

Technology Workshops



Track	Organization	Title	Schedule & Location
APPLICATION	 aldevron	Maximizing rProtein Insect Cells and mAb Production Throughput	Monday, March 11 10:30 am –11:00 am Tera Room
	 BIA separations	Methacrylate Monolithic Columns for the Downstream Processing and In-Process Control of Viral Vectors and Vaccines	Monday, March 11 10:30 am –11:00 am Cityview Room
	 PALL Life Sciences	The Pall XRS 20 Bioreactor: “Next Generation” Single-Use Bioreactor Development	Monday, March 11 11:00 am –11:30 am Riverview Room
	 EVMS Eastern Virginia Medical School	From Model Organism to a Career in Biotech	Monday, March 11 11:30 am –12:00 noon Riverview Room
ANCILLARY	 PALL Life Sciences	Single-Use Technologies for Formulation and Filling: Considerations and Solutions	Thursday, March 14 12:00 noon–12:30 pm Riverview Room
	 charles river	Synergy with a Multi-Modal Approach to Safety Testing and Characterization of Biopharmaceutical Substrates and Final Products: Reducing Risk and Increasing the Level of Confidence	Thursday, March 15 12:00 noon–12:30 pm Cityview Room
	 Finesse	Increasing Single-Use Facility Intelligence: The Advent of SMART Technologies	Friday, March 15 12:00 noon–12:30 pm Cityview Room
	 Thermo SCIENTIFIC	Maximizing BioProcessing Efficacy Through Implementation of State-of-the-Art Single-Use Technology Solutions	Friday, March 15 12:00 noon–12:30 pm Cityview Room

Ally Hauser • Aldevron

Maximizing rProtein Insect Cells and MAb Production Throughput

ABSTRACT: Aldevron is a contract service provider for plasmids, proteins, and antibodies with a goal to support scientific innovation, offer a high-quality experience and enhance client results. The presentation will focus on two programs utilized to accelerate our clients' research. First, we are currently partnering with DNA 2.0 to investigate improvements in codon optimization for baculovirus expression and have identified several promising algorithms for codon optimization in insect cells. Application of these algorithms may provide a method to consistently enhance recombinant expression levels. Current results and future experiments will be discussed. The second example demonstrates our streamlined gene-to-Ab workflow starting from sequencing the antibody from hybridoma cells or gene synthesis from an electronic sequence. In both cases, the finished product is the purified antibody. Aldevron has demonstrated completion of 24 purified MAbs in under six weeks.

BIOGRAPHY: Ally Hauser's professional experience include five years of bench research at Case Western Reserve University, three years of university technology transfer at WARF, and 12 years of technical scientific support and project management for protein expression products and services focused on *E. coli*, insect, and mammalian expression systems at Novagen and Aldevron.



Nika Lendero Krajnc, PhD • BIA Separations

Methacrylate Monolithic Columns for the Downstream Processing and In-Process Control of Viral Vectors and Vaccines

ABSTRACT: In the last decade, methacrylate monoliths have been gaining importance due to their:

- high porosity,
- convection-based transport
- high capacity for extremely large molecules

These features are highly related to the monolithic structure since high porosity results in low column pressure drop and milder purification conditions. Convection-based transport, which is not affected by column flow rate, is an extremely important feature that accelerates the separation and purification process, and is especially pronounced for large molecules. Pores in the monoliths are open and highly interconnected to form a network of channels. The mobile phase is forced through the pores, and the molecules you want to capture are bound to the active sites by convection. Since there are normally no dead-end pores in the monoliths, there are no stagnant regions and the mass transfer between stationary and mobile phases is extremely fast. This is especially beneficial for purifying very large molecules with small mobility like large proteins, polynucleotides, and viruses. Furthermore, monoliths exhibit very high binding capacity for extremely large molecules because the accessible surface is the wall of the interconnected channels through which the sample travels.

In this work, the advantages of monoliths over other (conventional) chromatographic stationary phases will be discussed. The characteristics and overview of CIM monolithic columns, and their applicability for the DSP of viruses like influenza and adenoviruses, will be shown. Examples of in-process control (PAT) of various process stream fractions of large biomolecules will be discussed.

BIOGRAPHY: Dr. Nika Lendero Krajnc is the Chief Research and Development Officer for BIA Separations. She finished her BSc at University of Ljubljana with elective subjects in organic chemistry under the faculty of Chemistry and Chemical Technology in 2003. For her diploma work, she received the Student Prešeren award. She continued her doctoral study at BIA Separations in the R&D department under the supervision of Dr. Aleš Podgornik. During her studies, she wrote four scientific papers and was a co-author in several scientific papers, as well as a book chapter that deals with the applications and characterization of methacrylate chromatographic monoliths. In 2010, she obtained a scholarship from the international programme "For Women in Science", founded by the Slovenian National Commission for UNESCO, L'Oréal Slovenia, and The Slovenian Science Foundation. In that same year, she finished her PhD in Chemical Science at the University of Ljubljana and received the Krka Prize for her research work. Then she became a Research Scientist II in the R&D department, and for two months she was working as Project Manager. In September 2011, she was promoted to the position of Chief Research and Development Officer at BIA Separations. Her expertise is in characterizing chromatographic supports that are used in downstream processes of biomolecules and viruses, understanding the interactions of large biomolecules with surfaces of chromatographic supports (especially ion exchangers), and optimizing chromatographic supports for purification of large biomolecules, especially pDNA.

