North Jersey Chromatography Group Annual Symposium

Biopharmaceutical Analysis

October 11, 2024. 10am - 4pm Double Tree by Hilton. 200 Atrium Dr, Somerset, NJ, 08873

Guest Speakers







JAMES GRINIAS PROFESSOR OF CHEM&BIOCHEM, ROWAN UNIVERSITY STEPHAN KOZA CONSULTING SCIENTIST, WATERS

COPORATION



ARMEN BECK POSTDOCTORAL FELLOW MERCK

Speaker	Торіс	Schedule
James Grinias	Analysis of Pharmaceutical and Biopharmaceutical Compounds with Compact Capillary LC	11:15-11:45 AM
Stephan Koza	Advances in SEC for Biotherapeutics1:00-1:30 H	
James Greco	What can MALS add to my biological analysis needs?	1:30-2:00 PM
Armen Beck	Data Efficient Chromatography Retention Time Predictions of Biopharmaceuticals Using Graph Networks	3:15-3:45 PM
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REGISTER NOW!

Registration Fee: \$25 Lunch and Refreshment Included



MORE INFORMATION

NJCG1234@GMAIL.COM

Agenda

Tentative Time	Moderator/Speaker	Title	
10:15-11:00 am	NJCG Staff	RegistrationVendor Show and Posters	
11:00-11:10 am	Nimisha Thakur, NJCG Chair (Merck)	Welcome Introduction from NJCG	
11:10-11:15 am	Isabelle Vu Trieu (Waters Corporation)	Introduction from Waters Corporation	
11:15-11:45 pm	Speaker 1 Jim Grinias, Professor (Rowen University)	Analysis of Pharmaceutical and Biopharmaceutical Compounds with Compact Capillary LC	
11:45-1:00 PM	NJCG Staff	Lunch/Vendor Show	
1:00-1:30 pm	Speaker 2 Stephan Koza (Waters Corporation)	Advances in SEC for Biotherapeutics	
1:30-2:00 pm	Speaker 3 James Greco, Regional Account Manager (Wyatt Technology)	What can MALS add to my biological analysis needs?	
2:00-2:05 pm	Sandra Keyser, NJACS Chair (Merck)	NJ-ACS Overview	
2:05-3:15 pm	NJCG Staff/Vendors	Break •Vendor Show and Posters •Refreshment drinks	
3:15-3:45 pm	Speaker 4 Armen Beck (Merck)	Data Efficient Chromatography Retention Time Predictions of Biopharmaceuticals Using Graph Networks	
3:45-4:00 pm	Yuan Ren, NJCG Secretary (BMS)	•Raffle •Closing Remarks	

Acknowledgement





Analysis of Pharmaceutical and Biopharmaceutical Compounds with Compact Capillary LC

James P. Grinias Rowan University

Abstract

The use of portable and compact instrumentation has expanded the possibilities of integrating capillary-scale LC techniques into realms typically dominated by analytical-scale methodology. Low-volume detector flow cells and UV-LED light sources allow for improvements in absorbance detection for columns with internal diameters in the 0.1 – 0.3 mm range. Compact single-quad mass spectrometers with integrated vacuum systems also allow for LC-MS measurements when combined with compact capillary LC platforms. Considerations for column selection (in terms of length, internal diameter, particle size, and particle morphology) include pressure limits (both column and instrument), required efficiency for a given separation, and the balance between operating flow rate and the maximum volume that can be delivered from the pumping system in a single method.

We have employed compact capillary LC instrumentation in a wide variety of application areas that will be discussed. The analysis of pharmaceutical compounds has focused on QA/QC methodology (including impurity monitoring) and strategies for on-line reaction monitoring. Compact LC-MS has also been used for targeted screening of illicit drug compounds towards implementation in point-of-care settings. New instrument developments for temperature control along with the ability to connect the instrument to high resolution MS instrumentation have improve the ability to analyze antibody-based biopharmaceutical drugs. The common LC methods used in these and other application areas have the potential to be transformed through this technology that is greener and simpler to operate while still providing efficient chromatographic separations.

Analysis of Pharmaceutical and Biopharmaceutical Compounds with Compact Capillary LC

James P. Grinias Rowan University

Biography

James Grinias is a Professor of Chemistry & Biochemistry at Rowan University. His research interests primarily focus on liquid-phase separations, especially the fundamentals of column and instrument design in liquid chromatography. For over a decade, he has focused on increasing the efficiency and throughput of these separations, especially with capillary-scale columns. He has applied these techniques to a wide variety of molecular classes, including pharmaceutical compounds, neurotransmitters, physiological metabolites, and drugs of abuse. More recently, his group has focused on instrument miniaturization, especially for portable liquid chromatography separations, two-dimensional separation techniques, and microfluidic platforms.

