qepler

- 10+ Program Hours | 8+ Networking Hours
- Refreshments & Coffee Breaks
- Business Lunches & Dinner
- Case Studies
- Panel Discussions | Q & A

BRONZE SPONSOR

SGS

SPEAKER SPONSOR

intertek
Total Quality. Assured.

EXTRACTABLES & LEACHABLES SUMMIT 2019

October 15-16, 2019 | Berlin, Germany

Venue:
NH Collection Berlin Friedrichstrasse
Friedrichstraße 96

NH COLLECTION
HOTELS

CHAIR DAY 1

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

CHAIR DAY 2

Dr. Tino Otte
Senior Scientific Consultant
Intertek (Schweiz) AG, CH

Tim Hulme
Principal Consultant
Smithers Rapra Ltd., UK

Prof. Dr. Johannes Harleman
Independent Consultant

Carsten Worsøe
Principal Scientist
Novo Nordisk A/S, DK

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

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

Dr. Clemens Günther
Director Nonclinical Safety Consumer Care
Bayer AG, DE

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

Dr. Lars Albermann
Head of Pharma and Food Regulatory Subject Matter Experts
Merck, DE

Dr. Gilbert Tumambac
Sr. Principal Scientist
Pall Biotech, USA

Rick Reiley
Principal Scientist
GlaxoSmithKline, UK

Dr. Bettine Boltres
Principal Scientific Affairs, Packaging & Delivery Systems
West Pharmaceutical Services Deutschland GmbH & Co KG, DE

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

Markus Obkircher
Director R&D, Head of Reference Materials and Proficiency Testing
Merck, DE

Dries Cardoen
Team Responsible of E&L Study Directors - Inhalation/Topical/Transdermal products
Nelson Labs, BE

Jason Creasey
Managing Director
Maven E&L Ltd, UK

qepler

BRONZE SPONSOR

SGS

Tel: +49 6128 744 245
Fax: +49 6128 744 700
Website: http://www.sgsgroup.de/de-DE/Life-Sciences.aspx

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 95,000 employees, SGS operates a network of over 2,400 offices and laboratories around the world. Our customers in the bio-pharmaceutical industries rely on us to provide them with outsourcing services on both the quality and safety of drug ingredients and the development process – from the early development stages until the commercialization of finished products. Our Quality Control testing activities help improve efficiency, reduce costs, shorten time to market and ensure the safety of pharmaceutical products.

SGS – YOUR PARTNER FOR EXTRACTABLES AND LEACHABLES

SGS provides a complete service for testing extractables in bio/pharmaceutical products, container material, medical devices, single-use systems (SUS) and other consumables used in pharmaceutical production, such as filters, tubes connectors and others, as well as leachables in final products.

COMPREHENSIVE TESTING FOR:

- Container materials
- Medical devices
- Single-use systems (SUS)
- Leachables in final products
- Leachables during pharmaceutical production
- Material failures and damage analysis
- Impurity profiling
- Particle identification and particle distribution

QUALIFIED CONSULTING IN:

- E&L study concepts
- Risk analysis support
- Toxicological safety assessments
- Root-cause analysis support

SGS BENEFITS

QUALITY & COMPLIANCE

- Professional and personal project management
- Submission-ready analytical reports
- Reliable and accurate testing
- Studies engineered to your unique needs
- Fully accredited, professionally recognized organization
- State-of-the-art facilities, equipment and techniques

RESOURCE MANAGEMENT

- Ensures high efficiency
- Quick turnaround time
- Cost savings

SPEED & DEVELOPMENT

Speed up the drug development process and bring your product to the market quickly. Our extractables evaluation services and consultancy services enable you to identify relevant analytes for leachables testing or studies.

GET TO MARKET QUICKLY, SAFELY & EFFICIENTLY: SGS INSTITUT FRESENIUS GMBH, KASTELER STRASSE 45, 65203 WIESBADEN, GERMANY
T +49 611 962 - 5910, DE.WIE.OPERATIONALSALES@SGS.COM, WWW.INSTITUT-FRESENIUS.SGSGROUP.DE

SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY.

WHEN YOU NEED TO BE SURE

SGS

SPEAKER SPONSOR

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.

qepler

EXTRACTABLES & LEACHABLES SUMMIT 2019

October 15 | Berlin, Germany

07:50 - 08:20 — Registration and Welcome Coffee

08:20 - 08:30 — Opening Address from the Chairman

08:30 - 09:10

USP <665> draft standard: A rational risk-based approach to characterization of polymeric biopharmaceutical manufacturing systems

USP <665> draft will be the first standard for characterization of specifically single-use systems (SUS) used in manufacturing. In this session we will discuss:

- Risk assessment with respect to patient safety to assign a risk level
- Risk level appropriate testing of components
- Approach for compliance for filters and SUS from a SUS supplier's perspective

Dr. Lars Albermann | Head of Pharma and Food Regulatory Subject Matter Experts | Merck, DE

09:10 - 09:50 — Speed Networking

09:50 - 10:30

Strategies for assessment of impurities and E&Ls

- Definitions of E&L and impurities
- Qualification thresholds
- Use of QSAR
- Role of API in assessment
- Experience with regulators on PQRI proposals

