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2nd Annual

EXTRACTABLES & LEACHABLES SUMMIT 2020

22-23 October

● **VIRTUAL CONFERENCE**

12:00 - 18:30 CET (Central European Time)

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EXTRACTABLES & LEACHABLES VIRTUAL SUMMIT 2020

October 22 | 1st DAY

Central European Time (CET)

12:00 - 12:20 — **Registration**

12:20 - 12:30 — **Opening Address from the Chairman**

12:30 - 13:00

E&L Considerations for Adoption of new Single-Use components: A Case Study with Millipak® Final Fill

A successful adoption of single use technology in a Biopharmaceutical process largely relies on the confidence in selection of such materials for the process. Changes to an existing process can be difficult even when there are potential benefits to the change. Considerations include compatibility, functionality and E&L evaluation.
This presentation will evaluate the change control process using an example of the implementation of Millipak® final fill into existing processes. Evaluation of the functional testing and extractables data will be presented. The case study will continue with the risk assessment and patient safety evaluation.

- Risk assessment of Single-Use Final Fill application
- Material changes and change control
- Extractables and Leachables Safety Evaluation Comparison

Jessica Shea | Senior Validation Consultant, Global Support,
BioReliance® Validation Services | MilliporeSigma, DE

13:00 - 13:10 — **Q & A**

13:10 - 13:40

Top 5 Topics for inclusion in a future ICH document on Extractables and Leachables.

- Definitions and Glossary of Key Terms
- Key Risk Factors which drive leachables in Drug Products
- Principles of Study Design for Extractable Studies & Leachable Studies
- Agreed Process for Safety Risk Assessment of Leachables

Jason Creasey | Managing Director
Maven E&L Ltd, UK

Maven E&L

13:40 - 13:50 — **Q & A**

13:50 - 14:00 — **Break**

14:00 - 14:30

TBA

Raphael Nudelman, Ph.D., ERT | Director, Chemical & Computational Toxicology
Teva Pharmaceutical Industries Ltd., IL

teva

14:30 - 14:40 — **Q & A**

14:40 - 15:10

BPOG's extractable recommendation – the final chapter

Ken Wong | Deputy Director
Sanofi Pasteur, USA

SANOFI

15:10 - 15:20 — **Q & A**

15:20 - 15:30 — **Break**

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EXTRACTABLES & LEACHABLES VIRTUAL SUMMIT 2020

October 22 | 1st DAY

Central European Time (CET)

15:30 - 16:00 — Slot Reserved for a Sponsor — **SPONSOR**

Sandro Laiso | Business Development Manager DACH Chemicals & Pharmaceuticals
Intertek (Schweiz) AG, CH

16:00 - 16:10 — Q & A

16:10 - 16:40 — PQRI Final L&E Recommendations for Parenteral Drug Products and Practical Applications

- Calculating the AET and Comparison to the TTC
- Considerations for Combination Products
- Risk Based Assessments for Biologic Products

Diane Paskiet | Director – Scientific Affairs
West Pharmaceutical Services, Inc., USA

16:40 - 16:50 — Q & A

16:50 -17:00 — Break

17:00 - 17:30 — Minimizing E&L studies

- Summary of the Regulatory Demands for E&L in EU and US
- Evaluation of the Primary Packaging Materials and Drug Product
- E&L Study planning
- Safety Risk Assessment reporting

Pirkko Lahti Lic Sc (Tech) | Senior Development Manager
Orion Corporation, FI

17:30 - 17:40 — Q & A

17:40 - 18:10 — Mass Spectrometry and the Role of Isotopic Labelling in Low Abundant Impurities / Mutagenic Impurities

Jürgen Schäfer | Lab Head Mass Spectrometry
Sanofi, DE

18:10 - 18:20 — Q & A

18:20 - 18:30 — Closing remarks and end of Day 1

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EXTRACTABLES & LEACHABLES VIRTUAL SUMMIT 2020

October 23 | 2nd DAY

Central European Time (CET)

12:00 - 12:20 — Registration

12:20 - 12:30 — Opening Address from the Chairman

12:30 - 13:00 — TBA

Dr. Christian Trendelenburg | Senior Toxicologist & Project Leader (PTM)
Novartis, CH

13:00 - 13:10 — Q & A

13:10 - 13:40 — TBA

Dr. Andreas Nixdorf | Life Sciences - Business Development Manager
Extractables & Leachables Testing | SGS Institut Fresenius GmbH, DE

13:40 - 13:50 — Q & A

13:50 - 14:00 — Break

14:00 - 14:30 — Similarities and differences between medicinal products and medical devices for Extractable and leachable testing