He received his Ph.D. from the University of North Carolina at Chapel Hill in 2014 and then moved onto a postdoctoral fellowship at the University of Michigan until the end of 2016. James has received a number of awards for his work to date, including the HPLC 2013 Csaba Horváth Award, the 2020 Young Investigator Award from the Chinese American Chromatography Association, a National Science Foundation CAREER grant, the 2021 Satinder Ahuja Young Investigator in Separation Science Award, and the 2021 LCGC Emerging Leader Award. He was also named to The Analytical Scientist's "Top 40 Under 40" Power List in 2018 and 2022. To date, he has published nearly 50 articles and been author or co-author on over 120 oral/poster presentations.

In addition to his research interests, James has held several service roles within the research community. He has been a co-editor for a special issue of the Journal of Chromatography A and is a regular reviewer for several other analytical journals. He recently served as the President of the Chromatography Forum of Delaware Valley and is currently the Chair of the American Chemical Society Subdivision on Chromatography and Separations Chemistry. James also regularly serves on the organizing committee of the HPLC Symposium Series.



Advances in SEC for Biotherapeutics

Stephan Koza Waters Coporation

Abstract

A few years past, Waters introduced a series of size-exclusion chromatography (SEC) columns that used metallic hardware that is modified to be hydrophilic, thereby minimizing interactions with proteins. This hardware in combination with more inert PEO-bonded organosilica 250 Å pore-size SEC particles resulted in columns that can be used effectively for protein separations under a wider range of conditions. In this brief presentation, some of the earlier background and application of this technology will be reviewed. This technology has also enabled the recent development of a high-throughput (-1.5 min/analysis) column for the analysis of high-molecular weight species in monoclonal antibodies, plus 450 Å and 1000 Å pore-size columns for the analysis of larger analytes including intact virus, results from which will also be presented.

Biography

Stephan Koza has worked at Waters Corporation for over 10 years and has a primary focus on the use of LC, LC-MS, and sample preparation chemistries and columns for the analysis of biomolecules. Prior to joining Waters, he had nearly twenty years of experience with biopharmaceutical characterization and analytical method development with Genetics Institute, Wyeth, and Pfizer. Stephan received his doctorate in analytical chemistry at the University of New Hampshire.



What can MALS add to my biological analysis needs?

James Greco Wyatt Technology

Abstract

Please join us in a discussion defining what light scattering is, how it can be seamlessly added to your chromatography methods, and applications examples for biologics of interest today. The addition of Multi Angle Light Scattering (MALS) enables the determination of many Critical Quality Attributes (CQA's) of your biopharmaceutical samples so you can gain valuable insights from your peak profiles.

We will explore applications examples of antibody based biosimilars identification, oligomerization quantitation, ADC/AOC payload analysis, adeno-associated virus particles, and lipid nanoparticles. Data will be shared on each topic above displaying the full capability of MALS, and highlights of any real-world limitations. The talk will also discuss the benefits of Field Flow Fractionation (FFF or AF4) sprinkled in as needed, highlighting why it is powerful, and when it is an applicable orthogonal technique to consider.

Biography

James Greco is as a Regional Account Manager at Wyatt Technology, bringing over 16 years of experience in the biopharma industry. James started his industry career at BMS, working for 9 years on biophysical characterization of biotherapeutics. Eventually, he joined Wyatt Technology in 2017 as a Field Application Scientist, where he supports and provides advanced training for customers in a broad array of fields from small peptides, biologics, viral particles, and even polymers. In 2022 James transitioned to Regional Account Manager and takes great joy in helping people solve analysis challenges they face each day. He graduated from Salve Regina University with a BS in Biology.



Data Efficient Chromatography Retention Time Predictions of Biopharmaceuticals Using Graph Networks

> Armen Beck Merck

Abstract

Contemporary approaches to chromatography method development often require extensive screening to identify suitable conditions for separating complex mixtures by Liquid Chromatography (LC). In order to reduce research burden and solvent usage, researchers have developed various approaches for predictive software that links molecular structure or features to the retention time. Our research has been focused on investigating the gain in prediction and performance efficiency with application of graph neural networks compared to traditional forms of machine learning for these retention time predictions. We are currently applying neural network based transfer learning approaches to reversed phase LC method development of pharmaceutical molecules over the small to mid molecular weight range with retention time data collected under different chromatographic conditions. We will be sharing our findings regarding how differing neural architectures and training paradigms determine the downstream predictive performance of these transfer learning approaches. The workflow efficiencies obtained by application of these predictive approaches will be discussed.

Biography

Armen Beck is a postdoctoral fellow at Merck & Co., Inc. where his studies are centered around developing machine learning models for retention time prediction. During the past year, Armen has investigated the data dependency of quantitative structure retention relationship modeling and develop methods with neural networks using low amounts of task specific data under the supervision and guidance of Pankaj Aggarwal. Prior to his fellowship, Armen was awarded his doctorate after studying under Professor Gaurav Chopra at Purdue University, where he transitioned from a synthetic organic background to one concerning machine learning and optimization of chemical systems.