USP Workshop on Therapeutic Peptides and Oligonucleotides

March 1st, 3rd and 5th, 2021
10am – 1pm EST

USP Biologics™

Speaker Biographies

(Listed alphabetically by last name)
February 19, 2021

Nadim Akhtar, Ph.D.
Principal Scientist Characterization & Control Strategies
AstraZeneca

Nadim Akhtar has a PhD degree in chemistry and has been working for AstraZeneca since 2007. During this time Nadim has worked across different fields including small molecules, new modalities (oligonucleotides, peptides, polymeric nanoparticles, dendrimers) and predictive science supporting both drug substance and drug product activities. Nadim currently sits in the **New Modalities and Parenteral Development** (NMPD) function where he is responsible for developing characterisation methods and control and regulatory strategies.

Presentation: Terminal Sterilisation of Oligonucleotide Drug Products
Terminal sterilisation is the process whereby a product is sterilised in its final container. This sterilisation process has always been preferred choice of the regulators. New EMA guidance requires a substantial effort to enable terminal sterilisation of parenteral products and has raised the bar for data required to justify an aseptic sterile filtration process. This guidance also applies to synthetic oligonucleotides. This presentation will discuss specific considerations and challenges associated with terminal sterilisation of oligonucleotides. European Pharma Oligonucleotide Consortium (EPOC) is authoring a position paper on this topic and key recommendations from this paper will also be shared.

Dominik Altevogt, Ph.D.
Pharma Technical Regulatory Manager
F. Hoffmann-La Roche Ltd.

During over 10 years in the pharmaceutical industry, Dominik Altevogt has led multiple regulatory submissions and health authority interactions for small molecule drugs, with special focus on synthetic peptides and oligonucleotides. He started his career in the field of CMC regulatory affairs working for a peptide manufacturer. Since 2014, Dominik is CMC Regulatory Manager at Roche. He holds a Ph.D. in organic chemistry from the University of Freiburg, Germany.

Presentation: Regulatory Considerations for Setting Smart Starting Material Specifications

ABSTRACT: Starting material specifications are a key element of the overall control strategy for synthetic oligonucleotides. In this presentation, we share our experience with setting smart specifications that on the one hand are meaningful controls for a specific oligonucleotide sequence and on the other hand enable us to use a platform approach to flexibly source starting materials to multiple oligonucleotide projects.

Michael G. Bartlett, Ph.D.
Associate Dean for Science Education, Research and Technology
University of Georgia

Michael G. Bartlett is the Georgia Athletic Association Professor in Pharmacy and Associate Dean for Science Education, Research and Technology at the University of Georgia, College of Pharmacy. His research program focuses on the development of novel bioanalytical methodology to advance drug development including oligonucleotides, proteins and small molecule therapeutics. He is the Editor-in-Chief of the journal Biomedical Chromatography and has published over 170 peer review articles and book chapters.

Presentation: Recent Advances in Degradation Product Characterization of Therapeutic Oligonucleotides Using Liquid Chromatography Mass Spectrometry

ABSTRACT: Synthetic antisense phosphorothioate oligonucleotides (PS) have undergone rapid development as novel therapeutic agents. The increasing significance of this class of drugs requires significant investment in the development of quality control methods. The determination of the many degradation pathways of such complex molecules presents a significant challenge. Additional challenges can arise from the complex mobile phase systems used to characterize oligonucleotides. These mobile phases are quite sensitive to pH and temperature, which if not properly controlled, will adversely affect the robustness of the assays. We have applied our systems to study degradation of several different antisense oligonucleotides representing various chemistries used in oligonucleotide therapeutic agents to provide in-depth characterization and identification of the degradation products.

Michael R. DeFelippis, Ph.D.
Chair, USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee, and Chair, USP BIO1 Expert Committee

Michael R. De Felippis joined The Lilly Research Laboratories of Eli Lilly and Company in 1990 after obtaining his doctorate in biochemistry from The Ohio State University. He is currently a Distinguished Research Fellow in the Bioproduct Research and Development division. His work focuses on commercializing biopharmaceutical products with particular emphasis on characterizing physicochemical properties, devising control strategies, and preparing CMC-related documentation to support product licensure in global markets. Dr. DeFelippis has published manuscripts, review articles and book chapters on the subjects of protein and peptide structural characterization and formulation design/delivery strategies.