- What are Medical devices and Medical products Regulatory expectations
- Similarities and differences between medicinal products and medical devices for Extractable and leachable testing

Dr. Andrew Feilden | European E&L strategic Director
Hall Analytical, UK

14:30 - 14:40 — Q & A

14:40 - 15:10 — TBA

Ping Wang, Ph.D., MBA | Scientific Director
Janssen, USA

15:10 - 15:20 — Q & A

15:20 - 15:30 — Break

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EXTRACTABLES & LEACHABLES VIRTUAL SUMMIT 2020

October 23 | 2nd DAY

Central European Time (CET)

15:30 - 16:00 TBA

Rick Reiley | Principal Scientist
GlaxoSmithKline, UK

16:00 - 16:10 Q & A

16:10 - 16:40 TBA

Tom van Wijk | Principal Scientist
Abbott Healthcare Products B.V., NL

16:40 - 16:50 Q & A

16:50 -17:00 Break

17:00 - 17:30 TBA

Bram Jongen | Head of R&D, PPS |
Datwyler Pharma Packaging International NV, BE

17:30 - 17:40 Q & A

17:40 - 18:10 RESERVED

Folker Steden | Director Product Management and Scientific Service
SCHOTT AG, DE

18:10 - 18:20 Q & A

18:20 - 18:30 Closing remarks and end of Day 2

SPEAKER'S BIOGRAPHIES

Jessica Shea
Senior Validation Consultant, Global Support, BioReliance® Validation Services
MilliporeSigma, DE

Jessica Shea is responsible for Extractables and Leachables Global Support at Merck. Previously, she was the manager of the Extractables and Leachables (E&L) Laboratory for the BioReliance® Validation Services. She has more than 12 years of E&L experience, including method validation, designing of custom testing, and interpreting industry and regulatory guidance.

Raphael Nudelman, Ph.D., ERT
Director, Chemical & Computational Toxicology
Teva Pharmaceutical Industries Ltd., IL

Raphael completed his Ph.D. in organic chemistry from the Weizmann Institute of Science in Israel, followed by postdoctoral positions in the US Air Force Research Lab in Aberdeen Proving Ground, Maryland USA and in Duke University Medical Center, North Carolina USA. He joined Teva Pharmaceutical Industries' Medicinal Chemistry department in 2003 and in 2010 he established the Chemical & Computational Toxicology group which he currently heads.
Raphael is a member of the American Chemical Society (ACS), the American Association of Pharmaceutical Scientists (AAPS), and of the Israel Chemical Society (ICS). From 2011 to 2016, Raphael was the President of the Medicinal Chemistry Section of the Israel Chemical Society, and was as a Council member of the European Federation of Medicinal Chemistry (EFMC). He is a member of the Advisory Council of High School Chemistry Education in the Israel Ministry of Education and a member of the Advisory Editorial Boards of Elsevier's journal Drug Discovery Today: Technologies, and of Trends in Medicine and Health (TMH).

Jason Creasey
Managing Director
Maven E&L Ltd, UK

Jason Creasey is a graduate Analytical Chemist. He has recently setup as an independent consultant providing advice in the area of extractables and leachables, after working for GSK in the area of extractables and leachables since the mid 1990's.
Over that time, he has seen demand in this area grow exponentially and Jason has held roles of increasing seniority relating to the support that GSK has given to extractables and leachables (E&L). Before setting up Maven E&L Ltd, he was the director of a team of analytical chemists who are responsible for GSK's global R&D support for E&L activities across a wide range of product types and modalities. This included; biopharmaceutical and small molecules including Inhalation, Parenteral and Cell & Gene Therapy use. He has had the pleasure of commenting on PQRI guidelines on E&L for GSK, the E&L section in EMEA guidelines on inhalation and nasal products and co-authoring a chapter within a book entitled "Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products".
Jason has been a member of several external groups concerned with the development of best practice guides for extractable and leachables issues these include; the IPAC-RS material working group, BPOG and continues as a scientific advisor to Extractable and Leachable Safety Information Exchange otherwise known as ELSIE. Currently he is working and commenting on risk- based approaches to E&L requirements, which he hopes will form part of an ICH guidance in the not too distant future.

