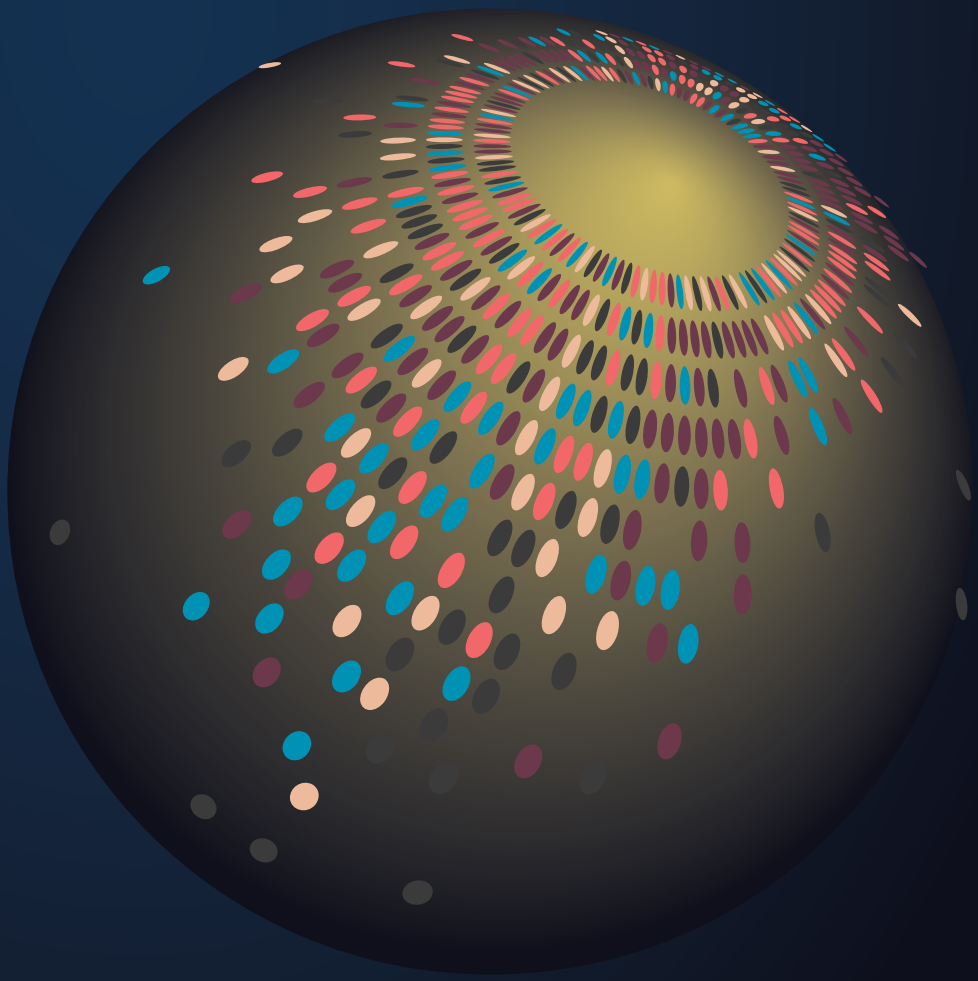
The Ever-Changing World of Extractables & Leachables Part 2

A free virtual conference

Feb 24th 2021: 3pm BST | 10am EDT | 4pm CEST



Hosted by

hallanalytical

VR ANALYTICAL

Sponsored by

PerkinElmer®
For the Better

The ever-changing world of extractables and leachables virtual conference. Part 2.

Join global industry and regulatory experts as they discuss E&L hot topics on pharmaceuticals, biopharmaceuticals and medical devices.
Extractables and leachables are important considerations in the production of medical devices and medicinal products. While COVID-19 is around, new ventilators and delivery devices for vaccines require urgent testing.
This conference offers insight into this ever-changing world of E&L.

Conference Running Order (times in GMT)

Presentations last 25 minutes and each will include a live Q&A.

15:00 **Introduction from Moderator**

15:05 **Dennis Jenke, Ph.D., Triad Scientific Solutions**
"Are you Managing the AET or is it Managing You?"

15:30 **Douglas J. Ball, MS, DABT, Managing Partner and Toxicology Consultant, D&B ChemTox, LLC**
"PQRI Best Practices: Use of a Classification Strategy to Develop Safety Thresholds for Leachables in Parenteral Drug Products"

15:55 **William P. Beierschmitt, Ph.D., DABT, FATS, DABT, Managing Partner and Toxicology Expert, D&B ChemTox, LLC**
"Toxicological Risk Assessment of Extractables & Leachables"

16:20 **5 minute break**

16:25 **James Hathcock, Ph.D., Sr. Director, Regulatory and Validation Strategy, Pall Biotech**
"Selection and Qualification of Bioprocess Single-Use Systems using Standardized Data. What to Check and When to Test."