Prof. Dr. Johannes Harleman | Independent Consultant

10:30 - 11:00 — Morning coffee and networking break

11:00 - 11:40

Safety assessment of extractables/leachables: Challenges with different administration routes

- Safety thresholds for extractables/leachables in pharmaceutical products will be introduced
- Applicability of these thresholds to products for different administration routes will be discussed
- Specific safety considerations and approaches for parenteral and ophthalmic products are summarized

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

11:40 - 12:20

Toxicological assessment of non-genotoxic E&L

- Regulatory Guidance
- Searching for toxicological information
- No data available - The Threshold of Toxicological Concern (TTC) approach
- Point of departure available - How to define the Permitted Daily Exposure

Dr. Clemens Günther | Director Nonclinical Safety Consumer Care | Bayer AG, DE

12:20 - 12:45

Challenges and pitfalls during E&L studies and how to handle them

SPEAKER SPONSOR

For patient safety reasons a precise knowledge about potential drug impurities is essential. With increasing complexity of container closure systems and single use process equipment the risk of leachables being introduced as real drug impurities increases significantly. Authorities are extensively focusing on determination of leachables present in the real drug matrix which increases the analytical effort and complicates data interpretation.

According to general guidelines the E&L studies are commonly divided into different parts:

- Screening of containers and process equipment for extractables
- Screening of the formulation stored under accelerated conditions for potential leachables
- Tox-assessment and definition of the target leachables and their specification
- Leachables method validation
- GMP monitoring of leachables during a stability study in real samples

During this presentation we will focus on the problems which may occur when extractables or leachables above the analytical evaluation threshold are detected during the different steps. Several case studies will be presented.

Content:

- Illustration of a suitable study design covering production process, filling line and final container closure system
- Extractables of multi-material-equipment and how to clarify their source
- Temporary leachables detected during stability study
- Unknown leachables and how to identify them

Dr. Tino Otte | Senior Scientific Consultant | Intertek (Schweiz) AG, CH

intertek
Total Quality. Assured.

qepler

EXTRACTABLES & LEACHABLES SUMMIT 2019

October 15 | Berlin, Germany

12:45 - 13:45 — Business lunch

13:45 - 14:25

Setting up effective E&L Studies

- Extractable condition selection
- Leachable study design
- Leachable study monitoring and design

Tim Hulme | Principal Consultant | Smithers Rapra Ltd., UK

14:25 - 15:05

Comparative Extractables Study of Autoclavable Polyethersulfone Filter Cartridges for Sterile Filtration

Sterile filters are ubiquitous in biopharmaceutical manufacturing processes. They are in direct contact with the process fluid, and the profiling of the extractables is of high importance, especially in process steps "close to patient" such as single-use final fill.
The talk will compare and discuss the extractables profiles of sterilizing-grade 0.2 µm polyethersulfone membrane filter cartridges from different vendors. Pure ethanol and purified water were used as extraction media. Several orthogonal analytical techniques such as HS GC-MS and GC-MS and LC-HRMS in combination with ICP-MS for single analyte detection and the sum parameters total organic carbon, non-volatile residue, conductivity, and pH were used to obtain a most comprehensive extractables profile. Various extractables were found such as antioxidants and degradation products thereof, hydrocarbons, and processing aids. The identified compounds can all assigned to the materials of construction, such as plastic parts or membranes. Focus is given also on the challenges one encounters in Extractables screening studies for example in the analysis of hydrophilizing agents. A basic toxicological evaluation for material safety assessment will be presented showing the overall low risk of the extractables toward patient safety.

- Quantitative extractables profile for widely used polyethersulfone membrane filters for sterile filtration
- The relationship between raw material production and membrane manufacturing to the main membrane-related extractables
- Relevance and limits of the TOC reconciliation of screening studies
- Toxicological evaluation for material safety assessment of Extractables results to process conditions

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

15:05 - 15:35 — Afternoon coffee and networking break

15:35 - 16:15

Neat and Ready-to-use Calibrants for Extractables & Leachables Testing Methods

- New Certified Reference Materials for Extractables & Leachables Testing
- Neat products and ready-to-use calibrants for accurate analysis
- Characterization by quantitative NMR (qNMR) spectroscopy, HPLC and GC
- Following ISO/IEC 17025 and ISO 17034 accreditation workflow
- Tested for homogeneity and long-term stability
- Time and cost saving solution for customers

Markus Obkircher | Director R&D, Head of Reference Materials and Proficiency Testing | Merck, DE

16:15 - 16:55

Risk Based approaches to Extractable and Leachable Study design

- Factors affecting Dose Form risk of leachables
- A structured approach to assessment of leachable risk
- Linking risk to extractable or leachable studies
- How extractable and /or leachable studies reduce project risk

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

16:55 - 17:35

Achieving Data Integrity with High Resolution Mass Spectrometry Instrumentation

- Discuss the Expectations from Health Authorities and Challenges Specific to E&L Community
- Overview of GSK's approach to Data Integrity
- Case Study – Agilent's Masshunter with ECM software on an Agilent GC-MS QToF 7200b
- Case Study – Water's Unifi Software on a LC-MS QToF Xevo G2-XS