Presentation: Workshop Overview and Introduction to Session 1; Co-Moderator for Panel Discussion on Day 1

Gerhard Haas, Ph.D.
USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and Vice Chair, USP BIO1 Expert Committee

Gerhard Haas, Ph.D., is VP Quality Europe at Bachem. He joint Bachem in 1992 after his doctorate in organic chemistry at the University of Stuttgart, Germany. During his almost 30 years at Bachem in Switzerland and the U.S., he held various roles including R&D, Production, QC, QA, and RA thus acquiring a broad experience in all areas related to synthetic peptides.

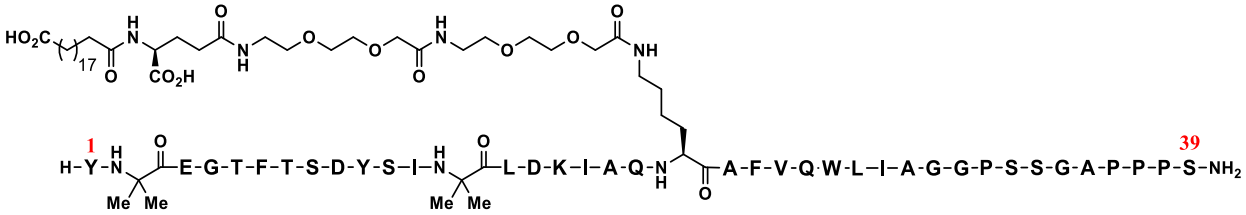
Presentation: Welcome to Session 3 and Highlights of Session 2; Co-Moderator for Panel Discussion on Day 3

Ankur Jalan, Ph.D.
Research Scientist
Eli Lilly and Company

Ankur Jalan joined the Synthetic Molecule Design and Development (SMDD) as a Research Scientist in December 2019, after spending 14 months as a post-doctoral scientist in the peptide group in the SMDD. He graduated with a Bachelor of Pharmacy from India and then pursued a Ph.D. in Organic Chemistry from Steven Castle's lab at Brigham Young University, Utah. During his Ph.D., he worked on the total synthesis of a natural anti-cancer peptide Yaku'amide A, solid phase peptide syntheses of bulky *α,β*-dehydroamino acids containing *β*-hairpins, and synthetic methodology development. At Eli Lilly, he is working on the convergent hybrid solid phase/liquid phase syntheses of peptides. He is also developing greener and sustainable convergent hybrid methods for the synthesis of peptides, which have immense potential for improving peptide yields and reducing organic waste.

Presentation: Synthesis of Tirzepatide by Native Chemical Ligation (NCL), a Once-weekly dual GIP and GLP-1 Receptor Agonist

ABSTRACT: Tirzepatide, a 39-amino acid synthetic peptide, is a once-weekly novel dual GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like-peptide-1) receptor agonist. Tirzepatide is in phase 3 clinical development at Eli Lilly and Company for blood glucose management in adults with type 2 diabetes, chronic weight management, and for obesity related heart failure with preserved ejection fraction. In addition, Tirzepatide is being studied as a potential treatment for non-alcoholic steatohepatitis (NASH). The Tirzepatide sequence consists of a 39 amino acid peptide backbone containing the non-coded amino acid aminoisobutyric acid (Aib) in two positions, a C-terminus amide, as well as a C20 fatty acid moiety covalently attached at lysine 20.



Many challenges exist in developing reliable processes to manufacture high volume complex synthetic peptides due to inherent limitations of Solid Phase Peptide Synthesis (SPPS) and Liquid Phase Peptide Synthesis (SPPS). These challenges were overcome by developing a four fragment Hybrid SPPS/LPPS process which takes advantage of the best features of both synthetic strategies. Though the convergent hybrid synthesis strategy is a very appealing substitute to the linear SPPS, there is a need in the peptide industry for more efficient and greener hybrid syntheses. Native chemical ligation (NCL) is a powerful methodology to synthesize large polypeptides and proteins utilized in academia, but to date does not have any known commercial implementations. Herein, we have developed an NCL synthesis for Tirzepatide where two unprotected peptide fragments are coupled in aqueous media without any epimerization. The tandem chemoselective fragment ligation / desulfurization approach is potentially the greenest of all hybrid approaches to produce a synthetic peptide.

