# Technology  Workshops

## Monday, April 2, 2012

BIA separations
**1:30 pm**
**Riverview Room**

ALFA WASSERMANN
Separation Technologies
**2:00 pm**
**Riverview Room**

Refine TECHNOLOGY
**2:30 pm**
**Riverview Room**

Thermo SCIENTIFIC
**2:30 pm**
**University South Room**

**Marko Banjac** • Manager of Downstream Process Development, BIA Separations

### *Next Generation: CIMmultus for Virus and mAb purification*

**ABSTRACT:** Next generation of CIMmultus monolithic columns called CIMmultus™ will be presented. CIMmultus are advanced composite columns for purification of biologics that are offering stainless steel performance for a price of disposable devices. Moreover, these disposable multiuse CIM monolithic columns are able to improve process economics of antibodies and other biomolecules polishing steps. A few examples of mAb and virus purification process improvement will be shown.

**BIOGRAPHY:** Marko Banjac is Manager of Downstream Process Development for BIA Separations, GesmbH. Mr. Banjac has more than nine years of hands-on experience in Downstream Process Development for industrial production of pDNA, various viruses and vaccines. He is a co-inventor of a patented process for purification of live attenuated, Vero cell grown, Influenza virus vaccines. Marko has extensive experience in technology transfers to GMP production facilities.


## Monday, April 2, 2012

2:00 pm, Riverview Room

**Tony Brazzale** • Manager for EMPAT, North America**,** Alfa Wassermann Separation Technologies

### *EMPAT™ QC Sampling System for Automatic Aseptic Collection of Multiple QC Samples During cGMP Production*

**ABSTRACT**: The latest FDA Guidance for Industry on Process Validation (Jan 2011) focuses on building quality into a process across the entire lifecycle of the process. As part of this process validation, there is a great emphasis placed on sampling and sampling requirements at various stages. Systematic error and potential false positives for contamination related to manual sampling by technicians are not uncommon throughout the industry, at a significant cost.

Automated sampling, combined with an electronic paperless audit trail are incorporated to build quality into a sampling protocol in process validation and throughout the life cycle of a product. This new product launched by Alfa Wassermann, called EMPAT, is designed to fill an unmet need in the industry: computer controlled automated aseptic sampling for greater quality in sampling and potential reduction of CAPA system entries.

**BIOGRAPHY:** Tony Brazzale is the North American Manager for EMPAT at Alfa Wassermann. His over 15 years in the industry includes scientific, operational, sales, marketing, and business development experience working for companies such as Abbott Laboratories, Wyeth, Biotage, Argonaut Technologies, BIA Separations, and Alfa Wassermann. A sought after speaker and chairperson he has spoken nationally and internationally within the industry. An ISBioTech member, he is also Chair-elect of the American Chemical Society's Division of Business Development and Management, and will be Chairing a portion of the upcoming World Vaccine Manufacturing Congress.


## Monday, April 2, 2012

2:30 pm, Riverview Room

**Earl Pineda** • Product Manager, Refine Technology

### *The ATF™ System*

**ABSTRACT**: Challenges in the industry (such as generics, competitive products for the same indication or desired cost reductions) are forcing many to explore new production options away from the traditional fed-batch. Increasingly popular is the application of the ATF™ System to generate ultra high viable cell concentrations (>100m cells/ml) for a "concentrated" or "intensified" process.

The use of the ATF System in a typical viral vaccine process will be shown along with an explanation of a major intensification of the whole upstream process in a "Factory of the Future."

The development of single use ATF Systems will be highlighted and future plans for expansion of this range.

**BIOGRAPHY:** Earl Pineda is Product Manager at Refine Technology. He holds a Bachelors of Science in Biochemistry and a Masters of Arts in Product design. Earl has worked for biotechnology companies including Biomarin, Amgen and Novartis, where he focused on process development/technical transfer, as well as process characterization/validation. At Biomarin, Earl has helped develop inclined settler perfusion systems for both microcarrier-based and suspension cell cultures. He has expertise with different mammalian cell culture processes including batch, fedbatch, perfusion using various perfusion devices, concentrated fedbatch using the ATF system, and he has performed numerous E. coli and yeast fermentations. Earl has also worked as a designer at IDEO, a design consultancy, and Denso, a division of Toyota group. At Refine, Earl is designing and developing new products, including disposable ATF systems, which will be introduced into the market in 2012.


## Monday, April 2, 2012

2:30 pm, University South Room

**Tariq Haq** • Thermo Scientific

### *Cell Culture Media and Process Optimization Approaches for Optimal Biotherapeutic Production – Development of HyCell™ CHO, a High Performing CHO Production Medium*

**ABSTRACT**: Unique bioprocess requirements of production clones make it necessary to optimize the medium and process in order to obtain the most optimal bioproduction. It is vital to quickly assess and meet the specific needs of bioprocessing systems to satisfy the demands of product yield and quality. A media optimization approach that has the ability to thoroughly evaluate the nutrient demands of cell culture from high-throughput format to bioreactor scale, take into consideration potential key component toxicities, and provide necessary process specific supplementation guidance is critical to develop media and feed formulations. DoE factorial strategy along with our Metabolic Pathway Design™ approach has been successfully applied to achieve media and feed optimization. High-throughput screening (HTS) equipment facilitated the development and testing of the media formulations. Development and comparative analysis was performed in 96-deepwell plates with subsequent scale-up and comparison of promising formulations in shake flasks and bioreactor studies. Results revealed exceptionally similar trends in both cell density and product quantity, validating the HTS plate design and Metabolic Pathway Design approach. This strategy has been successfully utilized to develop clone specific media formulations and innovative high performing standard products such as HyCell™ CHO medium. Case studies will discuss specific media optimization work and results for HyCell CHO.

**BIOGRAPHY:** Tariq Haq is currently a Senior Global Product Manager in the BioProcess Production unit of the Biosciences division at Thermo Fisher Scientific responsible for Media, Buffers and Process Liquids product portfolio. He has over 15 years of experience in BioProcess and Biotechnology industry. His expertise includes bioprocess production, vaccines, antibodies, transgenics, biosensors, cell culture media and therapeutic development. He has authored scientific publications and chapters in peer-reviewed journals and publications such and Science and Vaccine. Tariq holds degrees in Biotechnology, and Biochemistry and Biophysics.