Rick Reiley | Principal Scientist | GlaxoSmithKline, UK

17:35 - 18:15 — Panel Discussion

18:15 - 18:20 — Chairman's closing remarks and end of day one

19:00 - 21:00 — Business dinner

EXTRACTABLES & LEACHABLES

qepler

EXTRACTABLES & LEACHABLES SUMMIT 2019

October 16 | Berlin, Germany

08:00 - 08:30 — Registration and Welcome Coffee

08:30 - 08:40 — Opening Address from the Chairman

08:40 - 09:20

Extractables and Leachables challenges of for prefilled syringes

- Critical E&L related components in prefilled syringes
- Relationship between extractables, simulated leachables and leachables
- What is the optimal tool to predict leachables in a prefilled syringe?
- Case studies on simulated studies in prefilled syringes

Carsten Worsøe | Principal Scientist | Novo Nordisk A/S, DK

09:20 - 10:00

Leachables strategies for finished biopharmaceuticals

BRONZE SPONSOR

Extractables and leachables are product-related impurities that result from product contact with components such as gaskets, stoppers, storage bags, cartridges, and prefilled syringes that are used for processing, storage, and/or delivery of biopharmaceuticals. Leachables are of concern for patients due to potential effects on product quality and safety. It is possible that such an impurity could directly impact the patient or indirectly impact the patient by interacting with the protein by chemical reactions. Adducts and leachables may or may not be detected as product-related impurities in leachables screening stability studies depending on the rigor of the analytical program. The need for the development of a thorough and holistic extractable and leachable program based on risk assessment, review of existing literature, and consolidation of industry best practices is discussed. Risk mitigation strategies for an extractable-leachable program must be divided into different stages. The integration of analytical activities with health-based risk-assessment information into the design of an extractable-leachable program is highlighted.

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

10:00 - 10:30 — Morning coffee and networking break

10:30 - 11:10

The rubber formulation composition and its impact on extractables and leachables

- Composition of Rubber for Parenteral Packaging
- Different rubber formulations geared towards specific properties
- The evolution of rubber formulation cleanliness throughout the years
- Expectations of Extractables information sharing from a rubber closure supplier

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

11:10 - 12:00

Extractables from Rubber Closures – Assessment and Control

- Theoretical Extractables from Rubber Closures
- Design of an Extractables Study
- Control Strategy

Dr. Bettine Boltres | Principal Scientific Affairs, Packaging & Delivery Systems | West Pharmaceutical Services Deutschland GmbH & Co KG, DE

12:00 - 13:00 — Business lunch

13:00 - 13:40

Extractables and Leachables profiles from glass tubing and container made out of pharmaceutical glass

- General overview of potential E&L from glass materials down to ppm level
- Primary packaging material for parenterals is getting an integral part of the whole drug formulation system
- Not every glass is equal – An overview about different E&L profiles of commonly used glass types (so called Type 1, Type 3, high, middle and low borosilicate glasses)
- Discussion of influencing factors like the converting, different buffer systems and chemical environments, different pH values, filling volumes and for example thermal sterilization

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

qepler

EXTRACTABLES & LEACHABLES SUMMIT 2019

October 16 | Berlin, Germany

13:40 - 14:20

Adoption of standardized extractables datasets for single-use system qualification and risk assessment

- Implementation of USP <665> and alignment with BPOG extractables protocol
- Insights from the execution of both the BPOG and USP <665> extractables protocols on various single-use components (biocontainer, filter, sterile connector, tubing)
- Examples of extractables datasets generated per BPOG and USP <665> extractables protocols
- Case studies illustrating how component extractables data are applied for risk assessment of potential leachables from single-use system
- Toxicological risk assessment of potential leachables from SUS

Dr. Gilbert Tumambac | Sr. Principal Scientist | Pall Biotech, USA

14:20 - 15:00

Errors in chromatographic screening

- The risk of omission: omitting a compound in chromatographic screening is a fatal error, as the assessment of the extractables or leachables profile is irreversibly compromised by committing the error
- The risk of inexact identification: if the wrong identity for a compound is secured, then clearly the substance's impact on the devices suitability cannot be assessed as the link between the extractable and its relevant toxicological information cannot be established.
- The risk of inaccurate and imprecise quantitation in chromatographic screening processes.

Dries Cardoen | Team Responsible of E&L Study Directors - Inhalation/Topical/Transdermal Products | Nelson Labs, BE

15:00 - 15:10 — **Chairman's closing remarks and end of day two**

15:10 - 15:40 — **Afternoon coffee and networking break**

SPEAKER SPONSOR

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.

BRONZE SPONSOR

SGS

Tel: +49 6128 744 245
Fax: +49 6128 744 700
Website: http://www.sgsgroup.de/de-DE/Life-Sciences.aspx

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 95,000 employees, SGS operates a network of over 2,400 offices and laboratories around the world. Our customers in the bio-pharmaceutical industries rely on us to provide them with outsourcing services on both the quality and safety of drug ingredients and the development process – from the early development stages until the commercialization of finished products. Our Quality Control testing activities help improve efficiency, reduce costs, shorten time to market and ensure the safety of pharmaceutical products.