Ping Wang, Ph.D., MBA
Scientific Director
Janssen, USA

Dr. Ping Wang is a Scientific Director with Janssen R&D. He has been leading Janssen's effort in the evaluation, selection and risk assessment related to polymeric materials used in the manufacturing, packaging and delivery of biologics, small molecules and transdermal drug products for the past decade. His main interests and expertise are risk-based material evaluation, E&L strategies and methodologies, single use systems, biocompatibility, biologics drug development, analytical technologies, regulatory implications and toxicological assessment of impurities. He is a board member of Extractables and Leachables Safety Information Exchange (ELSIE) Consortium. As an active member of Biophorum Operations Group (BPOG), he was a key contributor to the BPOG's standardized extractable protocol, and the best practice guide for leachable risk assessment. He is a holder of Regulatory Affairs Certificate (RAC).

Tom van Wijk
Principal Scientist
Abbott Healthcare Products B.V., NL

Tom van Wijk is a principal Scientist with over 20 years of experience in pharmaceutical analysis. Working at former Solvay Pharmaceuticals in early and late phase chemical and pharmaceutical development and currently supporting established marketed products at Abbott Healthcare Products in the Analytical Science and Technology Department. Specialized in small molecule impurity profiling, mass spectrometry and method development for the active materials as well as the formulated products. One of his key interests is developing applications and strategies to control trace levels of potential mutagenic impurities in pharmaceutical products. Received his PhD from the Faculty of Pharmaceutical Sciences at the Utrecht University in November 2016.

Ken Wong
Deputy Director
Sanofi Pasteur, USA

Specialties:
- Qualification of process stream contact materials including single-use technologies and packaging materials.
- Extractables & Leachables compliance remediation strategy development, execution, implementation and realization.
- Container closure intergrity test, Extractable and Leachable (E&L) test methods development and validation.
- Strategy development for process contact and packaging material changes and specification changes.
- Analytical laboratories (CRO) managements and technical assessments.
- Risk ranking / assessment model design.
- Shipping cold chain and container qualification.

Bram Jongen
Head of R&D, PPS
Datwyler Pharma Packaging International NV, BE

After his Masters in Polymer Chemistry at the University of Louvain, Belgium, Bram Jongen acquired a Ph.D. in Water Soluble Polymers used for advanced drug administration.
Bram started as Technical Support Manager for Datwyler about 14 years ago, supporting customers in a vast area, from Western European countries to countries like India, Korea, and South Africa. Thereafter, he headed the Global Product Introduction & Support team, a global team of highly experienced and educated people, having each their own expertise in the world of pharmaceutical closures. Bram himself acquired profound Extractables & Leachables expertise. His team managed customer projects of technical nature and supported Datwyler's product and portfolio management.
Since end of 2012, he has been acting as Head of R&D, leading a group that focuses on developing new rubber and new coating materials.

Pirkko Lahti, Lic Sc (Tech)
Senior Development Manager
Orion Corporation, FI

Pirkko Lahti is currently working as Senior Development Manager. Pirkko ensures that primary packaging materials meet quality specifications and regulatory requirements of Parenterals, Ophthalmics and Nasal products. She joined Orion Corporation in 2008. Orion is developing, manufacturing and marketing human and veterinary pharmaceuticals and active pharmaceutical ingredients. She has been setting up Orion's E&L strategy and risk-based evaluation system. She has received Licenciate degree in Polymer materials and processing at the University of Tampere, Finland.

SPEAKER'S BIOGRAPHIES

Dr. Christian Trendelenburg
Senior Toxicologist & Project Leader (PTM)
Novartis, CH

Christian-Friedrich Trendelenburg is a senior toxicologist in Preclinical Safety (PCS) at the No-vartis Institutes for Biomedical Research (NIBR) in Basel/Switzerland. He is a scientific expert for the safety evaluation of impurities, extractables/leachables and excipients, with major focus on the safety evaluation of pharmaceutical products for children. As Preclinical Safety project leader in the Neuroscience and Global Health therapeutic areas he represents PCS in global pro-ject teams to support drug development by summarizing, evaluating, and interpreting nonclinical safety aspects. He graduated in biochemistry from the University of Kaiserslautern/Germany and has a PhD (Dr. rer. nat.) in Toxicology. Christian has a strong background in all areas of safety sciences including agrochemical, food, chemical (home & personal care) and pharmaceutical products. He is a EUROTOX-certified toxicologist and member of the German and Swiss toxi-cological societies (DGPT & SST).

