be used to monitor PEGylated peptides or proteins for their stability to degradation and to ascertain if any point mutations, truncations, or improper glycosylation events have occurred.

Several examples of the utilization of the top down analysis capabilities of a high performance MALDI-TOF/TOF MS to directly analyze recombinant proteins and antibodies for modifications, truncations, etc. or other processing events will be presented. The use of a high resolution qTOF will also be examined and its ability to ascertain intact protein structure and post translational modifications will be assessed.

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**Monday, October 26 12:00 – 1:00 pm**

## **Waters Corporation**

**Location: Ocean Breeze**

***Developing UPLC Separations of Proteins, Peptides, and Polynucleotides, Glycans, Amino Acids and Biomarkers.***

*Thomas Wheat, Waters Corporation*

The application of the principles of UltraPerformance Liquid Chromatography® (UPLC®) to separations of biologically significant molecules is rapidly developing. UPLC is a kind of separation science based on columns packed with very small particles used on instruments designed to fully utilize these packing materials. This chromatographic approach improves resolution, sensitivity and speed. In applying the UPLC technology in biochemistry, there are different kinds of improvements, and we have found it necessary to develop new column chemistries for some applications. When used for amino acid analysis, the high resolution of the UPLC application solution leads to a robust analytical method with unequivocal identification and reliable quantitation. UPLC peptide maps can be optimized for either increased resolution to ensure detection of all peptides present in the sample or for reduced runtime with the same resolution as a well-developed HPLC method. The column chemistry developed for peptide separations minimizes secondary interactions so that there are more options for developing improved separations, including good resolution of glycopeptides. Protein separations give the best resolution on specially designed UPLC columns with large pores and short chain bonded phases. The high resolution of these columns reveals some novel details about the mechanisms underlying reversed phase protein separations. For polynucleotides, robust separations of single base differences over a wide size range are routinely obtained. The general approach is suitable for DNA, modified DNA, and RNA. When applied to biomarker discovery, the improved resolution of UPLC technology increases the number of detectable compounds because low abundance analytes are not obscured by concentrated species. UPLC technology has now been extended to the analysis of protein oligosaccharides. A UPLC amide column is used in HILIC mode for the profiling neutral, complex, and charged oligosaccharides. The growing number of applications confirms the general utility of UPLC for biochemical and biopharmaceutical analyses.

## VENDOR SEMINARS

**Tuesday, October 27 12:00 – 1:00 pm**

### **Advanced Materials Technology**

**Location: Coral Ballroom – Salon 2**

#### **Fused-Core® Particle HPLC Technology for Biomolecule Separations**

Separations of biological molecules by HPLC can benefit from faster separations, as well as higher resolution. During the past several years Advanced Materials Technology has pursued these goals by developing Fused-core® silica particles for its Halo® series of HPLC columns. These silica particles are composed of solid interior cores, with porous shells of appropriate pore diameter for a variety of applications for separating proteins, peptides and polynucleotides. In contrast to sub-two micron (STM) packing materials, highly efficient and high-speed separations can be obtained using these 2.7-micron core-shell packings, while operating within well-established instrumental pressure limits. In typical applications, columns of these new particles demonstrate remarkable efficiency and high peak capacities, as well as broad compatibility with desired operational conditions, such as temperature, mobile phase composition, and back pressures. This seminar is focused on the practical applications of such materials for reversed phase biomolecule separations, describing the conditions for maximizing resolution, sample throughput, and integration with proteomic workflows.

**Tuesday, October 27: 12:00 pm – 1:00 pm**

### **Tosoh Bioscience**

**Location: Coral Reef Salon 1**

#### **Novel Ion-Exchange Products for the Biopharmaceutical Industry**

J. Kevin O'Donnell, Ph.D. Technical Service Manager, Tosoh Bioscience LLC

For over 20 years, Tosoh Bioscience has provided liquid chromatography products to the biopharmaceutical industry. In order to maintain our leadership role in providing these solutions, it is important to develop new products to meet the needs of an evolving and demanding industry. Tosoh Bioscience recently introduced the TSK-GEL STAT analytical product line for ion exchange analysis. These new prepacked columns feature a non porous resin designed for rapid analysis, excellent selectivity, and increased capacity compared to traditional non porous resins currently on the market. One particular application that these columns are ideally suited is the real time analysis of the pegylation reaction of various proteins. For larger scale applications, Tosoh Bioscience introduced the Toyopearl GigaCap series of high capacity (> 100 g/L-resin) ion exchange resins. These resins exhibit capacities greater than existing products on the market while showing unique selectivity and excellent binding and elution kinetics important for manufacturing scenarios.