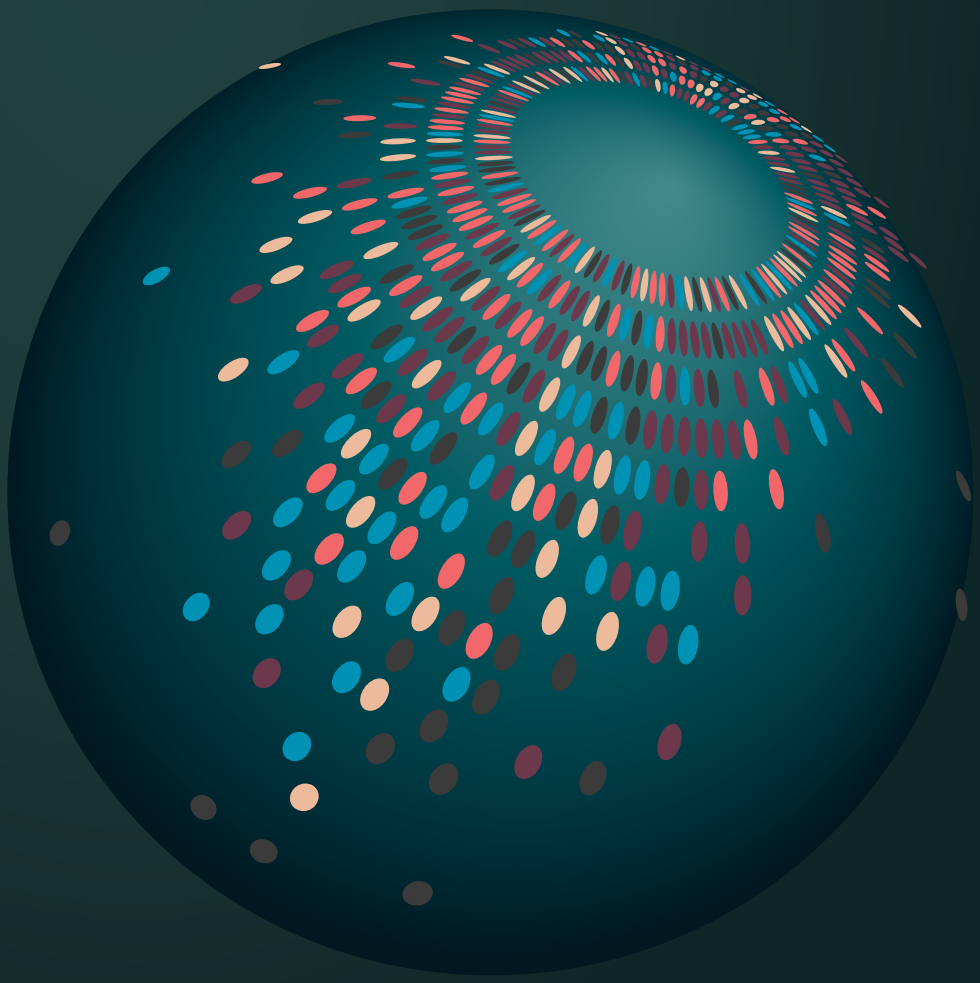
The Ever-Changing World of Extractables & Leachables

Lessons Learned & Future Challenges

A free virtual conference

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



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

Lessons Learned and Future Challenges

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. This conference will give you an insight into a number of different topics within the 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 **Ted Heise, PhD, RAC – MED Institute, Managing Partner & Toxicologist, D&B ChemTox, LLC**
"ISO 10993-18: Establishing an AET for Chemical Characterization of Medical Devices"

15:30 **Alicja Sobantka, PhD, Material Qualification, Octapharma**
"E&L in Biological Combination Products"

15:55 **5 minute break**

16:00 **Nick Morley, Principal Scientist, Hall Analytical**
"Managing Change in This Ever-Changing World of Extractables and Leachables"

16:25 **Rachel Sanig, Senior Scientist, Waters Corporation**
"Strategies to Overcome Challenges in Extractable Screening Studies"

16:50 **5 minute break**

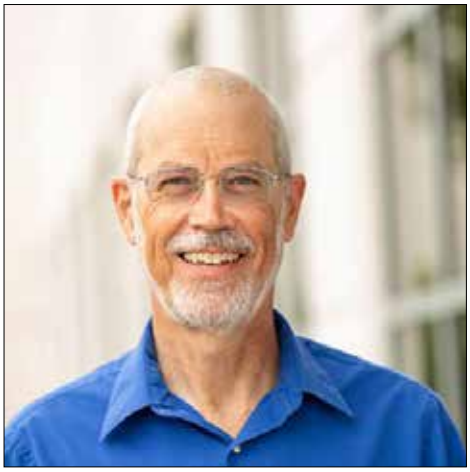
16:55 **Dan Norwood, Principal Consultant, Feinberg Norwood & Associates Pharma Consulting**
"What is the Future of Leachables and Extractables Assessment?"

