EXTRACTABLES & LEACHABLES WORKSHOP

July 4-5,2019 | Hyderabad

SPEAKERS PROFILE

Dr. Allan W. Ader

Managing Director, SafeBridge Consultants, Inc

Dr. Allan Ader is co-founder and Principal Toxicologist for SafeBridge Consultants, Inc., the premier resource for high level risk assessment, safety, health and environmental support to the biotechnology and pharmaceutical industry, located in Mountain View, CA. Dr. Ader has extensive experience in Developing Occupational Exposure Limits and assessing compounds for toxicity and potency for compound categorization / banding and recommending handling practices and controls based on the toxicity/potency characteristics , Assisting companies in testing of chemicals for their toxic effects and interpreting data from these tests, performing health-based risk assessments including evaluating toxicological and exposure information to determine potential health effects of chemicals, and responding to crises caused by occupational health illnesses from chemicals by assessing and evaluating risks and communicating them to employees and management. Dr. Ader has over 25 years of experience in the pharmaceutical and chemical industry including working for Syntex, Inc. in Palo Alto, CA and Olin Corporation, New Haven, CT. He received a Ph.D. in Industrial Health (Toxicology) from the University of Michigan and an M.S. in Industrial Hygiene from Temple University. He is a diplomat of the American Board of Toxicology.

Dr. Amarender R. Donthidi

Principal Scientist, Aurobindo Pharma

Dr. Amarender R Donthidi is a Principal Scientist heading an Injectable and Ophthalmic group in Aurobindo Pharma Ltd. Before joining Aurobindo, he was associated with Mylan Pharma during 2010 to 2017 as an Associate Director working mainly on Injectable drug products. He has worked with Teva and Reckitt Benckiser in UK. His experience includes formulation development of different conventional and complex dosage forms in Ophthalmic, Nasal, Inhalation and Oral drug products. He holds a doctorate degree from Glasgow Caledonian University, UK and a Master's and Bachelor's degree in pharmaceutical sciences from BITS Pilani and Kakatiya University respectively.

Dr. Andrew Feilden

Technical Director, Smither Rapra Ltd

Dr. Andrew Feilden is the Technical Director at Smithers Rapra and Smithers Pira where he leads the technical aspects of the chemistry department. Prior to that he was the chemistry operations director, for 6 years, where he lead the chemistry group at the Shawbury site in the UK. The Shawbury site carries out extractable and leachable testing, GPC analysis and food contact testing. He has delivered numerous international podium presentations on extractables and leachables. Andrew has been with Smithers for over 7 years, prior to that he worked for AstraZeneca, specialising in extractables and leachables. He has a degree and D Phil from the university of York, is a Fellow of the Royal Society of Chemistry and is a Scientific advisor to IPAC-RS

Dr. Atul K. Nalavade

Head – Analytical services GVS Cibatech Pvt. Ltd., Borosil Klasspack

Dr. Atul Nalavade is Head-Analytical services at GVS Cibatech Pvt. Ltd. GVS Cibatech has a dedicated USFDA registered analytical laboratory for extractables and leachables studies. Atul has a strong interest in analytical method development for extractables and leachables. He obtained his PhD in Chemistry from Gitam University with an emphasis on genotoxic impurities method development and validation in various drug molecules. Since 2012, Atul is involved in study design, analysis planning and consultation of extractables and leachables studies. He has performed for more than 150 studies on various dosage forms, process components and medical devices with major focus on Parentarals. Atul has overall experience of 17 years and prior to working with GVS Cibatech, he has worked with analytical research departments of Intertek, Macleods pharma and Ranbaxy research laboratories.