Hong Jiang
Head of Analytical Development for Antisense Oligonucleotides
Biogen

Hong is the Head of Analytical Development for Antisense Oligonucleotides at Biogen. Before joining Biogen in 2016, she held positions at Wyeth BioPharma and Novartis Institutes for BioMedical Research, where she worked in protein drug formulation, small molecule drug metabolism, and method development for multiple modalities.

Presentation: Antisense Oligonucleotide Specification and Release Tests using a Risk-Based Platform Approach

ABSTRACT: The establishment of appropriate specifications and release tests for drug substance and product is a crucial part of an analytical control strategy to support the manufacturing of pharmaceuticals. Antisense oligonucleotides (ASO) drugs are synthetic polymeric molecules that share many important attributes with pharmaceuticals. Without a formal regulatory guideline specifically written for oligonucleotides, a risk-based platform control strategy can be formed by following the general CMC principles and related guidance for both small molecule and biologics. The focus of this talk will be using a risk-based platform strategy to set the DS and DP specifications and select the appropriate release tests, while considerations for other related aspects will be discussed.

Xiaohui (Jeff) Jiang, Ph.D.
President
The Sweetwood Group, LLC

Jeff Jiang is the President of The Sweetwood Group LLC, which is a consulting firm providing regulatory and technical service to clients in pharmaceutical industry. Before working the consulting business, Dr. Jiang was a Deputy Division Director in the Office of Research and Standards under the Office of Generic Drugs, in CDER, U.S. FDA. His work at the FDA was focused on complex generic drugs to develop and implement novel scientific methods for establishing active ingredient sameness, pharmaceutical equivalence, and bioequivalence for generic drugs. Dr. Jiang's work at the FDA resulted in published FDA guidance such as Conjugated Estrogens

Tablets and the ANDA peptide guidance, as well as generic drug approvals including Glatiramer Acetate Injection, Sevelamer and Colesevelam Suspension and Tablets. Prior joining the FDA, Dr. Jiang worked in biopharmaceutical industry and government agencies.

Presentation: Considerations of Comparative Studies for Complex Synthetic Peptide Products

ABSTRACT: During the development of complex generic peptide products, the amount of comparative studies required by the FDA have been on an upward trend in recent years. It has been a challenge for generic applicants to plan such studies prior to the initial product development. As a result, upon receiving ANDA review feedbacks from the FDA, applicants may have to produce additional batches of the proposed products and acquire more RLD batches to perform the additionally required comparative studies. This inevitably causes significant delays in regulatory approval.
The proposed drug product and the RLD product in finished dosage form are usually used in comparative studies. Under certain situations, compendial standards (e.g., USP standards) may serve as the comparator. The purposes of such studies can be categorized as establishing the identity of the active ingredient, comparing impurity profiles, and demonstrating comparable properties of the proposed and the RLD products. There are certain pitfalls that applicants should be aware of and try to avoid in planning, along with performing, such comparative studies. These potential issues may include, but are not limited to, batch selection, sample manipulation, study time point, and data analysis. The presentation will provide an overview on comparative studies used in the development of complex peptide products and recommendations on how to plan such studies ahead of time.

Tobias Kapp, Ph.D.
Bachem AG

Tobias Kapp joined Bachem in 2016. Since then he held different positions in process research, chemical development and manufacturing at the site in Bubendorf, CH.

In his current position as Director Research and Development, he is responsible for leading and coordinating manufacturing and process development activities for costumer projects in the field of peptide APIs. The projects he is involved in range from early development up to late development stage. One of his core competencies is the introduction of adequate control strategies for starting material related and process related impurities, tailored to the corresponding development stage.

