Final Agenda

Day 1 | Day 2 | Download Brochure

THURSDAY, JANUARY 17

7:45 am Registration and Morning Coffee

HIGH-THROUGHPUT TO IMPROVE DOWNSTREAM PROCESSES

8:10 Organizer’s Welcome Remarks
Mary Ruberry, Senior Conference Director, Cambridge Healthtech Institute

8:15 Chairperson’s Opening Remarks
Kelcy Newell, PhD, Senior Scientist, Laboratory Automation & High-Throughput Process Development, MedImmune, LLC

KEYNOTE PRESENTATION

8:20 Downstream Processing in Biomanufacturing: Multimodal Chromatography, Affinity Precipitation and Integrated Bioprocessing
Steven Cramer, PhD, William Weightman Walker Professor, Isermann Department of Chemical and Biological Engineering, Rensselaer Polytechnic Institute

Targeted experiments and molecular simulations will be used to shed light on the importance of protein surface clusters and ligand properties for creating selective separations in multimodal chromatography. Affinity precipitation using smart biopolymers for the simultaneous recovery and purification of both mAb and non-mAb biologics will then be presented. Finally, results will be given on a novel approach for the rapid development of integrated downstream biomanufacturing processes for biological products.

9:00 Platformization of Multi-Specific Protein Engineering II: From Automated Transfection to High-Throughput Multi-Parametric Characterization of Large Variant Libraries
Joerg Birkenfeld, PhD, Section Head, High Throughput Biologics, R&D Biologics Research/Protein Therapeutics, Sanofi-Aventis Deutschland GmbH

The success rate to identify a multi-specific lead molecule with favorable drug-like properties increases with the number of engineered variants tested. We recently established a novel, fully automated platform process for the in silico design and fast generation of large panels of multi-specific variants. Here, we report on the integration of miniaturized lab unit operations with cutting-edge automation for transient transfection, expression, purification and characterization of up to 10,000 engineered variants in high-throughput.

9:30 Sponsored Presentation (Opportunity Available)
10:00 Coffee Break in the Exhibit Hall with Poster Viewing

IMPROVING HIGH-THROUGHPUT PROCESSES

11:00 Applications of Modular Expression Toolboxes in High-Throughput Protein Expression

Ernst Weber, PhD, Laboratory Head, Biologics Lead Optimization, Project Leader, Ophthalmology, Bayer HealthCare

The presentation will focus on the setup of a modular expression toolbox, consisting of standardized elements influencing expression levels, which allow the rapid generation of multiple expression constructs and also the generation of complex expression optimization libraries. Advantages and implications of a modular cloning system including implementation into protein expression optimization workflows will be discussed and a number of successful case studies will be presented.

11:30 Self-Cleaving Tags Based on Split Inteins: Increased Reliability Enabling Higher-Throughput Applications

David Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

An important limitation of intein-based self-cleaving tag systems is a lack of reliability for arbitrary target proteins. In some cases, the intein tags cleave too quickly, while in others the tags cleave too slowly or not at all. In our recent work, we have developed several systems to interrogate the sources of rate variations, and can now provide detailed guidance on design and operation of these methods in higher-throughput applications.

12:00 pm Session Break

12:10 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:10 Ice Cream Break in the Exhibit Hall with Poster Viewing

NOVEL TOOLS TO STREAMLINE PROCESSES

2:15 Chairperson’s Remarks
Edward Kraft, PhD, Senior Scientific Manager, BioMolecular Resources, Genentech, Inc.

2:20 Improving High-Throughput Characterization of Intact Proteoform Using Ion-Photon and Ion-Ion Reactions in the Gas-Phase
Luca Fornelli, PhD, Assistant Professor, Biology, University of Oklahoma

Top-down proteomics (TDP) allows the characterization of proteoforms, or proteins with specific sets of genetic and chemical modifications. Therefore, TDP provides a description of the proteome with high molecular specificity, finding mechanistic connections with phenotypes of interest. Here, we describe novel tools to improve TDP. Ultraviolet photodissociation (UVPD) uses 213 nm photons to fully characterize proteoforms <30 kDa, while ion-ion proton transfer facilitates the identification of large proteoforms (30-60 kDa).

2:50 Nanodelivery of a Functional Membrane Receptor to Manipulate Cellular Phenotype

Matthew Coleman, PhD, Senior Scientist, Physical Life Sciences, Lawrence Livermore National Laboratory (LLNL)

We have developed a platform that enables multiplex investigation of G-protein-coupled receptors (GPCRs) by coupling cell-free expressed GPCR in E. coli with functional profiling at the single-molecule level for delivery of the active GPCR into mammalian cells. Specifically, our work shows that we can assemble full-length, wild-type β2AR associated with nanolipoprotein particles (NLPs) in cell-free E. coli lysates in a single step process. We then functionally characterized the nanoassemblies by demonstrating ligand-induced confirmation activation.

3:20 Sponsored Presentation (Opportunity Available)

3:35 Networking Refreshment Break

HIGH-THROUGHPUT ANALYTICS

4:00 Bridging the Silos: Integration of HTPD Scale-Down Models and High Throughput Analytics Enables and Accelerates Process Development of Biopharmaceuticals

Kelcy Newell, PhD, Senior Scientist, Laboratory Automation & High-Throughput Process Development, MedImmune, LLC

As biopharmaceutical companies shift their pipeline to increasingly novel therapeutics, development is filled with new challenges including different novel product quality attributes, new product and process related impurities, and/or accelerated product degradation pathways. We have adopted a cross-functional approach to minimize disruption of development timelines and even enable acceleration to market when required. This talk will spotlight multiple cross-functional high-throughput process development strategies that have been successfully utilized for problematic biopharma molecules in development.
4:30 **A Computational High-Throughput Method for the Study of Modified RNA Interactions with Proteins**

Phanourios Tamamis, PhD, Assistant Professor, Chemical Engineering, Texas A&M University

Little is known about the abundance of protein-RNA modification interactions and how these interactions may regulate protein function. Here, we present the first, to our knowledge, computational protocol for the characterization of interactions between proteins and RNAs containing post-transcriptional modifications. As an initial test case, we implemented our CHARMM-based protocol to investigate interactions between *E. coli* polynucleotide phosphorylase protein with modified RNAs, demonstrating a reasonably high agreement between computational and experimental results.

