qepler

SPONSORS

intertek
Total Quality. Assured.

SARTORIUS

SCIEX

EXTRACTABLES & LEACHABLES

2nd Annual

EXTRACTABLES & LEACHABLES SUMMIT 2020

22-23 October

- VIRTUAL CONFERENCE

12:00 - 18:30 CEST (UTC/GMT +2 hours)

www.qepler.com +420 608 030 490 register@qepler.com

qepler

SPEAKERS BOARD

Dr. Andrew Feilden, CSci CChem FRSC
European E&L strategic Director
Hall Analytical, UK

Bram Jongen
VP Materials & Surface Technologies
Datwyler Pharma Packaging International NV, BE

Jason Creasey
Managing Director
Maven E&L Ltd, UK

Jessica Shea
Senior Validation Consultant, Global Support, BioReliance® Validation Services
MilliporeSigma a business of Merck KGaA, USA

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

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

Dr. Tino Otte
Head of Sales and Consulting
Intertek (Schweiz) AG, CH

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

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

Dr. Roberto Menzel
Laboratory Supervisor and Manager Extractables
Sartorius Stedim Biotech, DE

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

Dr. Christian Trendelenburg
Associate Director
Novartis, CH

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

Neil Devenport
Snr Support Small Molecule Quantitation & Identification
SCIEX, DE

qepler

SCIEX

In life science research and analytical testing laboratories, your data are only as reliable as the technology you utilize to capture them. Whether your lab is dedicated to routine testing or the discovery and development of life-changing drugs, you require systems that provide reproducible results without sacrificing flexibility.

Experience Confidence in Your Results
Since successfully commercializing the first triple quad mass spectrometer in 1981, SCIEX has been committed to meeting the needs of scientists around the globe. Our mass spec systems—as well as other life science products including capillary electrophoresis instruments, front-end HPLC MS products, software, and complete integrated solutions—are designed by scientists like you for scientists like you. Our products are used extensively in labs focused on pharma and biopharma discovery and development, clinical phase and QC/QA laboratories.

As novel therapeutic types continue to evolve, the successful pharma and biopharma labs of the future will be those that embrace innovation to revolutionize their development pipeline.

Your ability to bring safe drugs and biotherapeutics to market as quickly and safely as possible is your ultimate goal. You need to make decisions fast, and having the right information available to you at key stages in the pipeline is vital.

Transforming Your Biologics Pipeline Capacity and Capability
SCIEX has a longstanding track record in helping scientists in pharma discovery, development and manufacturing to transform pipeline capacity and capability through the adoption of CE and LC-MS technologies.

Make your lab successful and make critical decisions faster
Our overall aim is to make you more productive and in doing so saving time, money and resources. That's why we approach workflows with complete end-to-end solutions. Our unparalleled application knowledge works hand-in-hand with best-in-class hardware, software and support, engineered and integrated to make you more productive and successful.

With SCIEX, you benefit from innovative technology that makes complex workflows easier and more efficient, while delivering the utmost in data quality. Highly reliable instrumentation, with high sensitivity and dynamic range for a variety of analytical applications. Advanced software with automation to make data processing easier. And global service and support, so your workflows aren't interrupted unexpectedly.

Let SCIEX Help Bring Your Lab to New Levels

SCIEX is more than a manufacturer and distributor. We partner with you on your journey to better research, as the needs and demands of your lab grow. View product information for our entire portfolio below. Select a link to learn about solution options, kits, example results, part numbers, related products, and much more.

WHO YOU WILL MEET

qepler

intertek

Total Quality. Assured.

Tel: +41 61 686 4800
Fax: +44 61 686 4899
Email: business.support@intertek.com
Website: www.intertek.ch

Intertek is the industry leader with over 42,000 people in 1,000 locations in over 100 countries. Whether your business is local or global, we can ensure your products meet quality, health, environmental, safety, and social accountability standards for virtually any market around the world. We hold extensive global accreditations, recognitions, and agreements, and our knowledge of and expertise in overcoming regulatory, market, and supply chain hurdles is unrivaled.