17:20 **Jason Creasey, Managing Director, Maven E&L Ltd**
"What next for E&L?- Data, Information, Knowledge to Wisdom"

17:45 **Panel Discussion:**
"Qualification of screening methods, how is this achieved?"

18:05 **Final remarks from Moderator and Close**

Speakers



Ted Heise, PhD, RAC – MED Institute, Managing Partner & Toxicologist, D&B ChemTox, LLC

Theodore (Ted) Heise has three decades of experience in regulatory and clinical affairs, and currently serves as Vice President for Regulatory and Clinical Services at MED Institute. In this capacity, Dr. Heise leads efforts to develop scientifically robust regulatory and clinical study strategies for the company's clients: entrepreneurs, consultants, and developers bringing new medical products through the complex steps of the development process.

Graduating Magna Cum Laude with a B.S. in chemistry from the University of Nebraska at Omaha, Dr. Heise went on to earn a Ph.D. in analytical chemistry from Iowa State University. He has been a member of the Regulatory Affairs Professionals Society since 1993, and the American Chemical Society since 1988.

For the past 15 years Dr. Heise has been a U.S. delegate to ISO TC 194, the technical committee for international consensus standards that govern biocompatibility testing and clinical investigations of medical devices. He currently serves as convenor of TC 194/WG 14. As convenor, Dr. Heise led the process of re-writing ISO 10993-18 to reflect current best practices in chemical characterization, including evaluation of extractables and leachables from medical devices. He also is a member of the USP expert committee on packaging, and is supporting revisions of the chapters on biocompatibility.

Alicja Sobantka, PhD, Material Qualification, Octapharma

Alicja Sobantka is employed at the Octapharma where she is responsible for material qualification at the corporate level including chemical safety assessment of polymeric processing, packaging, and administration materials and the planning and supervision of extractables and leachables studies. Headquartered in Lachen, Switzerland, Octapharma is one of the largest human protein manufacturers in the world, developing and producing human proteins from human plasma and human cell lines.

Prior to joining Octapharma, Alicja had a tenured position as a researcher at the French National Institute for Agricultural Research (INRA) where she investigated various approaches to increase sustainability in the food processing industry. Alicja has also acquired broad experience in material and polymer science and technology at the Institute for Composite Materials (IVW) in Kaiserslautern, at the Centre for Neutron Science (JCNS), and at the Institute for Nuclear Waste Disposal and Nuclear Safety (IEK-6) at the Research Centre in Jülich, Germany.

Nick Morley, Principal Scientist, Hall Analytical

Nick Hall 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 and consultative support to new and existing customers in the field of E&L. He has experience working on a range of products including pharmaceuticals and biopharmaceuticals (inhalation, topical and parenteral), medical devices, and nicotine delivery systems. He is experienced in authoring successful regulatory files (BLA, NDA, MAA), performing leachable risk assessments, and defining E&L testing strategies. Nick has led workshops and given a number of presentations on the subject of E&L testing.

Nick has a BSc in Chemistry, and is a BSI Committee member and British representative on the CEN (European standards Committee) working group for extractables and leachables of electronic cigarettes and e-liquids.

Rachel Sanig,
Senior Scientist, Waters Corporation

Rachel Sanig received a 1st Class Masters and BSc (Hons) in Chemistry from the University of Leeds. She joined Waters as an applications scientist in 2016 and is experienced across the clinical, pharmaceutical, and biopharmaceutical markets using a range of chromatography and mass spectrometry analysis techniques. She joined the Chemicals and Materials team in 2018 and now works as a senior scientist in the areas of fine specialty chemicals, polymers, and materials research, and with a focus on applications in extractables and leachables.