BIOGRAPHIES

Dr. Tino Otte
Senior Scientific Consultant
Intertek (Schweiz) AG, CH

Tino Otte, Senior Scientific Consultant at Intertek, is an expert for analysis of impurities and contaminations in pharmaceutical products.
He holds a degree in polymer-chemistry from the University of Halle/Saale and a Ph.D. from the Darmstadt Technical University, where he graduated in 2010. He joined Intertek (Schweiz AG) in 2016. Prior to joining Intertek, he worked with different research, development and manufacturing companies where he served in several functions in product management and development of analytical services. He has more than 7 years of experience in GMP regulated environment within multiple areas of product analysis including method development, validation and QC.

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 group leader for the organic trace analysis in the environmental analytical division at Eurofins Scientific. In 2015, he joined Sartorius Stedim Biotech where he established and is heading the internal Extractables analysis laboratory. He is responsible for material and product qualification studies for single-use systems and components for the biopharmaceutical industry.

Prof. Dr. Johannes Harleman
Independent Consultant

Hans is an experienced Preclinical Safety expert. He graduated in veterinary medicine in 1978 in Utrecht, the Netherlands. He did his PhD studies at the University of Illinois at Urbana Champaign, department of veterinary pathobiology. He worked as a pathologist and manager for several pharmaceutical companies in Switzerland, United Kingdom and Germany (Ciba-Geigy, Smith Kline & French, ASTA Medica/Degussa, Novartis, Merck, Astra Zeneca). He worked as an independent toxicology and pathology consultant in 2013- 2014. Currently he is Vice President Global Preclinical Development and Management at Fresenius-Kabi in Bad Homburg Germany. In February 2004 he became honorary professor at the Tieraertzliche Hochschule in Hannover. He contributed to many successful registrations of both NBEs, NCEs and chemicals. He has ca 50 publications in peer reviewed journals or contributions to book chapters.
Short version: Hans graduated in veterinary medicine in 1978 in Utrecht, the Netherlands. He did his PhD studies at the University of Illinois at Urbana Champaign, department of veterinary pathobiology. He worked as a pathologist and preclinical safety manager for several pharmaceutical companies in Switzerland, United Kingdom and Germany. Currently he is Vice President Global Preclinical Development and Management at Fresenius-Kabi in Bad Homburg Germany.

Carsten Worsøe
Principal Scientist
Novo Nordisk A/S, DK

Carsten Worsøe is a principal scientist in an analytical development department at Novo Nordisk. In his 20 years at Novo Nordisk, his main responsibility has been to develop analytical methods for Extractables and Leachables (E&L) test procedures of new packaging/container closure systems under development. Within Novo Nordisk Carsten has been one of the main actors to bring relevant people in packaging materials, toxicology, formulation, regulatory and analytical chemistry together to perform risk assessments and strategies for E&L testing in development and supply projects within parenteral delivery (prefilled cartridges, prefilled syringes and pump infusion systems etc.).

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.

Tim Hulme
Principal Consultant
Smithers Rapra Ltd., UK

Tim has over 30 years' experience in chemical analysis, both with classical techniques and a wide variety of instrumental techniques. Before working at Smithers Rapra, Tim worked for ConvaTec (wound care/medical devices company) as an analytical scientist and before that at Glaxo Group Research (pharmaceutical company), also as an analytical scientist.
Tim's principal responsibility is for the project management of Extractables and Leachables projects but he also runs many customised analytical chemistry projects, both large and small.
Tim has a BSc (Hons) in Applied Chemistry from the University of Hertfordshire and then studied an MSc in Pharmaceutical Analysis at Liverpool John Moores University. He is a Chartered Chemist (CChem), Chartered Scientist (CSci), a Member of the Royal Society of Chemistry and a Fellow of the Royal Microscopical Society.

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.

BIOGRAPHIES

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.

Dr. Clemens Günther
Director Nonclinical Safety Consumer Care
Bayer AG, DE

Dr. Clemens Günther received his diploma in biology and doctorate for natural sciences from the Free University, Berlin-Germany.
From 1990 to 2006 he started his professional career at Schering AG, Berlin-Germany.
From 2007 to 2013, Dr. Clemens Günther was Director and Head of Global Preclinical Development at Intendis GmbH, branded later-on as Bayer Dermatology. In this position, he was responsible for Nonclinical Safety for the marketed product portfolio of Bayer Dermatology as well as the global preclinical development strategy including human DMPK for development and life cycle management projects.
Since integration of Intendis into Bayer in 2013, he became Director Nonclinical Safety Consumer Care within the Division of Bayer Pharmaceuticals.
Meanwhile Dr. Clemens Günther has gained 29 years experience in nonclinical safety. He has been involved in nonclinical development and regulatory toxicology of small molecules, biologics, medical devices and drug device combination products.

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).