Intertek (Schweiz) AG provides a comprehensive range of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) compliant analytical services including chemical trace analysis, reverse engineering, complex analyses, substance identification, method development, and a wide range of other applications in conjunction with consulting expertise and engineering support.

Intertek - WEBINARS:

- Webinar Recording: Design of Robust and Sensitive Extractables and Leachables Studies
  https://www.intertek.com/pharmaceutical/webinar-design-extractables-leachables-studies/
- Webinar Recording: Extractables and Leachables Studies for Process Materials and Container Closure Systems
  https://www.intertek.com/pharmaceutical/webinar-extractables-leachables-process-materials-container-closure/
- White Paper: Extractables and Leachables Strategies for Pharmaceutical Production Tubing
  https://www.intertek.com/pharmaceutical/whitepaper-extractables-leachables-pharmaceutical-tubing/

SCIEX

Regardless of your scientific field, your purpose is to help improve the future of science and ultimately, well-being, to realize life's potential. At SCIEX, we want to empower and inspire you to break new ground in scientific discovery and diagnostic accuracy. That's why thousands of life science experts around the world use our innovative technology to make the right decisions quickly. Decisions that positively impact lives.

We pioneer extraordinary solutions in mass spectrometry paired with capillary electrophoresis and liquid chromatography. But we don't just develop products. It's what we do together that sets us apart. With our customers and partners, we bring the power of life-changing answers to the questions you have today, and those that you have yet to ask.

It's time to see the future differently!

We Specialize In:
Clinical Diagnostics & Clinical Research | Food & Beverage Testing | Environmental Testing | Forensics Testing | Life Science Research | Pharma and BioPharma Solutions

Positions

- C-Level, Presidents, Chairs, Members of the Board & VPs
- Vice presidents, Directors, & Heads
- Leaders & Managers
- Principals, Engineers, Analysts & Scientists
- Instructors & Trainers & Teachers
- Advisors, Coordinators, Auditors & Consultants
- Other Professionals, Experts & Specialists

Divisions

- Analytical Chemistry
- Bioprocessing
- Bioproduction
- CCIT
- CMC
- Container Development
- Device Engineering
- E & L
- Formulation
- Glass
- Manufacturing Science & Technology
- Materials Science & Selection
- Medical Devices
- Packaging & Labelling
- Parenterals
- PFS
- Polymers
- Product & Process Development
- QA/QC
- Quality Testing
- R & D
- Regulatory Affairs
- Risk Management & Assessment
- Rubber
- Safety Assessments
- Scientific Affairs
- Single Use Systems
- Standardisation
- Toxicology
- Validation
- Others

Industries

- Pharmaceutical
- Biotechnology
- Chemical
- Medical Devices
- Plastics
- CMOs/CDMOs
- CROs
- NOPs
- Regulatory Agencies
- Training providers
- Other

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 a business of Merck KGaA, USA

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

13:40 - 13:50 Q & A

13:50 - 14:00 Break

14:00 - 14:30

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

14:30 - 14:40 Q & A

14:40 - 15:30

BioPhorum (BPOG) Extractable Recommendations for SUS – Final Chapter, and an end user's data mining experience

- Will discuss the new BPOG protocol ver 2.0, and own experience with various extractable data sets, acquired over the years.

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

15:30 - 15:40 Q & A

15:40 - 15:50 Break

October 22 | 1st DAY

Central European Time (CET)

15:50 - 16:20

E&L Studies tailored for Transdermal Delivery Systems

SPONSOR

Transdermal patches and related pharmaceutical products have a huge potential for leaching substances from different assembly parts and secondary packaging due to the variety of materials involved. Extractables and leachables (E&L) are unwanted, potentially harmful, substances which could be applied to the patient during medication. The impact of E&L is often underestimated which leads to increased attention of the authorities to this specific topic.