Dan Norwood, Principal Consultant,
Feinberg Norwood & Associates Pharma Consulting

Dr. Daniel Norwood is the Principal Consultant with FNA Pharma Consulting (previously SCIO Analytical) which he joined in June 2015. Prior to that, Dr. Norwood worked for 16 years at Boehringer Ingelheim Pharmaceuticals, Inc. in various pharmaceutical development roles, including as Director of Physical and Chemical Analysis. He retired from Boehringer Ingelheim in June 2015 with the title of Distinguished Research Fellow in Analytical Development.

Prior to joining Boehringer Ingelheim, Dr. Norwood held pharmaceutical development positions at Magellan Laboratories and the Glaxo Research Institute. At Magellan Laboratories, he established the Structural Analysis Group which became widely recognized for its work in pharmaceutical impurity structure elucidation, and leachables and extractables characterization. He served as chair of the Product Quality Research Institute (PQRI) working group on leachables and extractables in inhalation drug products, whose recommendations are generally recognized as the standard in this area. He is also a member of the PQRI working group on leachables and extractables in parenteral and ophthalmic drug products (PODP), and has served on various technical teams of theInternational Pharmaceutical Aerosol Consortium on Regulations and Science (IPAC-RS). From 2010 to 2020, he served as a member of the USP Expert Committee on Packaging, Storage and Distribution where he chairs the subcommittee on extractables and leachables.

Dr. Norwood completed his bachelor's degree in Biochemistry at Virginia Tech and his masters and doctorate degreesin Environmental Chemistry at the University of North Carolina at Chapel Hill, School of Public Health.

Jason Creasey,
Managing Director, Maven E&L Ltd

Jason Creasey is a graduate analytical chemist. He setup in 2019 as an independent consultant forming his company, Maven E&L to provide advice on the topic of extractables and leachables (E&L). Prior to this, he worked for GSK where he was the director of their R&D E&L Team. He has worked in this topic area since the mid 1990's on a wide range of modalities and dose forms.

He is a scientific advisor to ELSIE. Since setting up Maven E&L; he continues to present, discuss, and write about E&L. He now publishes a regular E&L blog through LinkedIn and his Website (www.MavenEandL.com), for the exchange of ideas and discussion.

As well as supporting client projects, among recent E&L activity, he is presenting and commenting on risk- based approaches to E&L requirements that he hopes will form part of an ICH guidance in the not-too-distant future.

Moderator

Andrew Feilden. Hall Analytical.

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.

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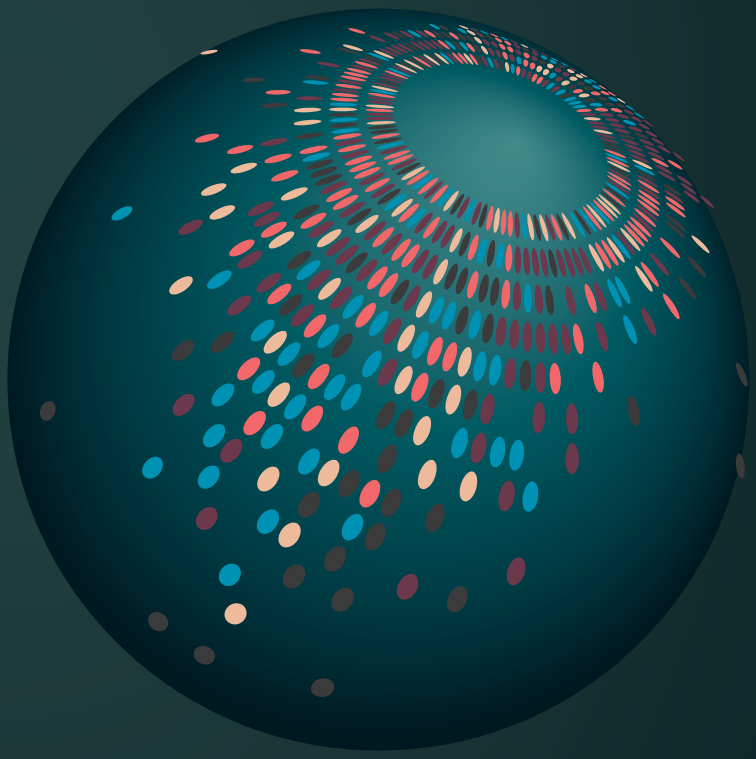

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