Dr. Gilbert Tumambac
Sr. Principal Scientist
Pall Biotech, USA

Gilbert Tumambac, Ph.D. is a Sr. Principal Scientist in the Regulatory and Validation group at Pall Biotech (Port Washington, NY). He has over 13 years of industry experience which includes 5 years with Merck & Co., Inc. working on analytical method development, validation and impurity identification, and over 8 years with Pall where he currently serves as one of the E&L SMEs supporting single-use and continuous processing technology. He has a PhD in Organic Chemistry from Georgetown University in Washington, DC.

Markus Obkircher
Director R&D, Head of Reference Materials and Proficiency Testing
Merck, DE

Markus Obkircher is the head of Merck's Reference Materials Research & Development division with teams in the US and Switzerland. He is responsible for the in-house development of new analytical standards and certified reference materials. Prior to this position he was R&D Manager in Buchs, Switzerland, with a strong focus on synthesis, characterization and certification of reference materials. He joined Merck / Sigma-Aldrich five years ago after heading the development unit for a custom API manufacturer. Before that he completed his post-doctoral studies at Harvard in Boston and his PhD thesis in Basel, Switzerland.

BIOGRAPHIES

Dr. Bettine Boltres
Principal Scientific Affairs, Packaging & Delivery Systems
West Pharmaceutical Services Deutschland GmbH & Co KG, DE

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 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.
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.
Bettine is an active member of the USP Packaging and Distribution Expert Committee as well as the ISO TC76/WG 4 on elastomers, 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.

Dries Cardoen
Team Responsible of E&L Study Directors - Inhalation/Topical/ Transdermal products
Nelson Labs, BE

Dries Cardoen received his Ph.D. from the Faculty of Biology at the University of Leuven (Belgium) in 2011. After his academic career as a post-doctoral researcher, he started at Nelson Labs (formerly Toxikon Europe) in 2013 as study director in the Extractables & Leachables Department. From the start, he specialized in E&L projects of inhalation drug products. He is currently leading the team of study directors that is specialized in E&L testing of inhalation drug products and topical and transdermal drug products.

Folker Steden, PhD
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.

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.

Dr. Lars Albermann
Head of Pharma and Food Regulatory Subject Matter Experts
Merck, DE

Originally a molecular biologist, Lars Albermann received his PhD from the Westfälische Wilhelms-Universität in Münster, Germany, in 2004. He subsequently spent 3 years as a postdoctoral researcher at the National University of Ireland, Galway. He has been working in several regulatory positions in pharmaceutical industry as well as contributing to a number of industry associations over the last 12 years. Currently, he is responsible for a team of regulatory experts at Merck Life Science Regulatory Management. The team is working on regulatory topics relevant for the entire portfolio of pharma and food related products on a global level.

EVENTS CALENDAR 2020

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 ANNUAL DRUG/DEVICE COMBINATION PRODUCTS SUMMIT ..... December 4-5, 2019
Prague, Czech Republic
Get up to date with the regulatory and quality compliance strategies for combination product development.
https://qepler.com/pdf/2ddc.pdf
REGISTRATION IS OPEN NOW!

2ND ANNUAL PHARMACEUTICAL LYOPHILIZATION SUMMIT ..... February 12-13, 2020
Berlin, Germany
Overviewing regulatory updates and advanced technologies, developing lyophilization process that ensure quality at all stages.
http://qepler.com/pdf/2lyo.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL HIGHLY POTENT APIs SUMMIT ..... February 19-21, 2020
Prague, Czech Republic
Enhancing HPAPIs manufacturing and handling via new technologies, engineering improvement and successful contamination control strategies.
https://qepler.com/pdf/2hpapi.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

PHARMACEUTICAL ASEPTIC PROCESSING SUMMIT ..... May 19-20, 2020
Prague, Czech Republic
Ensuring safe highly potent aseptic production based on new regulations and technologies implementation.
https://qepler.com/pdf/ap.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

3RD ANNUAL PRE-FILLED SYRINGES SUMMIT ..... May 28-29, 2020
Prague, Czech Republic
Improving process development at all stages and enhancing patient safety through new drug delivery systems.
https://qepler.com/pdf/3pfs.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL INHALED DRUG DELIVERY SUMMIT ..... September 17-18, 2020
Prague, Czech Republic
Enhancing respiratory drug delivery and improving patient care through new approaches of product development and advanced technologies.
https://qepler.com/pdf/2idd.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

MEDICAL DEVICE REGULATIONS SUMMIT ..... September 22-23, 2020
Prague, Czech Republic
Exploring EU MDR and IVDR updates and preparing company for new requirements implementation.
https://qepler.com/pdf/mdr.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

CMC EXCELLENCE SUMMIT ..... October 15-16, 2020
Prague, Czech Republic
Excelling chemistry, manufacturing and control based on regulatory requirements and compliance: overviewing different development stages.
https://qepler.com/pdf/cmc.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL EXTRACTABLES & LEACHABLES SUMMIT ..... October 22-23, 2020
Prague, Czech Republic
The latest developments that accelerate E&L: regulatory requirements, new methodologies, study design, safety assessment.
https://qepler.com/pdf/2enl.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