With a focus on complex drug-delivery-products, such as transdermal patches, we look at how E&L studies can be effectively applied to understand how the formulation or sweat of the patient interact with the different materials to ensure a safe medication. Illustrative examples from E&L studies are provided with special attention to an efficient study design which will fulfil the regulatory requirements but not unnecessarily exceed the worst case conditions.

Tino Otte | Head of Sales and Consulting
Intertek (Schweiz) AG, CH

intertek
Total Quality. Assured.

16:20 - 16:30 — **Q & A**

16:30 - 17:00

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

West
By your side for a healthier world

17:00 - 17:10 — **Q & A**

17:10 - 18:00

Panel Discussion

- BPOG protocols
- Leachables an ICH guidance - Will the guideline be based on theoretical assessments or comprehensive analytical screening?
- Choice of thresholds for Safety Concern Thresholds
- Fixing response factors for LC-MS and GC-MS

18:00 - 19:00 — **Networking hour**

18:00 - 18:10 — **Closing remarks and end of Day 1**

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

Safety assessment of extractables/leachables: Challenges with ophthalmic administration routes.

- General safety considerations for the safety assessment of extractables/leachables (E&L) in pharmaceutical products will be summarized
- Current safety thresholds applicable to E&L in pharmaceutical products will be introduced
- Specific safety considerations and approaches for E&L in ophthalmic products will be discussed

Dr. Christian Trendelenburg | Associate Director
Novartis, CH

13:00 - 13:10 Q & A

13:10 - 13:55

Leachable Study design Space in Complex formulated Drug Products such as Biopharmaceuticals.

- Assessment factors that must be presented to the authority through the leachable study design
- Assessment Robustness: Matrix Impacts, Large Volume problem and others
- Strategic elements that can be incorporated into the study design: Simulation, Negative Controls, Aging Controls

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

13:55 - 14:05 Q & A

14:05 - 14:15 Break

14:15 - 14:45

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

14:45 - 14:55 Q & A

14:55 - 15:25

The effect of X-ray and ClO2 sterilization techniques on Extractables & Leachables of Rubber Closures.

- A comprehensive overview of different sterilization techniques for rubber closures
- The effect of classic sterilization techniques (Steam, Gamma irradiation and EtO) on E&L
- The impact of X-ray on E&L as alternative to Gamma sterilization
- The impact of ClO2 on E&L as alternative to EtO sterilization

Bram Jongen | VP Materials & Surface Technologies |
Datwyler Pharma Packaging International NV, BE

15:25 - 15:35 Q & A

15:35 - 15:45 Break

October 23 | 2nd DAY

Central European Time (CET)

15:45 - 16:15

Assessing lot-to-lot variability of single-use devices by Extractables studies - are we hunting ghosts?

SPONSOR

- Potentials and limits of analytical screening methods to reveal lot-to-lot differences of SUS
- Factors leading to inconsistent extractables results
- Results of a SUS bag film material investigation, repeatability and lot-to-lot variance
- Insight into SU supplier Extractables testing strategies

Dr. Roberto Menzel | Laboratory Supervisor and Manager Extractables
Sartorius Stedim Biotech, DE

SARTORIUS

16:15 - 16:25 Q & A

16:25 - 16:55

Analytical strategies for extractables and leachables

- Analytical technique selection
- Challenges of coverage of E&L
- Perspective on E&L analysis

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

Abbott

16:55 - 17:05 Q & A

17:05 -17:15 Break

17:15 - 17:45

Controlled extraction of single use Tubing - A Phthalate Case Study

SPONSOR

Key Features of the X500R QTOF System for E&L Analysis:
- Sensitive, fast scanning, benchtop hybrid quadrupole time of flight mass spectrometer
- SWATH acquisition enabled for the most comprehensive data independent analysis
- Retention time alignment deconvolution when processing the data provides clean spectra that can be used for structure elucidation or library searching
- Richly featured, user friendly, SCIEX OS software for acquisition and data processing for quantitative and qualitative workflows
- Extractable and Leachable focused NIST subset library of industry standard spectra and compounds that is user customizable

Neil Devenport | Snr Support Small Molecule Quantitation & Identification
SCIEX, DE