Presentation: Vendor Selection for Unusual Amino Acid Derivatives

ABSTRACT: Starting material quality is critical for the final API quality. For the synthesis of therapeutic peptides, the normal proteinogenic Fmoc amino acid derivatives are readily available as starting materials in excellent quality. However, this is not necessarily the case for unnatural amino acid derivatives that are not routinely produced in large quantities. In addition to material quality, other aspects such as vendor sustainability, manufacturing capability, lead times, etc. are also important. Hence, just going for the highest material purity is not the best idea and analytical testing is not sufficient to select the material of choice.
A case study will be presented for the evaluation and selection of manufacturers for unnatural amino acid derivatives. Starting materials from different manufacturers will be compared based on their impurity profiles and the results in a product specific use test, covering all stages of the manufacturing process. Critical impurities are distinguished from non-critical impurities based on their potential to generate API impurities that cannot be purged during the peptide manufacturing process.

Maura Kibbey, Ph.D.
Senior Scientific Fellow, Global Biologics
USP

Dr. Maura Kibbey is Senior Scientific Fellow for Education and Training in USP's Global Biologics Department. Dr. Kibbey collaborates with scientific experts and trainers to bring more educational offerings to USP's biologics stakeholders. Previously, Maura directed a team of liaisons working with the five USP Expert Committees and multiple Expert Panels for biologics, peptides, and antibiotics to develop standards that support biopharmaceutical quality assessment and development. Before joining USP, Dr. Kibbey worked for several biotechnology and diagnostic companies in the Washington DC area as well as at the National Institutes of Health. Her scientific expertise includes development and validation of many different assay types for measurement of individual molecules, their activities, or binding interactions. She has published over 40 peer-reviewed articles and has been an invited speaker or workshop organizer for numerous scientific conferences.

Presentation: USP Welcome

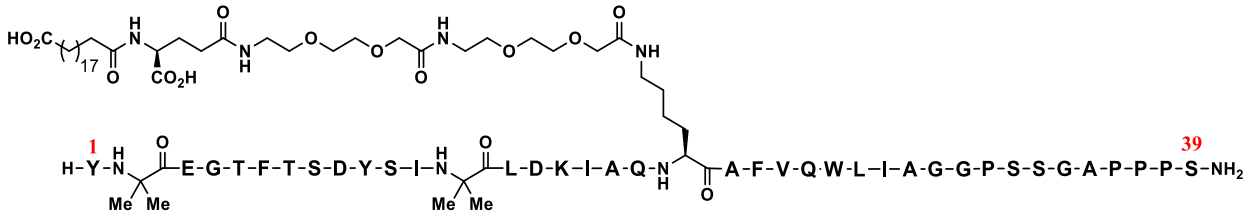
Michael E. Kopach, Ph.D
Senior Research Advisor
Eli Lilly and Company

Mike earned a Ph. D. in Organic chemistry from the University of Virginia in 1995 under the guidance of Prof. W.D. Harman. He then completed postdoctoral studies in natural product synthesis at Colorado State University with Prof. A. I. Meyers. Mike began his industrial career in 1997 at Roche where his primary responsibilities included development and implementation of commercial processes for Nelfinavir, Xenical and Enfuvirtide - the first synthetic peptide produced on tonnage scale. In 2001, Mike joined Eli Lilly and Company and has led several small molecule API projects including Olumiant, an important Rheumatoid Arthritis drug which launched in 2017 and is currently being evaluated as a Covid 19 treatment. After a fourteen year career within Lilly Small Molecule R&D, Mike helped established a synthetic peptide division at Lilly, and is leading efforts to advance sustainability practices in this important discipline which is a critical unmet need. Throughout his industrial career Mike has led research teams applying green chemistry principles to process research and development, and has published several collaborative articles in this field. For over the past decade Mike has represented Eli Lilly and Company at the ACS Green Chemistry Institute® Pharmaceutical Roundtable including serving two year terms as co-chair from 2011-2013 and another from 2017 - 2019. Mike was been very active helping grow the Roundtable to > 35 companies and adding new modalities such as Peptides and Oligonucleotides as critical areas of focus.