INTRADERMAL & TRANSDERMAL DRUG DELIVERY SUMMIT ..... October 29-30, 2020
Prague, Czech Republic
Advanced developments in IDD & TDD therapies and delivery systems: development, design & delivery.
https://qepler.com/pdf/tdd.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

CLEANROOM TECHNOLOGY SUMMIT ..... November 12-13, 2020
Prague, Czech Republic
Get the latest updates in cleanroom technologies, new regulations, compliance strategies, engineering and design, EM and contamination control.
https://qepler.com/pdf/ct.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

PHARMACEUTICAL QUALITY RISK MANAGEMENT SUMMIT ..... November 17-18, 2020
Prague, Czech Republic
Building effective QRM processes and programs: regulatory updates, risk mitigation strategies, LCM, new tools, risk-based decision making.
https://qepler.com/pdf/qrm.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL GENOTOXIC IMPURITIES IN PHARMACEUTICALS SUMMIT ..... November 19-20, 2020
Prague, Czech Republic
GTI strategies & new methodologies: analysis, in silico & regulations. Challenges & opportunities.
https://qepler.com/pdf/2gti.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

3RD ANNUAL DRUG/DEVICE COMBINATION PRODUCTS SUMMIT ..... December 3-4, 2020
Vienna, Austria
Combination products development based on regulatory requirements, safety assurance, quality compliance and risk management excellence.
https://qepler.com/pdf/3ddc.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

CONTACTS

Please send your session title and summit name to:

Denis Polikarpov
Executive Director
Tel: +420 608 030 490
Email: denis.polikarpov@qepler.com
LinkedIn: https://www.linkedin.com/in/denis-polikarpov-conferences/
Whatsapp, Viber: +420 608 030 490

Evgenia Makar
Co-founder & Chief Executive Officer
Tel: +420 608 030 490
Email: evgenia.makar@qepler.com
LinkedIn: https://www.linkedin.com/in/evgenia-makar/
Whatsapp, Viber: +420 608 030 490

REGISTRATION FORM

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

SUMMIT NAME: Extractables & Leachables Summit 2019

REGISTRATION DATE:

TOTAL PRICE:

PROMOCODE:

PACKAGE NAME:

PACKAGE NAME	Register by 12.07.2019	Register by 16.08.2019	Register by 13.09.2019	Standard price
Individual ticket (2 Days)	€1195 (save €500) ☐	€1395 (save €300) ☐	€1495 (save €200) ☐	€1695 ☐
Individual ticket (1 Day)	€795 (save €200) ☐	€845 (save €150) ☐	€895 (save €100) ☐	€995 ☐
Group ticket (2-3 delegates)	€995 (save €600) ☐	€1195 (save €400) ☐	€1295 (save €300) ☐	€1595 ☐
Group ticket (4+ delegates)	€795 (save €700) ☐	€895 (save €600) ☐	€995 (save €500) ☐	€1495 ☐
Non-profit organizations	€695 (save €300) ☐	€795 (save €200) ☐	€895 (save €100) ☐	€995 ☐
Documentation €499 ☐	Promotional materials distribution €699 ☐	Speaker €2495 ☐	Pop up stand €3495 ☐	Bronze €4095 ☐
Booth €5495 ☐	Silver €6995 ☐	Gold €7995 ☐		

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, coffee breaks, lunches, dinner and conference materials. Payment is due 10 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.

PACKAGES

ONLINE PACKAGES

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

PACKAGE NAME	PRICE
DOCUMENTATION Post-event presentations and other materials. Presentation content is subject to speaker's approval for distribution.	€499
PROMOTIONAL MATERIALS DISTRIBUTION (Distribution of your company's promotional materials to all attendees)	€699

SPONSORSHIP PACKAGES

BENEFITS	SPEAKER €2495	POP UP STAND €3495	BRONZE €4095	BOOTH €5495	SILVER €6995	GOLD €7995
Number of passes included	1	1	2	2	3	4
Registration fee for additional company representatives	€1295	€1295	€1195	€1195	€1095	€1095
Coupon (1 free pass for the other Qepler events)					•	•
Pop up stand in the break area (3m wide x 3m height; includes 1 table, chairs, 1 electrical socket)		•	•			
Exhibition booth with LCD monitor for video presentations in the break area (3m wide x 3m deep; includes 1 table, chairs, 1 electrical socket)				•	•	•
Pull-up banner at the entrance to the auditorium (to be provided by sponsor)					•	•
Speaking slot	20 min		20 min	20 min	30 min	30 min
Opening keynote presentation						15 min
Recognition in chairman's opening address	•	•	•	•	•	•
Seat on a panel discussion			•	•	•	•
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			1/4 Page	1/4 Page	1/2 Page	1 Page
Company flyer/brochure included in conference folder (to be provided by sponsor)			•	•	•	•
Online distribution of your company's promotional materials to all attendees			•	•	•	•
Lanyards for summit badges, notepads, pens and other promotional materials (max. 5) given to all participants and speakers (to be provided by sponsor)						•

MARKETING CAMPAIGN

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

PARTICIPATION FEE

Fees are inclusive of the 2-day summit, materials, online post-event documentation/presentation package, lunches, snacks, refreshments and business dinner.