SCIEX

17:45 - 17:55 Q & A

17:55 - 18:25

Influencing factors on Extractables and Leachables at different glass materials

As the complexity of modern drug products grows from a chemical and physical point of view, the evaluation of possible drug/container interactions are an increasing focus area in primary packaging material development.
These interactions mainly depend on several factors: the chemical composition of the glass packaging material, the conversion process (namely the transformation of glass tubing into containers), possible additional surface treatments and, finally, the drug product itself. Regarding the first aspect, the composition of glass varies among different glass types as well as among different manufacturers. In consequence, the composition of a glass gives first indications for potential sources of extractables.
A case study will be presented revealing differences in the extractables levels among different glass types, such as borosilicate glass and aluminosilicate glass.
Furthermore, also the influence of the conversion process and possible surface treatments on the chemical stability of both glass types will be illustrated.

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

SCHOTT

18:25 - 18:35 Q & A

18:35 - 18:45 Closing remarks and end of Day 2

SPEAKER'S BIOGRAPHIES

Jessica Shea
Senior Validation Consultant, Global Support, BioReliance® Validation Services
MilliporeSigma a business of Merck KGaA, USA

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.

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.

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.

Dr. Tino Otte
Head of Sales and Consulting
Intertek (Schweiz) AG, CH

Tino Otte received his PhD at Darmstadt Technical University (Germany). The focus of his research was on the chromatographic characterization of synthetic and natural macromolecules.
After graduating he worked for different companies in the instrumental analysis and pharmaceutical services industry.
Before joining Intertek he was applied as a product manager for laboratory equipment at Hamilton Bonaduz AG followed by his positions as divisional manager for pharmaceutical services at UFAG Laboratorien AG in Sursee/Switzerland where he was responsible for development and validation of analytical methods used for characterization and quality control of pharmaceutical formulations.
Tino Otte is now Senior Consultant at Intertek in Switzerland responsible for contract analysis projects in GMP and medical environment. He is an expert for impurity characterization in pharmaceutical products and extractables-leachables studies.

Bram Jongen
VP Materials & Surface Technologies
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 16 years ago, and picked up a role of heading 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.
2013 till 2020, he has been acting as Head of R&D, leading a group that focuses on developing new rubber and new coating materials. Since early 2020, he became VP Materials & Technologies, overseeing the development teams in Datwyler's HealthCare branch, but also the Mobility, Food & Beverages, General Industry and Oil&Gas teams.

Neil Devenport
Snr Support Small Molecule Quantitation & Identification
SCIEX, DE

Neil Devenport has been part of SCIEX since 2014 following completion of PhD.
This role focuses on the demonstration and training of new MS technologies and analytical processes which over the past couple of years has been primarily general unknown screening methodologies.

SPEAKER'S BIOGRAPHIES

Dr. Christian Trendelenburg
Associate Director
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).

Dr. Roberto Menzel
Laboratory Supervisor and Manager Extractables
Sartorius Stedim Biotech, DE

Dr. Roberto Menzel has a Ph.D. in Chemistry from the University in Jena.
He started his career as an assistant editor in the natural science book section at Wiley VCH, Weinheim followed by a position as a group leader in the organic trace analysis in the environmental analytical division at Eurofins Scientific.
In 2015, he joined Sartorius Stedim Biotech where he is heading the internal analytical laboratory and manages the Sartorius Extractables team. Main working areas are material and product qualification studies for single-use systems and components for the biopharmaceutical industry.

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..