Presentation: Synthesis of Tirzepatide by Native Chemical Ligation (NCL), a Once-weekly dual GIP and GLP-1 Receptor Agonist

ABSTRACT: Tirzepatide, a 39-amino acid synthetic peptide, is a once-weekly novel dual GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like-peptide-1) receptor agonist. Tirzepatide is in phase 3 clinical development at Eli Lilly and Company for blood glucose management in adults with type 2 diabetes, chronic weight management, and for obesity related heart failure with preserved ejection

fraction. In addition, Tirzepatide is being studied as a potential treatment for non-alcoholic steatohepatitis (NASH). The Tirzepatide sequence consists of a 39 amino acid peptide backbone containing the non-coded amino acid aminoisobutyric acid (Aib) in two positions, a C-terminus amide, as well as a C20 fatty acid moiety covalently attached at lysine 20.



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Marc Lemaitre, Ph.D.
USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and USP BIO1 Expert Committee member

Marc Lemaître holds a degree in Organic Chemistry and a PhD in Biochemistry from the University of Liège, Belgium. Since 1985 Marc's professional interests has been the study of Nucleic Acids and therapeutic as well as diagnostic applications. After 5 years of post-doc research including 2 years at the Pasteur institute in the team of Nobel Prize Luc Montagnier, Marc held positions of increasing seniority in R&D, operations, business development, and general management within CMO's, Pharma and Biotech companies.
Based in the USA since 2006 he worked for Glen Research [Sterling, VA], then as CEO of Girindus America [Cincinnati, OH], a CMO with a focus on the cGMP manufacture of oligonucleotides for therapeutic applications.

Since 2013 Marc is working as independent consultant specialized in CMC and working mostly with start-up and Pharma companies developing therapeutic oligonucleotides and some peptides.
He is member of the Board of Director of the Oligonucleotide Therapeutics Society since 2015 – treasurer 2015-2018.

Presentation: Welcome to Session 2 and Highlights of Session 1

Rosario LoBrutto
Head of Scientific Affairs
Sandoz, Inc. (A Novartis Division)

Rosario has 25 years of experience in driving R&D, commercial, and operational excellence in development, scale-up and launch preparation of generic/branded products at Merck, Novartis, TEVA and Sandoz. This includes development of APIs/drug products containing small molecules, synthetic polypeptides and proteins and drug-device combination products. Currently at Sandoz he is Head of Scientific Affairs responsible for external partnership product development and oversees due diligence evaluating CMC/bio-analytical aspects of new product opportunities amenable to co-development, in-licensing or acquisition. Moreover, he advances pipeline strategy and leads team for identification, evaluation and prioritization of internal/external assets.

Presentation: Co-Moderator for Panel Discussion on Day 2

Lawrence Perez, Ph.D.
Senior Reviewer
Center for Drug Evaluation and Research, US FDA

Lawrence Perez has been a CMC Reviewer for Office of Pharmaceutical Quality within the FDA since 2015. Before that, Lawrence was a medicinal chemist with Novartis Oncology. Lawrence has been active in the areas of pharmaceutical regulations and drug discovery, with his most notable work being the discovery and development of the oncology drug Farydak®.

Presentation: CMC and Regulatory Challenges for Oligonucleotide Drugs
ABSTRACT: Oligonucleotide drugs are a special class of therapeutics that are not explicitly cover by the regulatory and CMC guidances that cover low molecular weight therapeutics. This presentation will discuss some of the regulatory challenges for synthetic oligonucleotides seen in INDs and NDAs. In particular, the CMC issues for Manufacturing, Characterization and Control of Drug Substance will be discussed.

Christopher A Rhodes, Ph.D.
President & CEO
Drug Delivery Experts

Chris has extensive formulation and drug delivery experience and is the CEO of Drug Delivery Experts, which he founded in 2014. He played a significant role in the development of the products Byetta and Bydureon (injectable and exenatide microsphere), Myalept (leptin protein), Afrezza (inhaled insulin), and Lusedra (propofol prodrug).

Presentation: Drug Delivery Systems and Life Cycle Management for Peptides Beyond the Vial and Syringe
ABSTRACT: There are an abundant number of examples of commercial peptides in lyophilized powder or aqueous solution format and some peptides in nasal, pulmonary, and

long-acting systems. This talk will provide an orientation to the potential formulation and product options beyond the vial and syringe, and will outline the options, the challenges, and the successes to bring the audience a good high level understanding of how to proceed forward.