TRAVEL AND ACCOMMODATION

Hotel accommodation and travel expenses are not included in the fee. Special rates for the event venue will be sent upon availability.

VENUE

Event venue 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. Presentation content is subject to speaker's approval for distribution.

DISCOUNTS

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

EVENTS CALENDAR 2019 - 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

PHARMACEUTICAL LYOPHILIZATION SUMMIT.....February 13-14, 2019
Prague, Czech Republic
Discuss best practices in tech & regulatory updates, process, formulation, testing, monitoring and new products development.
http://qepler.com/pdf/lyo.pdf

HIGHLY POTENT APIs SUMMIT.....February 20-21, 2019
Berlin, Germany
Assess and reduce manufacturing and handling challenges for highly potent active pharmaceutical ingredients.
https://qepler.com/pdf/hpapi.pdf

GENOTOXIC IMPURITIES IN PHARMACEUTICALS SUMMIT.....April 11-12, 2019
Berlin, Germany
GTI strategies & new methodologies: analysis, in silico & regulations. Challenges & opportunities.
https://qepler.com/pdf/genetoxic.pdf

INHALED DRUG DELIVERY SUMMIT.....May 23-24, 2019
Berlin, Germany
Assess and harness novel approaches to the development of inhaled drug products for enhanced patient care.
https://qepler.com/pdf/inhalation.pdf

2ND ANNUAL PRE-FILLED SYRINGES SUMMIT.....June 4-5, 2019
Barcelona, Spain
Enhance expertise sharing in developing pre-filled syringes and provide attendees with ample networking opportunities.
https://qepler.com/pdf/pfs.pdf

EXTRACTABLES & LEACHABLES SUMMIT.....October 15-16, 2019
Berlin, Germany
Get the latest updates in regulation, analytical testing, risk & safety assessment, biocompatibility.
https://qepler.com/pdf/enl.pdf
REGISTRATION IS OPEN NOW!

2ND ANNUAL DRUG/DEVICE COMBINATION PRODUCTS SUMMIT.....December 4-5, 2019
Prague, Czech Republic
Get up to date with the regulatory and quality compliance strategies for combination product development.
https://qepler.com/pdf/2ddc.pdf
REGISTRATION IS OPEN NOW!

CONTACTS

Please send your session title and summit name to:

Denis Polikarpov
Executive Director
Tel: +420 608 030 490
Email: denis.polikarpov@qepler.com
LinkedIn: https://www.linkedin.com/in/denis-polikarpov-conferences/
Whatsapp, Viber: +420 608 030 490

Evgenia Makar
Co-founder & Chief Executive Officer
Tel: +420 608 030 490
Email: evgenia.makar@qepler.com
LinkedIn: https://www.linkedin.com/in/evgenia-makar/
Whatsapp, Viber: +420 608 030 490

EVENTS CALENDAR 2020

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 ANNUAL PHARMACEUTICAL LYOPHILIZATION SUMMIT.....February 12-13, 2020
Berlin, Germany
Overviewing regulatory updates and advanced technologies, developing lyophilization process that ensure quality at all stages.
http://qepler.com/pdf/2lyo.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL HIGHLY POTENT APIs SUMMIT.....February 19-21, 2020
Prague, Czech Republic
Enhancing HPAPIs manufacturing and handling via new technologies, engineering improvement and successful contamination control strategies.
https://qepler.com/pdf/2hpapi.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

PHARMACEUTICAL ASEPTIC PROCESSING SUMMIT.....May 19-20, 2020
Prague, Czech Republic
Ensuring safe highly potent aseptic production based on new regulations and technologies implementation.
https://qepler.com/pdf/ap.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

3RD ANNUAL PRE-FILLED SYRINGES SUMMIT.....May 28-29, 2020
Prague, Czech Republic
Improving process development at all stages and enhancing patient safety through new drug delivery systems.
https://qepler.com/pdf/3pfs.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL INHALED DRUG DELIVERY SUMMIT.....September 17-18, 2020
Prague, Czech Republic
Enhancing respiratory drug delivery and improving patient care through new approaches of product development and advanced technologies.
https://qepler.com/pdf/2idd.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

MEDICAL DEVICE REGULATIONS SUMMIT.....September 22-23, 2020
Prague, Czech Republic
Exploring EU MDR and IVDR updates and preparing company for new requirements implementation.
https://qepler.com/pdf/mdr.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

CMC EXCELLENCE SUMMIT.....October 15-16, 2020
Prague, Czech Republic
Excelling chemistry, manufacturing and control based on regulatory requirements and compliance: overviewing different development stages.
https://qepler.com/pdf/cmc.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL EXTRACTABLES & LEACHABLES SUMMIT.....October 22-23, 2020
Prague, Czech Republic
The latest developments that accelerate E&L: regulatory requirements, new methodologies, study design, safety assessment.
https://qepler.com/pdf/2enl.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

INTRADERMAL & TRANSDERMAL DRUG DELIVERY SUMMIT.....October 29-30, 2020
Prague, Czech Republic
Advanced developments in IDD & TDD therapies and delivery systems: development, design & delivery.
https://qepler.com/pdf/tdd.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