Dr. Bettine Boltres

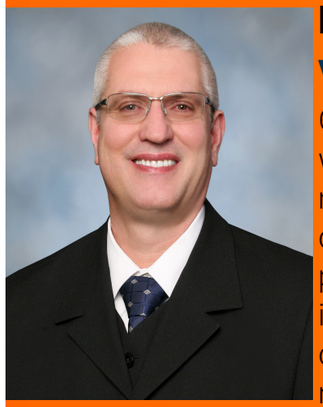
Principal Scientific Affairs, Packaging & Delivery Systems Scientific Affairs & Technical Customer Support Europe , West Pharmaceutical Services

As Principal Scientific Affairs, she is supporting the scientific exchange between West and the pharmaceutical industry. This is complementing her 7 years' work as Product Manager for Schott Pharmaceutical Tubing, where she provided scientific consulting for glass primary packaging.She has held numerous glass trainings at pharmaceutical companies, glass converters and universities. She is a frequent speaker at industry conferences and has chaired and moderated several conferences and technical training events for the PDA and other formats.She is also active in the PDA Glass Handling Task Force and co-chairing the European PDA Interest Group Packaging Science.A number of articles for several global magazines have been penned by her. In 2015 she published the book "When Glass Meets Pharma", which builds the bridge between glass for pharmaceutical primary packaging and drug substances. Since 2015 Bettine is an active member of the USP Packaging and Distribution Expert Committee as well as the ISO TC76/WG 4 on elastomers. Additionally, in 2018 joined the European Pharmacopoeia Commission Group of Experts 16 (elastomers and plastics) and the GLS Working Party (glass).Since January 2019 she is also a member of the PDA Board of Directors.Dr. Boltres is a (bio)chemist by training, receiving a diploma in chemistry from the university of Frankfurt, Germany and a PhD in biochemistry from the university of Cologne, Germany.

Dr. Desmond G. Hunt

Principal Scientific Liaison, USP

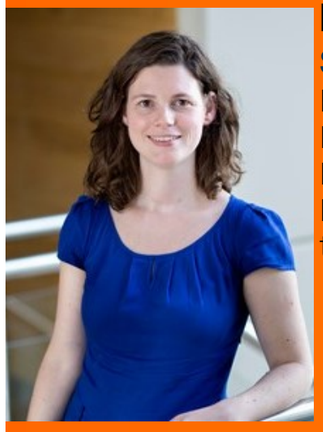
Dr. Desmond G. Hunt has been with USP since 2005 and holds the position of principal scientific liaison in the Compendial Science Group-General Chapters. He is the scientific liaison to the packaging and distribution and dosage forms expert committees, where he works to develop and revise USP Standards. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to pharmaceutical packaging, particulate matter in parenteral and ophthalmic dosage forms and good storage and transportation practices. He participates on several industry Working Groups and Technical Committees related to his areas of expertise. Dr. Hunt obtained his M.S. and Ph.D. from the University of Texas at Austin and prior to joining USP, was a Research Fellow at the National Institutes of Health, Bethesda, MD, USA



Dr. Gyorgy Vas

VasAnalytical , NJ ,USA

Gyorgy Vas has over 20 years of experience in scientific research and product development, and laboratory management. More than half of this time was spent in a cGMP environment, where that scientific expertise was applied to solve problems related to finished pharmaceutical products and medical devices. In his current position, he is advising regulatory filing strategy for multiple clients, and his group provides solutions for mitigate deficiency letters. He made significant achievement to implement state of the art solventless sample preparation techniques into the cGMP laboratory processes. Gyorgy is one of the few person in the field with expertise of method development and validation for ultratrace (parts-per-trillion) level impurities in finished pharmaceutical products and medical devices. He has developed and validated multiple analytical methods to detect and quantitate odor components at ultratrace level from finished pharmaceutical products and also developed and validated analytical and extraction methods, which uses very special extraction techniques to detect very low level leachable components from medical devices. Gyorgy Vas did his M.sc in analytical Chemistry from University of Kossuth, Debrecen, Hungary and Ph.D in Mass Spectrometry from University of Eotvos, Budapest Hungary. He was chair of American Society for Mass Spectrometry in 2014-2015 and is a coordinator of cGMP Instrument Qualification workgroup also at American Society for Mass Spectrometry



Karen Pieters,Ir.