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

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. He 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

qepler

REGISTRATION FORM

This registration form is editable.
When you have completed the form - please save and email it to register@qepler.com

SUMMIT NAME: VIRTUAL - 2ND ANNUAL EXTRACTABLES & LEACHABLES SUMMIT 2020

REGISTRATION DATE: _____

PACKAGE NAME	Standard price
Individual ticket - 1st Day (22th October 2020) - (*includes complete post-event conference materials distribution)	€195
Individual ticket - 2nd Day (23th October 2020) - (*includes complete post-event conference materials distribution)	€195
Individual ticket - 2 Days - (*includes complete post-event conference materials distribution)	€345
Group ticket - 2 Days (*2-3 delegates) - (*includes complete post-event conference materials distribution)	€265
Group ticket - 2 Days (*4+ delegates) - (*includes complete post-event conference materials distribution)	€195
Documentation package - (*presentation materials and video recording)	€395
Promotional materials distribution	€445

SPEAKER SPONSOR ☐ PARTNER SPONSOR ☐ GOLD SPONSOR ☐

ATTENDEE DETAILS	1ST ATTENDEE	2ND ATTENDEE	3RD ATTENDEE	4TH ATTENDEE	5TH ATTENDEE	6TH ATTENDEE
Title:						
Name:						
Surname:						
Company:						
Country:						
Job Title:						
Direct phone:						
Email:						
Special Requirenments: (If you have any special dietary requirements or other needs that would enhance your enjoyment of this summit, please specify)						

INVOICE DETAILS:

Title: _____ Name: _____ Surname: _____

Job Title: _____

Direct Phone: _____ Mobile: _____ Email: _____

Company: _____ Country: _____ City: _____ EU VAT #: _____

Address: _____ Postcode: _____

Payment Method:

Bank Transfer ☐ Credit Card ☐ Pay Pall ☐

Signature:
«I agree to be bound by Terms and Conditions of registratin»

TERMS & CONDITIONS:

REGISTRATION & PAYMENT

Upon receiving the signed registration form, we will process your application. The registration confirmation and the invoice will be sent to you within one (1) working day with the relevant payment instructions and terms. The registration fee includes access to all sessions and conference materials. Payment is due 14 working days from the invoice date. Payment should be made by Credit Card, Pay Pall or by Bank Transfer. The delegate is responsible for any bank charges/fees associated with the payment.

CANCELLATION & SUBSTITUTION POLICY

You may substitute a delegate at any time and at no extra cost. Cancellations must be in a written notice. Cancellations made 30 days or more before the event start date will be refunded less than 50% of the registration fee. Cancellations made less than 30 days before the event start date will receive no refund. If you cannot attend an event due to illness or other unforeseen circumstances, you may transfer your delegate pass to another upcoming event within one year from original event start date.

EVENT CHANGES & CANCELLATIONS

While all effort will be made to adhere to the advertised package, Qepler s.r.o. reserves the right to change event dates, sites or location, omit event features, or merge the event with another event as it deems necessary without penalty. In such situations no refunds, part refunds or alternative offers will be made. In the event that Qepler s.r.o. permanently cancels the event for any reason, and provided that the event is not postponed to a later date nor is merged with another event, you will receive a credit note or refund for 100% of the conference fee paid. Please note, Qepler s.r.o. will not be held liable for any accommodation or associated travel costs should the event be canceled or rescheduled.

DATA PROTECTION

The personal information provided by you will be held in the Qepler database. It may be used to infrom you about other Qepler products and services. Unless you click here ☐, your details may be made available to third parties for marketing purposes.
For data update please write to databasemanager@qepler.com.

PARTICIPATION PACKAGES

qepler

ONLINE PACKAGES:

If you are unable to attend, you may purchase these packages

PACKAGE NAME	PRICE
DOCUMENTATION Post-event package - presentation slides with video recording, a list of participants, and other materials. The presentation content is subject to the speaker's companies approval for distribution.	€395
PROMOTIONAL MATERIALS DISTRIBUTION Distribution of your company's promotional materials to all attendees	€445

SPONSORSHIP PACKAGES:

BENEFITS	SPEAKER €695	PARTNER €995	GOLD €1295
Number of passes included	1	2	3
Registration fee for additional company representatives	€245	€195	€145
Link to Landing Page/Video Presentation trough the live event translation.		•	•
Link to Virtual Exhibition Page trough the live event translation.			•
Opening keynote presentation			15 min
Speaking slot	20 min	30 min	30 min
Workshop slot			60 min
Recognition in chairman's opening address		•	•
Opening & closing speech			•
Chairman of Day 1			•
Chairman of Day 2		•	
Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•
Recognition on Qepler social media channels (LinkedIn/Facebook/Twitter/Instagram)	•	•	•
Colour advert in placed in agenda		1/2 Page	1 Page
Online distribution of your company's promotional materials to all attendees		•	•