Charles Golightly, PhD • Pall Life Sciences

***The Pall XRS 20 Bioreactor:
“Next Generation” Single-Use Bioreactor Development***

ABSTRACT: Single-use technologies have gained rapid adoption in many unit operations within the biotech manufacturing process. Today, manufacturers are moving the first generation of single-use bioreactor systems from the R&D facility into both pilot-scale and full commercial-scale bioproduction facilities. As these systems become more widely used in manufacturing environments, shortcomings in robustness, productivity, and overall ease-of-use are receiving more attention. Single-use bioreactor systems are almost unique in biotech operations with their requirement to integrate moving parts (the agitation system), multiple parameter process measurement and control devices, and multiple gas/fluid addition/withdrawal ports—all into a single-use biocontainer that maintains 100% fluid/gas integrity during the expected service life in use.

Recognizing the clear need for a “next generation” of high performance, single-use bioreactor systems, Pall Corporation is bringing new family of bioreactor systems to market. The first product is the XRS 20 Bioreactor system, with a novel “bi-axial” rocker-style bioreactor for applications ranging from seed trains (inoculum expansion), small-scale GMP operations (2 to 20 L culture volume), and general laboratory uses where high capability control systems are required. Development and validation of this new system will be described with discussion about physical parameters for design space definition and performance measurements as contrasted to conventional systems available in the market. The presentation will conclude with results from CHO culture trials for design validation, demonstrating significant increases in achieved cell densities, culture longevity, and cell productivity, compared to conventional rocker technologies.

BIOGRAPHY: Charles Golightly is Director of Marketing for Pall Life Sciences and Global Product Manager for Pall Single-Use Bioreactor Systems. He has over 24 years experience in the life sciences research industry and in the pharmaceutical and biotech manufacturing industry, in prior sales, marketing, and product management roles at Diagnostic Hybrids, Inc. and Life Technologies/Invitrogen. He holds a PhD in Zoology from Texas A&M University.

Aurora Esquela-Kerscher, PhD • Eastern Virginia Medical School (EVMS)

From Model Organism to a Career in Biotech

ABSTRACT: MicroRNAs have emerged as promising diagnostic and therapeutic targets for cancer. The Esquela-Kerscher laboratory uses a combination of *C. elegans* and mammalian models to functionally characterize the role of small non-coding RNAs in prostate cancer progression. Innovative studies such as these are being conducted in the newly established Leroy T. Canoles Jr. Cancer Research Center. This workshop will also discuss graduate programs at Eastern Virginia Medical School including the exciting Biotechnology Masters Program that focuses on training students to enter the biotechnology and pharmaceutical sectors.

BIOGRAPHY: Aurora Esquela-Kerscher received her BA from Washington University in St. Louis, Missouri, and completed her MS in biotechnology and PhD in the Biochemistry, Cellular, and Molecular Biology Graduate Program at the Johns Hopkins University School of Medicine. Dr. Esquela-Kerscher conducted a postdoctoral fellowship in Frank Slack's laboratory at Yale University studying the role of microRNAs during developmental and disease. She is currently an assistant professor in the Department of Microbiology and Molecular Cell Biology at Eastern Virginia Medical School in Norfolk, Virginia, and an adjunct assistant professor in the Department of Applied Science at the College of William and Mary. Dr. Esquela-Kerscher manages a new Biotechnology Masters Program at EVMS that emphasizes hands-on research training and internships with biotechnology partners.

Jerold Martin • Pall Life Sciences

Single-Use Technologies for Formulation and Filling: Considerations and Solutions

ABSTRACT: New technology choices when selecting a completely disposable system for filling applications:

- Polymeric single-use filling needle as a key components of the fluid path development
- Key aspects of the development of this filling technology and data regarding filling accuracy and repeatability
- Validation aspects including extractables and leachables.

BIOGRAPHY: Jerold Martin is Sr. Vice President, Global Scientific Affairs for Pall Life Sciences, and Chairman of the Bio-Process Systems Alliance (BPSA). He has over 36 years experience in the pharmaceutical and biotech industries and is a frequent speaker and author on filtration and aseptic processing, including co-authorship of numerous PDA Technical Reports, BPSA Single-Use Guides, and ASTM, ISO, and ASME-BPE Standards. In 2007 he was awarded the PDA Distinguished Service Award, and in 2012 he was named "Thought Leader of the Decade in Manufacturing" by *Biopharm International Magazine* for his efforts in promoting single-use manufacturing. He holds an MSc in Microbiology from the University of Toronto.