Study Director, Nelson Labs

Karen graduated as a bio-engineer in chemistry in 2006. After graduation, she worked for three years as a Quality Document Expert at Merck, Sharp & Dohme (MSD), gaining experience in the regulatory and analytical challenges of pharmaceutical industry. At 2010, Karen started working at Toxikon Europe, now known as Nelson Labs, as a study director for different applications.. She is now responsible for a team of Study Directors with a focus on Large Volume Parenterals, Ophthalmics and Disposables. She has presented on the set-up and challenges of extractables and leachables studies for these applications at several international conferences.

Dr. Prasanna K Devaraneni

Principal Scientist, Lupin Biotech Ltd

Dr. Prasanna K Devaraneni is working as principal scientist in formulation development at Lupin Biotech Ltd., Pune. He received Ph.D. in Biotechnology from School of Biotechnology, Jawaharlal Nehru University, New Delhi, for his work on thermal stability of multi domain proteins. He did his post doctoral work at Oregon Health Sciences University, Portland, OR, USA, working on fundamental mechanisms of protein translocation across the ER membrane, folding, assembly and co-assembly of potassium channels. He has published research articles on various topics of protein chemistry.

Sougata Pramanick

Senior Director, Compliance & Scientific Affairs, Emcure Pharmaceuticals

Sougata Pramanick obtained a Bachelor's Degree in Pharmacy from BIT, Mesra and a Master's degree from the Indian Institute of Technology, Varanasi (IIT-BHU). Professionally he has worked in Formulation R&Ds of various pharma majors of India including Dr Reddy's, Parke Davis (India), FDC, Zydus Cadila, Torrent and Strides Arcolab in the last 20+ years. He has been involved in the formulation of conventional and modified release solid oral dosage forms, Meltrex tabs, Oral emulsions, Dispersed Injectables (Suspensions/emulsions/nanoparticles), Lyo parenterals, Onco products, Ophthalmic products, Para IV ANDAs, etc. He has a dozen of US and PCT patent filings to his name. In Emcure he has personally steered 100+ ANDA submissions and has initiated NDDS in parenterals. He is currently responsible for the Quality Management System at Emcure. He oversees the audits (Internal & External) and prospectively verifies compliance to established laws, regulations, DI policy and company procedures. He is a member of the PDA.

Stijn Palmers

Study Director, Nelson Labs

Stijn Palmers graduated in 2011 as master in bioscience engineering, with a specialization in food technology. In 2016, he completed a PhD at Leuven University in Belgium on the production of safe and high quality foods for the consumer. During his research, he got acquainted with the inside and outside of analytical techniques like gas chromatography and liquid chromatography. This analytical expertise was further developed at Nelson Labs, where he works now as a study director specialized in extractables and leachables studies for parenteral applications such as prefilled syringes and vials (often rubber materials).

Dr. V. Srinivasarao

Head & Principal Scientist, Lupin Ltd

Dr. V. Srinivasa Rao has 18 years of Research experience and possesses more than 11 years of professional experience in the field of Analytical Research and Development in the pharmaceutical industry. He has been working extensively for more than 10 years in the field of extractable and leachables and addressed various regulatory queries related to E&L for various drug product i.e extractables testing of closer container systems, medical devices and manufacturing materials. He has also authored white papers to evaluate impact of a change on extractables using a risk based approach submitted to USFDA. Dr Rao also supported various organizations to establish E&L laboratory from grass route. Dr. Rao has published 78 papers in national and international journals on different research work including extractable & leachables and genotoxic impurities. He has been involved in more than 380 genotoxic impurities in method development and validations. He is an expert in analytical method development and validation from starting KSM to finished product in API and formulation projects. For his contribution in the field of analytical work, he has received various awards like "The Bio Contribute award for excellence in Process Excellence & cost Efficiency/Quality first and Teamwork/People excellence for contribution towards implementation of operational excellence initiatives at BGRC in 2016. He also got recognition award for being a Shastrakaushal (Researcher) at BGRC in 2017.Dr. Rao did his PhD from S.R.TM University, Andhra Pradesh