MARKETING CAMPAIGN

- Website
- Email Marketing
- Digital Advertising
- Social Marketing
- Press
- Direct Sales

PARTICIPATION FEE

Fees are inclusive of the complete summit materials, online post-event documentation/presentation package, list of participants, video records, and certificate of participation.

TRANSLATION

The event translation link will be announced online and sent to the delegates within a reasonable period before the summit start date.

POST-EVENT DOCUMENTATION

Presentations and other materials will be sent to the attendees within 72 hours after the event. The presentation content is subject to speaker's companies approval for distribution.

DISCOUNTS

Early booking discounts are not valid in conjunction with any other offers.

www.qepler.com
+420 608 030 490
register@qepler.com

WAYS TO REGISTER

EVENTS CALENDAR 2021

Please **choose** the **Summit / Summits** and **send** us suggested **Session Title** via email or webpage.
We will appreciate if you **share** our **calendar with** your **colleagues**!

qepler

CLICK HERE TO REQUEST INFORMATION

PHARMA - MEDICAL DEVICES - CHEMISTRY

DRUG DELIVERY - FORMULATION - R&D - DEVICES - COMBINATION PRODUCTS - PFS - LYOPHILIZATION - E & L - IMPURITIES - HPAPI - INHALATION - ASEPTIC PROCESSING - MDR - CMC - QRM - PFS - DDC - EM

2nd Genotoxic Impurities in Pharmaceuticals Summit ..... **July 15-16, 2021**
- VIRTUAL CONFERENCE

GTI strategies & new methodologies: analysis, in silico & regulations. Challenges & opportunities.
https://qepler.com/pdf/v2gti21.pdf
REGISTRATION IS OPEN
AGENDA WEB

3rd Annual Pharmaceutical Lyophilization Summit ..... **July 29-30, 2021**
- VIRTUAL CONFERENCE

Discuss best practices in tech & regulatory updates, process, formulation, testing, monitoring, new products development.
https://qepler.com/pdf/v3lyo21.pdf
REGISTRATION IS OPEN
AGENDA WEB

2nd Annual Inhaled Drug Delivery Summit ..... **August 5-6, 2021**
- VIRTUAL CONFERENCE

Assess and harness novel approaches to the development of inhaled drug products for enhanced patient care.
https://qepler.com/pdf/v2idd21.pdf
REGISTRATION IS OPEN
AGENDA WEB

3rd Annual Highly Potent APIs Summit ..... **October 7-8, 2021**
- VIRTUAL CONFERENCE

Assess and reduce manufacturing and handling challenges for highly potent active pharmaceutical ingredients.
https://qepler.com/pdf/v3hpapi21.pdf
REGISTRATION IS OPEN
AGENDA WEB

3rd Annual Extractables & Leachables Summit ..... **October 20-21, 2021**
- VIRTUAL CONFERENCE

Get the latest updates in regulation, analytical testing, risk & safety assessment, biocompatibility.
https://qepler.com/pdf/v3el21.pdf
REGISTRATION IS OPEN
AGENDA WEB

3rd Annual Drug/Device Combination Products Summit ..... **December 2-3, 2021**
- VIRTUAL CONFERENCE

Get up to date with the regulatory and quality compliance strategies for combination product development.
https://qepler.com/pdf/v3ddcp21.pdf
REGISTRATION IS OPEN
AGENDA WEB




CONTACTS

Please send your session title and summit name to:

Denis Polikarpov
Executive Director
Tel: +420 608 030 490
Email: denis.polikarpov@qepler.com

Evgenia Makar
CEO
Tel: +420 770 699 211
Email: evgenia.makar@qepler.com