5:00 **Application of Native MS for the Characterization of Bispecific Antibodies during Drug Development**

Markus Haberger, PhD, Senior Scientist, Pharma Technical Development Analytics Extended Characterization, Roche Diagnostics GmbH

High-molecular weight aggregates, such as antibody dimers and other side products derived from incorrect light or heavy chain association, typically represent critical product-related impurities for bispecific antibody formats. In this study, an approach employing ultra-pressure liquid chromatography size-exclusion separation combined with native electrospray ionization mass spectrometry for the simultaneous formation, identification and quantification of size variants in recombinant antibodies was developed. Samples exposed to storage and elevated temperature(s) enabled the identification of various bispecific antibody size variants.

5:30 **Close of Day**

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**FRIDAY, JANUARY 18**

8:00 am **Registration**

8:00 **BuzZ Sessions with Continental Breakfast**

Protein therapeutics is a fast-growing global market. As the science improves, so does the complexity of the R&D organization. Ensuring product quality plus speed to market requires insights from stakeholders working across the stages of protein science R&D. Join experts representing this PepTalk pipeline, peers, and colleagues for an interactive roundtable discussion. Topics include
highlights from the week’s presentations, new technologies and strategies, challenges, and future trends.

Click here for more details

Moderator: David Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

HIGH-THROUGHPUT PROTEIN PURIFICATION

9:00 Chairperson’s Remarks
Markus Haberger, PhD, Senior Scientist, Pharma Technical Development Analytics Extended Characterization, Roche Diagnostics GmbH

FEATURED PRESENTATION

9:05 Medium Scale (0.25-10L) High-Throughput Paramagnetic Purification of Biologics
John Kawooya, PhD, Director, Biologics Optimization, Discovery Research, Amgen, Inc.
Here, we describe a transformative medium-scale rare earth magnetic (NdFeB) system which purifies biologics directly from crude cell culture with cells. The capture step on the beads starts 18-24 hours before the end of protein expression, thereby eliminating the cycle time traditionally spent during centrifugation, clarification and sample loading. The output of the system is amplified by formatting and magnetizing sixteen tanks each capable of purifying more than 2 grams of protein in less than two hours.

9:35 High-Throughput Purification of Synthetic Peptides

Mathias Schaffrath, PhD, Group Head, R&D IDD In vitro Biology & HT Chemistry Library, Chiral & Peptide Purification, Sanofi-Aventis Deutschland GmbH
The purification of synthetic peptides is still a challenge. Reversed phase chromatography is in many cases the method of choice. Sometimes orthogonal reversed phase methods with two chromatographic steps and two different column selectivities are needed to increase the purity to more than 95%. Chromatographic experience, a thorough method development and up scaling is needed for successful separations. Partial automation of the process leads to remarkable throughput, which is particularly important in the field of research.

10:05 Evolving the High-Throughput Protein Purification Pipeline
Edward Kraft, PhD, Senior Scientific Manager, BioMolecular Resources, Genentech, Inc.

The development of high-throughput protein expression and purification pipelines are an essential component for predicting construct design success and scalability for protein production. This process requires significant expertise spread across biochemistry, biology, automation and informatics to create a system that has the flexibility to impact all types of proteins. This talk will present our work to continually adapt our high throughput protein production workflows to support the diversity of non-antibody proteins in support of research across Genentech.

10:35 Networking Coffee Break

AUTOMATION IN HTP PROCESSES

11:00 Library-Based Glycan Identification by Mass Spectrometry in Combination with Fluorescence Quantification as a Biopharma Solution for Automated Glycan Characterization

Sven Bahrke, PhD, Senior Director, Research & Development, Glycotope GmbH

In the present study, proteins comprising different numbers of glycosylation sites were analyzed by release of N-glycans with N-glycanase F, fluorescence labeling of N-glycans, data recording by use of HILIC-UPLC-FLD-ESI-QTOF MS/MS (hydrophilic interaction ultra-performance chromatography with fluorescence detection coupled to electrospray ionization quadrupole time-of-flight tandem mass spectrometry). Subsequently, automatic data processing was performed, and final reporting of all data in a certificate of analysis.

11:30 Beyond Miniaturization and Parallelization: Standard and Tailor-Made Automated Workflows for Smart Microbial Phenotyping and Bioprocessing

Marco Oldiges, PhD, Professor and Head, Bioprocesses and Bioanalytics, Institute of Bio- and Geosciences, IBG-1, Biotechnology, Forschungszentrum Jülich GmbH

Microbial production of heterologous proteins demands increased cultivation throughput at well-defined bioprocess conditions. Making use of miniaturization, parallelization and automation, standard and tailor-made workflows need to be put in place, comprising the full experimental pipeline from upstream processing, cultivation, process analytics, data management and design-of-experiment. Case studies illustrate how developments in miniaturized cultivation combined with smart lab automation and data processing are amalgamated in workflows for more efficient microbial phenotyping and bioprocess development.

12:00 pm Conference Wrap-Up
12:30 Close of Conference