Michael Hantman, PhD • Charles River Laboratories

***Synergy with a Multi-Modal Approach to Safety Testing and
Characterization of Biopharmaceutical Substrates and Final Products:
Reducing Risk and Increasing the Level of Confidence***

ABSTRACT: A multi-modal strategy for biopharmaceutical safety testing and cell substrate characterization includes both parallel and sequential testing by multiple methods to provide an increased level of confidence that the product is safe. Parallel tests typically generate complementary results which strengthen the optimal conclusion of safety, while sequential testing incorporates follow-up studies to resolve issues that may be generated in the primary testing. Data from case studies will illuminate the multi-modal approach including methods for massively parallel sequencing (MPS), specific and broad range nucleic acid amplification techniques (NAT), infectivity studies, microbiological growth studies, multi-locus sequencing (MLS), electron microscopy (EM), virus induction assays, and nucleic acid fragment analysis.

BIOGRAPHY: Michael J. Hantman is the Associate Director of Methods Development for Charles River Laboratories at the Malvern, Pennsylvania site. He received his PhD in Microbiology and Immunology from Temple University School of Medicine where he was working on genetic mapping and pathogenicity of *Streptococcus mutans* which are the main cause of dental caries. He then pursued postdoctoral fellowships at the Harvard Medical School, Massachusetts General Hospital, and the University of Washington where he focused on vaccine development with live vaccine vectors and host-pathogen interactions. For this work he used recombinant, attenuated salmonella strains expressing heterologous genes to stimulate multiple immune pathways. Over the past twelve years, Michael and his Methods Development team have developed a portfolio of over 70 assays and methods used for the detection and quantitation of adventitious agents in biopharmaceuticals, as well as the characterization of cell substrates used in the production of biopharmaceuticals. These methods focus primarily on nucleic acid amplification technologies, or (NAT)-based assays. These assays have been responsible for over 35 new assay validations and qualifications in the last four years, including specific and broad-range quantitative, fluorescent PCR assays for adventitious agents, residual DNA assays, copy number assays, and nucleic acid sequencing projects.

Alan Opper • Finesse Solutions

***Increasing Single-Use Facility Intelligence:
The Advent of SMART Technologies***

ABSTRACT: The availability of digital components with plug-and-play capability has the potential to revolutionize the design and validation of controllers used in bioprocessing. We will present examples of SmartParts used in bioreactor SmartSystems and extend the concept of flexible automation to the factory level.

BIOGRAPHY: Alan Opper has been the Eastern Regional Sales Manager for Finesse Solutions for the past five and a half years, during which he has achieved much success introducing the Finesse Technology to the marketplace. Prior to Finesse, Alan founded his own distribution company where for ten years he successfully introduced new technologies including automated cell counting, various bioreactors, and downstream bioprocessing equipment into the US marketplace. Alan has over 20 years of management, sales, and marketing experience in the biopharmaceutical field.



Spencer Parkinson • Thermo Scientific

Maximizing BioProcessing Efficacy Through Implementation of State-of-the-Art Single-Use Technology Solutions

ABSTRACT: Beyond its proven benefits in non-critical liquid handling applications, single-use technology has been proven and accepted in cell culture and fermentation bioprocesses. Recent advancements in single-use technologies continue to usher in bioprocessing improvements for increasingly sophisticated applications. The most recent innovation in single-use technology is the creation of a BioProcess Container (BPC) that separates microcarriers from supernatant in anchorage dependent, cell culture-based vaccine production. The bag-within-a-bag design ensures full and separate containment of the microcarrier “beads” and the cell culture supernatant. The design of the bag reduces holdup volumes to increase recovery efficiencies, and allows the harvest of more product with less effort. Product advancements, combined with an agile and capable supplier partnership, ensure collaborations on process improvements and product customization that can leverage these technologies to generate significant improvements in bioprocessing output, quality, and lead times. And where applicable, these technologies now permit us to move closer to the realization of the promised efficiencies of continuous processing. This workshop addresses these single-use technologies, advancements, and concepts.

BIOGRAPHY: Mr. Parkinson currently serves as Senior Market Manager, BioProcessing at Thermo Fisher Scientific Cell Culture and Bioprocessing in Logan, Utah. He holds an MS in Biochemistry from Vanderbilt University and an MBA from UCLA, and has over 31 years’ experience in medical devices and biotechnology. He has spent the last 18 years in multiple positions at what was HyClone and later became Thermo Fisher Scientific, in Business Development and Marketing.