Heiko Rinderhagen, Ph.D.
Head of Analytical Research and Development
Janssen-Cilag AG

Heiko Rinderhagen joined the pharmaceutical development of Johnson &Johnson in 2003. Since then he held different positions in chemical as well as in analytical development.

He is currently responsible for leading the analytical development of the Schaffhausen R&D group in Switzerland. His work focuses CMC small molecule and peptide process development in early as well is in late stage development with core competencies in analytical development in support process development: method development, high end analytical sciences and definition of control strategies in line with cGMPs and international guidelines.

He is also a member of the EDQM/EP expert group on Non biological complexes.

Presentation: Vendor Selection for Unusual Amino Acid Derivatives

ABSTRACT: Starting material quality is critical for the final API quality. For the synthesis of therapeutic peptides, the normal proteinogenic Fmoc amino acid derivatives are readily available as starting materials in excellent quality. However, this is not necessarily the case for unnatural amino acid derivatives that are not routinely produced in large quantities. In addition to material quality, other aspects such as vendor sustainability, manufacturing capability, lead times, etc. are also important. Hence, just going for the highest material purity is not the best idea and analytical testing is not sufficient to select the material of choice.
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Brian Rivera
Senior Product Manager
Phenomenex

Brian Rivera is a Senior Product Manager at Phenomenex, with over 15 years in HPLC analysis of large molecules. Before joining Phenomenex, his previous industry experience includes positions at Chiron Corporation (now Novartis), ProZyme (now Agilent), and Avid Bioservices, performing protein purification as well as analytical methods development and in-process analytical support. His primary focus was on protein characterization by size exclusion, glycan mapping, and intact reversed phase HPLC methods.

He has a Bachelor's Degree from the University of California, Davis.

Presentation: Method Development for the Characterization of Synthetic Oligonucleotides by LC-MS

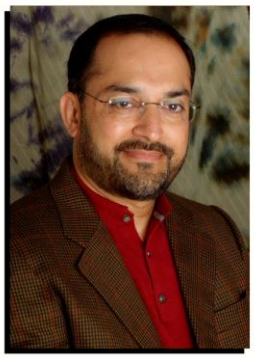
ABSTRACT: The primary method for quantitation and characterization of synthetic oligonucleotides is ion-pair reversed phase liquid chromatography (IP-RPLC). Mobile phase composition is typically an alkylamine such as triethylamine (TEA) and perfluorinated alcohol such as hexafluoroisopropanol (HFIP), with methanol as the strong solvent. In this presentation, we will demonstrate the impact of mobile phase optimization on chromatographic separation and MS sensitivity and spectral quality. Additionally, we will look into how temperature and flow-rate can impact oligo separations.

Alfred Ross, Ph.D.
Senior Principal Scientist – NMR Analytics, pCMC
Roche Innovation Center Basel

After studying Physics and Biology Alfred Ross moved into the field of the determination of structures of proteins by use of NMR spectroscopy. He obtained his PHD at the Max Planck Institute for Biochemistry in Martinsried/Munich and continued his scientific career as a postdoctoral fellow at the University of New South Wales (Sydney, Australia) where he applied NMR in the field of Oligonucleotides. Since 1997 Alfred Ross is with Hofmann La Roche in Switzerland, where he uses NMR for a broad range of applications including Biostructure, Metabonomics, support for development of formulations and processes as well as Analytical Chemistry of Counterfeits and Complaints of marketed drugs. Since recently, solid-state NMR completes this broad range of experiences. Since the introduction of therapeutic oligonucleotides at Roche in 2009 Alfred Ross uses methods of NMR spectroscopy also for this type of molecules to characterize structure, chemical modifications and dynamic behavior. Beginning with 2016 Alfred Ross is part of the analytics section in the pCMC organization of Roche.