16:50 **Aaron Hineman, Inorganic Product Line Leaders – Americas, PerkinElmer**
"The Evolution of ICP-MS Technology in Low-Level Elemental Impurity Analysis"

17:15 **5 minute break**

17:20 **Nick Morley, Principal Scientist, Hall Analytical Laboratories, LTD**
"Can we achieve certainty in these uncertain times (at least in the world of E&L)? "

17:45 **Ron Brown, Ph.D., Toxicology Consultant, Risk Science Consortium, LLC**
"How to Address Toxicological Uncertainty During the Derivation of PDE/TI Values"

18:10 **Final remarks from Moderator and Close**

Speakers

Dennis Jenke,
Chief Executive Scientist, Triad Scientific Solutions, LLC

Dr. Dennis Jenke is the Chief Executive Scientist at Triad Scientific Solutions, LLC, a consulting organization that provides the pharmaceutical, cosmetic, food and related industries with integrated, science-based, and practical solutions to suitability for use challenges for packaging, manufacturing components and systems, and administration devices. Prior to his position at Triad, Dr. Jenke was a Baxter Distinguished Scientist at Baxter Healthcare Corporation for nearly 35 years where his primary responsibilities included assessing material/product compatibility, specifically establishing the suitability for use of packaging systems, manufacturing systems and administration devices for pharmaceutical products (for example, leachables/extractables and product ingredient binding).
Dr. Jenke is a member of numerous industry groups whose charter is to establish best demonstrated practices in the area of material/solution compatibility.

Douglas J Ball, MS, DABT
Managing Partner &Toxicologist, D&B ChemTox, LLC

Doug obtained his BS and MS in Biology from St. John's University, Jamaica, NY and is board certified in general toxicology (DABT). Doug is a full member of the American College of Toxicology (ACT), Society of Toxicology (SOT) and has served as President, Vice President and Secretary/Treasurer for the Northeast Chapter of SOT (NESOT). Doug was previously employed as a toxicologist at Sandoz (now Novartis), Boehringer Ingelheim, and Pfizer. Over the past 40 years, Doug has assumed various project and regulatory strategy roles and is currently a Managing Partner and Toxicologist at D&B ChemTox, LLC.
Doug is a recognized expert in the evaluation and qualification of leachables and extractables (L&E) in drug products.

William Beierschmitt
Managing Partner &Toxicologist, D&B ChemTox, LLC

Dr. William Beierschmitt received his B.S. in Biology from Mount Saint Mary's University, and his Ph.D. in Toxicology from the University of Maryland. After completing post-doctoral work at the University of Connecticut Toxicology Program, he began a 30-year career in Pfizer's Drug Safety Research and Development department in Groton, Connecticut. While at Pfizer, Bill founded and lead a group that provided chemical risk assessment support to all the company's global research and develop sites and manufacturing facilities. Currently, Bill is a Managing Partner and Toxicologist at D&B ChemTox, LLC, a consulting group specializing in the safety qualification of chemical impurities in pharmaceutical products.

James Hathcock, PhD
Sr Director, Regulatory and Validation Strategy,
Pall Biotech

James Hathcock, PhD is Senior Director of Regulatory and Validation Strategy at Pall Biotech, which includes responsibility for E&L characterization strategy to support the safe and successful end-user implementation of technologies enabling pharmaceutical manufacturing. He leads the BPSA imitative on X-ray qualification for single-use disposables and is an active member of ASTM, ASME-BPE, PDA, ISPE, BPSA, Biophorum-supplier phorum as well a USP <665> expert panel member. Since joining Pall in 2008, James has led chemical and performance characterization of medical and biotech components, as well as relevant technical packages supporting regulatory filings. Prior to joining Pall, James served as professor of hematology at the Mt. Sinai School of Medicine in New York City, where he directed the protein purification laboratory related to drug characterization and discovery.

Aaron Hineman.
Inorganic Product Line Leader-Americas.
Perkin Elmer, Inc.

Aaron Hineman is curretly the Inorganic Product Line Leader for the Americas. Prior to this position he was a Senior Field Application Scientist with PerkinElmer. Aaron has a strong background in inorganic analytical chemistry including demonstrated hands-on expertise in state of the art ICP-MS and ICP-OES instrumentation, hyphenated speciation using chromatography coupled to ICP-MS, working in 21 CFR Part 11 compliant laboratories for elemental impurity analysis, and various microwave, acid and fusion sample preparation techniques. Prior to joining PerkinElmer he spent 10 years in environmental and geochemical laboratories developing analytical methodology and laboratory systems. His interests outside of work include snowboarding/skiing, obstacle races, biking, and running.