CLEANROOM TECHNOLOGY SUMMIT.....November 12-13, 2020
Prague, Czech Republic
Get the latest updates in cleanroom technologies, new regulations, compliance strategies, engineering and design, EM and contamination control.
https://qepler.com/pdf/ct.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

PHARMACEUTICAL QUALITY RISK MANAGEMENT SUMMIT.....November 17-18, 2020
Prague, Czech Republic
Building effective QRM processes and programs: regulatory updates, risk mitigation strategies, LCM, new tools, risk-based decision making.
https://qepler.com/pdf/qrm.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL GENOTOXIC IMPURITIES IN PHARMACEUTICALS SUMMIT.....November 19-20, 2020
Prague, Czech Republic
GTI strategies & new methodologies: analysis, in silico & regulations. Challenges & opportunities.
https://qepler.com/pdf/2gti.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

3RD ANNUAL DRUG/DEVICE COMBINATION PRODUCTS SUMMIT.....December 3-4, 2020
Vienna, Austria
Combination products development based on regulatory requirements, safety assurance, quality compliance and risk management excellence.
https://qepler.com/pdf/3ddc.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

CONTACTS

Please send your session title and summit name to:

Denis Polikarpov
Executive Director
Tel: +420 608 030 490
Email: denis.polikarpov@qepler.com
LinkedIn: https://www.linkedin.com/in/denis-polikarpov-conferences/
Whatsapp, Viber: +420 608 030 490

Evgenia Makar
Co-founder & Chief Executive Officer
Tel: +420 608 030 490
Email: evgenia.makar@qepler.com
LinkedIn: https://www.linkedin.com/in/evgenia-makar/
Whatsapp, Viber: +420 608 030 490

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

3RD ANNUAL PHARMACEUTICAL LYOPHILIZATION SUMMIT.....February 10-11, 2021
Vienna, Austria

http://qepler.com/pdf/3lyo.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

3RD ANNUAL HIGHLY POTENT APIs SUMMIT.....February 17-19, 2021
Vienna, Austria

https://qepler.com/pdf/3hpapi.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

ENVIRONMENTAL MONITORING SUMMIT.....March 11-12, 2021
Berlin, Germany

http://qepler.com/pdf/em.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

WEARABLE INJECTORS SUMMIT.....March 25-26, 2021
Berlin, Germany

https://qepler.com/pdf/wi.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL PHARMACEUTICAL ASEPTIC PROCESSING SUMMIT.....May 20-21, 2021
Berlin, Germany

https://qepler.com/pdf/2ap.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

4TH ANNUAL PRE-FILLED SYRINGES SUMMIT.....May 27-28, 2021
Vienna, Austria

https://qepler.com/pdf/4pfs.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

3ND ANNUAL INHALED DRUG DELIVERY SUMMIT.....September 16-17, 2021
Vienna, Austria

https://qepler.com/pdf/3idd.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL MEDICAL DEVICE REGULATIONS SUMMIT.....September 22-23, 2021
Berlin, Germany

https://qepler.com/pdf/2mdr.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

CONTAMINATION CONTROL SUMMIT.....September 29-30, 2021
Prague, Czech Republic

https://qepler.com/pdf/cc.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL CMC EXCELLENCE SUMMIT.....October 14-15, 2021
Berlin, Germany

https://qepler.com/pdf/2cmc.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

3RD ANNUAL EXTRACTABLES & LEACHABLES SUMMIT.....October 21-22, 2021
Vienna, Austria

https://qepler.com/pdf/3enl.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL PHARMACEUTICAL QUALITY RISK MANAGEMENT SUMMIT..... October 28-29, 2021
Berlin, Germany

https://qepler.com/pdf/2qrm.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

3RD ANNUAL GENOTOXIC IMPURITIES IN PHARMACEUTICALS SUMMIT.....November 9-10, 2021
Vienna, Austria

https://qepler.com/pdf/3gti.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL INTRADERMAL & TRANSDERMAL DRUG DELIVERY SUMMIT.....November 16-17, 2021
Berlin, Germany

https://qepler.com/pdf/2tdd.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

2ND ANNUAL CLEANROOM TECHNOLOGY SUMMIT.....November 18-19, 2021
Berlin, Germany

https://qepler.com/pdf/2ct.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

4TH ANNUAL DRUG/DEVICE COMBINATION PRODUCTS SUMMIT.....December 2-3, 2021
Barcelona, Spain

https://qepler.com/pdf/4ddc.pdf
THE CALL FOR SPEAKERS IS OPEN NOW!

CONTACTS

Please send your session title and summit name to:

Denis Polikarpov
Executive Director
Tel: +420 608 030 490
Email: denis.polikarpov@qepler.com
LinkedIn: https://www.linkedin.com/in/denis-polikarpov-conferences/
Whatsapp, Viber: +420 608 030 490

Evgenia Makar
Co-founder & Chief Executive Officer
Tel: +420 608 030 490
Email: evgenia.makar@qepler.com
LinkedIn: https://www.linkedin.com/in/evgenia-makar/
Whatsapp, Viber: +420 608 030 490