Presentation: Application of NMR Spectroscopy for Characterization and Identity Testing of Oligonucleotide Drug Molecules

ABSTRACT: With recent introduction of several new Oligonucleotide based drugs to the market, an increased need for high quality analytics to support the process of registration emerged. This requires an in-depth understanding of the chemical structure of the final molecule. Here we provide examples on how NMR spectroscopy is used in our laboratory to support the chemical synthesis of Oligonucleotides by use of regular and chemically modified monomer building blocks. Additionally, we demonstrate how NMR based fingerprinting is used for confirmation of structural integrity and identity of such complex molecules which are often present as diasteriomeric mixtures. Finally, we provide an example for the application of quantitative NMR (qNMR) for definition of reference standards needed for UV-based quantitative analysis (e.g. Chromatography). Limitations of the method will be discussed.



Yogesh S. Sanghvi, Ph.D.
President
Rasayan Inc.

In 1981, Dr. Sanghvi received his Ph.D. in organic chemistry from National Chemical Laboratory (Pune, India), where he worked on the synthesis of natural products. From 1982 – 1985, his post-doctoral research on the synthesis of modified nucleosides was carried out at University of London with Professor C.B. Reese. In 1986, he joined the Nucleic Acids Research Institute at ICN Pharmaceuticals, California. At ICN, he was involved in the design, synthesis and screening of novel nucleosides and nucleotides as antiviral and antitumor agents. From 1989 – 2003, he worked at Isis Pharmaceuticals, California. The focus of his research at Isis has been on the discovery, development and manufacture of oligonucleotide-based therapeutics, DNA and RNA modifications in combinatorial and diagnostic research.

Dr. Sanghvi have authored/co-authored over 190 scientific publications in leading journals, including several book chapters and have inventorship/co-inventorship of more than 30 patents. Throughout his professional history, he has attended and made numerous presentations at local and international scientific meetings and have successfully organized several symposiums. He is an editor of ACS book entitled *Carbohydrate Modifications in Antisense Research* and an Elsevier book entitled *Palladium-Catalyzed Modification of Nucleosides, Nucleotides and Oligonucleotides*.

In 2003, he founded Rasayan Inc., a company focused on the consulting, outsourcing services and supply of products related to nucleic acid field. Rasayan is engaged in the strategic planning, securing raw materials for manufacture of oligonucleotide-based drugs on large-scale, experimental design, optimization of synthesis and purification protocols on lab scale to kilo scale, including process chemistry. He is also founder of Sapala Organics, a CRO located in Hyderabad, India. His specific interests include design, synthesis, chemistry and biochemistry of novel carbohydrates, nucleosides, nucleotides, and oligonucleotides for their application in therapeutics, combinatorial chemistry and medical diagnostic research.

Presentation: Applications of Green Chemistry in Oligonucleotide Manufacturing
ABSTRACT: Processes that provide economical, safe, and green access to chemically modified oligonucleotides is of paramount importance in the manufacturing of therapeutic drugs. So far, ten oligonucleotides have been approved by the US FDA and over hundred products are undergoing human clinical trials. To support the anticipated large-scale commercial demand of these molecules, we have developed improved synthetic methodologies following the twelve principles of green chemistry. This presentation will summarize our efforts in enabling environmentally friendly chemistry.

Ved Srivastava, Ph.D.
Member of USP's Biologics Monographs 1 – Peptides Expert Committee

Dr. Ved Srivastava is Vice President of Chemistry at Intarcia Therapeutics at North Carolina, USA; and is the President of the American Peptide Society. Prior to that, he was the Head of Peptide Chemistry at GlaxoSmithKline (USA), and in the senior leadership role at Amylin Pharmaceuticals (Astra Zeneca, USA). He

co-founded, Phoundry Pharmaceuticals, a biotech company focused on the discovery of peptide hormone therapeutics. Phoundry was acquired by Intarcia Therapeutics in 2015.

Ved has over 25 years of experience with expertise in drug discovery and development in the area of metabolic diseases, CNS, and inflammation with major emphasis in peptide medicinal chemistry, chemistry manufacturing and control (CMC) and peptide drug delivery. Ved has participated in the development and commercialization of Symlin™, Byetta™ and Bydeureon™ first-in-class medicines for the treatment of diabetes.

Ved is the Editor of four peptide books (1) *Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls, (2) Peptide-based Drug Discovery: Challenges and New Therapeutics, (3) 'Comprehensive Medicinal Chemistry III, Volume 6, Biologics Medicine and* (4) *'Peptide 2015'*.