Nick Morley.
Principal Scientist. Hall Analytical.

Nick has over 12 years of experience in the field of extractables and leachables, both in large pharma and at a CRO. He is responsible for providing technical/ consultative support to new and existing customers in the field of E&L. Experience working on a range of products including pharmaceutical/biopharmaceutical (inhalation, topical and parenteral), medical device and nicotine delivery systems. Experienced in authoring successful regulatory files (BLA, NDA, MAA), performing leachable risk assessments and defining E&L testing strategies. Nick has lead workshops and given a number of presentations on the subject of E&L.
Nick has a BSc in Chemistry, is a BSI Committee member and British representative on the CEN (European standards Committee) working group for extractables and leachables of Electronic Cigarettes & E-liquids.

Ron Brown. Risk Science Consortium.

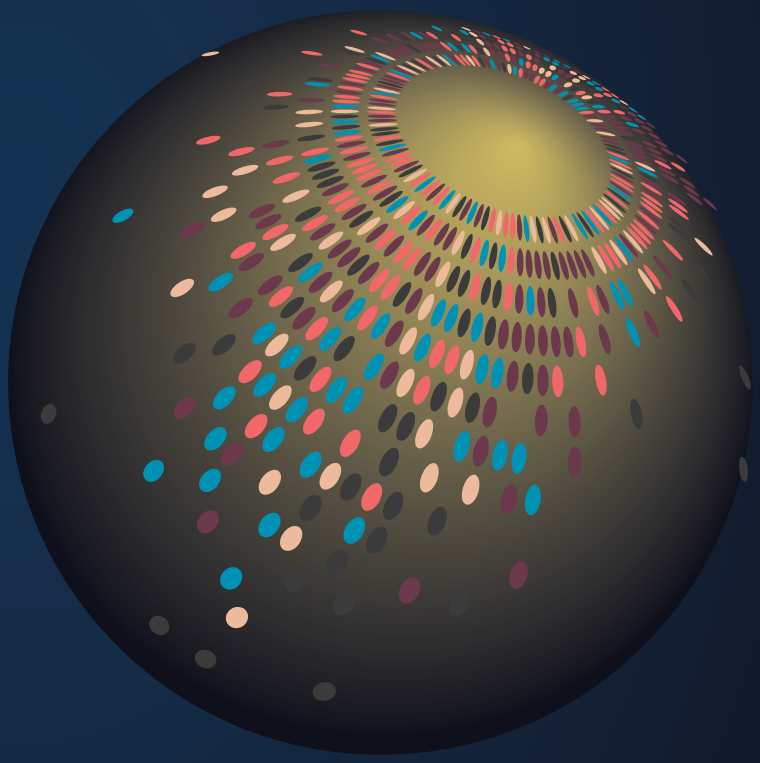
Ron Brown is a toxicologist with 35 years of experience in regulatory toxicology and risk assessment. He recently retired from the US FDA after 25 years of service and currently directs a small company, Risk Science Consortium, LLC, that provides consultation and training in toxicological risk assessment and computational toxicology. At the FDA, Ron was the senior toxicologist responsible for developing and reviewing toxicological risk assessments of extractable and leachable (E&L) compounds from medical devices.

Moderator

Andrew Feilden. Hall Analytical. Moderator.

Dr Andrew Feilden is the European E&L Strategic Director at Hall Analytical. He joined Hall in November 2019 where he is a technical expert in the field of E&L testing undertaking commercial, operational and technical thought leadership activities. He has presented on the field of extractables and leachables in over 16 countries world wide. Andrew has written a number of papers and publications and is the inventor of 2 patents. He has a degree and D Phil from the University of York, is a Fellow of the Royal Society of Chemistry and was a Scientific advisor to IPAC-RS and ex-cochair of ELSIE.

The Ever-Changing World of Extractables & Leachables Part 2



Contact

hallanalytical

Waterside Court,
1 Crewe Road, Wythenshawe
Manchester, M23 9BE, UK

Phone: + 44 (0)161 286 7889

email: sales@hallanalytical.com

web: www.hallanalytical.com

VR ANALYTICAL

63020 NE Lower Meadow Dr.
Suite 3
Bend, OR 97701

Phone: (541) 388-1253

email: info@vranalytical.com

web: www. vranalytical.com