Rick Reiley
Principal Scientist
GlaxoSmithKline, UK

Rick Reiley is a Principal Scientist at GlaxoSmithKline, working in the Analytical Sciences and Technology team and he leads a team of scientists focusing on Extractables and Leachables. Rick has extensive background in analytical chemistry using chromatography with mass spectrometry. He has worked broadly across the pharmaceutical industry, including parenterals, inhalation, topical and oral solid dosage forms, supporting both research and manufacturing. He began working on E&L in 2007 on sterile single use packs for radiopharmaceuticals at GSK's Clinical Imaging Centre. Rick moved on to manage the Incoming Materials QC laboratory at GSK Ware, focusing on inhalation and oral solid dose raw material and packaging material testing. He moved to PepTCell as an Analytical Chemistry Manager, providing analytical support to early stage research through product launch. Rick returned to GSK to lead the E&L team, providing packaging lifecycle support for the Pharmaceutical and Consumer Health divisions.

Dr. Andreas Nixdorf
Life Sciences - Business Development Manager Extractables & Leachables Testing
SGS INSTITUT FRESENIUS GmbH, DE

Andreas studied organic chemistry at the University of Bielefeld in Germany with the main focus on mass spectrometry and computational chemistry. Since the date of his PhD/doctorate in 1997, he worked in different scientific and managerial positions ranges from head of laboratory to GMP QA site manager in Life Science industry prior he proceeds with his carrier at SGS in 2007. From 2007 to 2010 he was responsible for project management and regulatory consultancy at the customer service Pharma at SGS Institute Fresenius GmbH. Andreas introduced Extractables & Leachables testing services at SGS in 2008 and got his current position of an business development manager in 2010. Andreas applies technical and regulatory knowledge, scientific experience and expert judgment to address solutions for a broad range of difficult problems.
He troubleshoots and directs the resolution of QC method issues by fostering effective interdepartmental and cross-functional partnerships with clients from pharmaceutical and medical industry. With over 20 years' experience in Life Science segment he is a frequent speaker at events and international conferences (PDA, A3P, ECA, VDI, BioInnovation, CPHI, Smithers RAPRA, IQPC, Vonlanthen Group, Chinese Medical Device Association, Dipartimento di Scienze del Farmaco in Pavia and others) in the fields of Medical Device, Single Use Systems and Finished Packaging safety evaluation. Companies in regulatory controlled industries are challenged by on-going regulatory systems. Changes must be set in practice and cross-functional teams with different functional expertise must be organized to work toward a common goal. Andreas wants to motivate experts from Life Industry or organizations working together to realize or achieve a better and effective cross departmental collaboration in order to improve regulatory requirements for safety testing of plastic materials that are used to produce the medical product.

Diane Paskiet
Director – Scientific Affairs
West Pharmaceutical Services, Inc., USA

Diane Paskiet has over twenty five years of experience with qualifying packaging and delivery systems for use with pharmaceutical products. She is Currently Director of Scientific Affairs at West Pharmaceutical Services where she is involved in science and regulatory programs associated with safety and compatibility of packaging systems. Previous to this role she was in charge of site operations for West-Monarch Analytical Laboratories. She is a co-recipient of the United States Pharmacopeia (USP) award for Innovative Response to a Public Health Challenge and awarded the PDA 2019 Packaging Science Award. She serves on the USP Packaging Storage and Distribution Committee and as Chair of Product Quality Research Institute (PQRI) Development Technical Committee (DTC) and Chair of Parenteral and Ophthalmic Drug Product Leachables and Extractables Working Group.
Ms. Paskiet is also on the faculty of the Parenteral Drug Association Training Institute and author/co-author of papers and book chapters related to pharmaceutical packaging and delivery devices.

Folker Steden | Director
Product Management and Scientific Service
SCHOTT AG, DE

Folker Steden graduated as a Chemist from the Rheinische Friedrich-Wilhelms University in Bonn Germany.
After finishing his awarded PhD doctoral thesis in inorganic Chemistry at the Universities of Bonn Germany and the Fredericton New Brunswick in Canada he worked as a post-doc at the Department of Chemistry at the Technical University of Dresden. After that period he transferred as the Head of R&D of the green high temperature resistant inorganic fiber manufacturer at belchem, responsible for R&D management, product development and ramp up.
11 years ago he joined SCHOTT as a scientific Consultant for technical and pharmaceutical tubing applications.
In the years 2010 to 2012 he was located in Shanghai responsible for Scientific Consulting, Business Development and B&I activities in Asia.
Since 2012, he is leading the Product Management Team of the tubing division of SCHOTT.
In this position he is working world wide as a "missing link" between customers and local R&D units, focusing on future customer needs and presents frequently on international conferences on subjects related to special glass for technical and pharmaceutical applications..

Sandro Laiso
Business Development Manager DACH Chemicals & Pharmaceuticals
Intertek (Schweiz) AG, CH

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