Ved is also a member of the BIO1- Peptides & Insulins Expert Committee. He earned a Ph.D. in organic chemistry from the University of Lucknow, India; and had subsequent postdoctoral appointments at the University of Georgia and the University of Colorado Medical School.

Presentation: Co-Moderator for Panel Discussion on Day 3

Jessica Stolee, Ph.D.
Director of Asset Development and Portfolio Management
Biogen

Dr. Stolee is a Director of Asset Development and Portfolio Management at Biogen, a Massachusetts-based biotechnology company focused on neurological diseases. She is responsible for end-to-end CMC development, supply, and life cycle management planning for mid to late-stage small molecule programs. In past roles, she led groups in Analytical Development supporting the small molecule and oligonucleotide pipeline (R2D through commercialization). Dr. Stolee was one of the primary authors of the CMC portion of Biogen's first oligonucleotide NDA (Spinraza). She received her Ph.D. in Chemistry from George Washington University where her work focused on the development of novel ionization methods for mass spectrometry.

Presentation: Co-Moderator for Panel Discussion on Day 2

René Thürmer, Ph.D.
CMC reviewer and is Deputy Head of the Unit Pharmaceutical Biotechnology
BfArM - Federal Institute for Drugs and Medical Devices, Germany

Dr. René Thürmer received his diploma in chemistry and his Ph.D. in biochemistry from the University of Tübingen. He joined the BfArM (Federal Institute for Drugs and Medical Devices, Bonn, Germany) in 2000. He currently serves as a CMC reviewer and is Deputy Head of the Unit Pharmaceutical Biotechnology.

His experience is in the field of formulation, manufacture and control of medicinal products, in particular in the field of oligonucleotides, peptides, proteins, liposomes, sustained release polymer drug products,

depot formulations, polymer-conjugated drug products, natural and synthetic surfactants, nanomedicine and others.

Presentation: CMC Regulatory Considerations for Oligonucleotides and Peptides: Similarities and Differences

ABSTRACT: This presentation will provide an overview what can oligonucleotide and peptide developers learn from each other in their regulatory experiences, regardless of whether they are working on an oligonucleotide or a peptide. Common CMC issues that face both groups will be highlighted and experiences from recent regulatory submissions will be discussed.

Michael S.Verlander, D.Phil.
Member of USP's Biologics Monographs 1 – Peptides Expert Committee and Chair of USP Expert Panel for Glatiramer Acetate.

Dr. Verlander is currently acting as an independent consultant supporting the pharmaceutical industry in the areas of quality and regulatory compliance; he also serves as a member of USP's Biologics Monographs 1 – Peptides Expert Committee and is currently chair of a USP Expert Panel for Glatiramer Acetate. Prior to this, he served as President of PolyPeptide Laboratories San Diego, a part of the PolyPeptide Group, from 2009-2013. He was previously Executive Vice President and co-founder of PolyPeptide Laboratories, Inc., in Torrance, California, a position he held since 1996. During his tenure, he had responsibility for Quality Assurance and Regulatory Affairs, served as Director of Global Quality Assurance and Regulatory Affairs for the PolyPeptide Group from 2003 to 2009, and guided the Group's sites through numerous successful facility inspections by FDA in both the US and Europe. He was also involved in the design, construction and start-up of a new PolyPeptide Group manufacturing facility for peptide APIs in India.

Prior to joining PolyPeptide Laboratories, Inc., Dr. Verlander was Vice President, Technical and Regulatory Affairs at Bachem California, Torrance, California (1986 – 1996); Director, Peptide Research and Peptide Production, Immunetech Pharmaceuticals, San Diego, California (1985 – 1986); and Research Director, BioResearch, Inc., San Diego, California (1978 – 1985). He was previously a member of the research faculty at the University of California, San Diego, Department of Chemistry (1972 – 1978), after completing his postdoctoral training at the Salk Institute for Biological Studies, La Jolla, California, and his graduate and undergraduate training in Chemistry at the University of Oxford.

Presentation: Co-Moderator for Panel Discussion on Day 1