



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

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A central diamond-shaped graphic containing a background image of laboratory glassware (vials, beakers) and a spiral notebook. A white rectangular border is superimposed on the image.

EXTRACTABLES & LEACHABLES

EXTRACTABLES & LEACHABLES SUMMIT 2019

October 15-16, 2019 | Berlin, Germany

Venue:
NH Collection Berlin Friedrichstrasse
Friedrichstraße 96

The logo for NH Collection Hotels, featuring a red circular emblem with a white geometric design above the text "NH COLLECTION HOTELS" in a sans-serif font.

NH COLLECTION
HOTELS

CHAIR DAY 2



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



Andrew Feilden
Technical director
Smithers Rapra Ltd., UK



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



Prof. Dr. Johannes Harleman
Former Vice-President Global Preclinical
Development & Management
Fresenius Kabi
Deutschland GmbH, DE



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



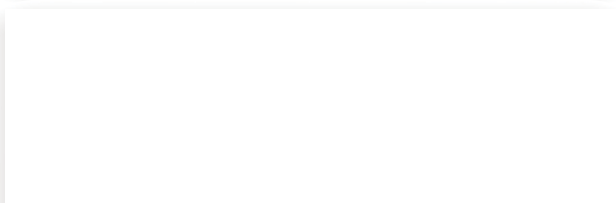
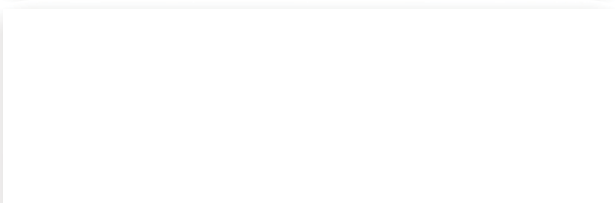
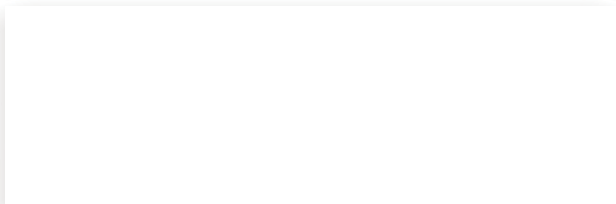
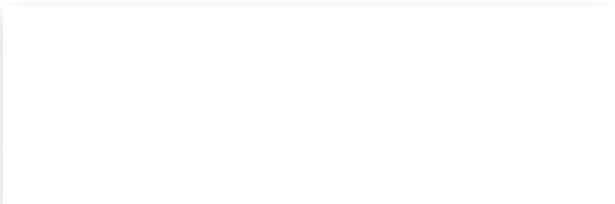
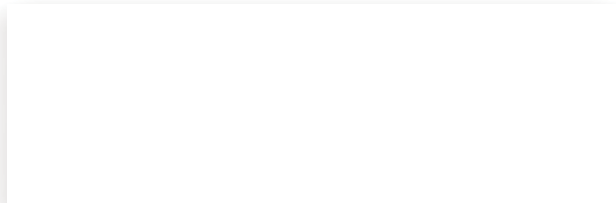
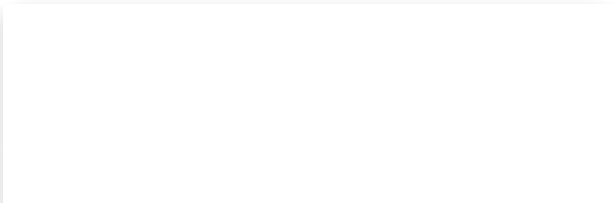
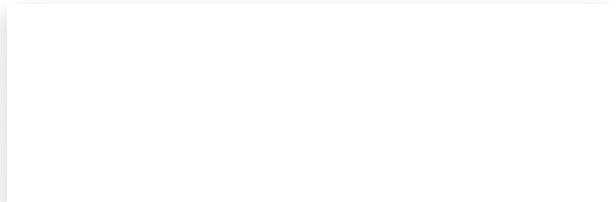
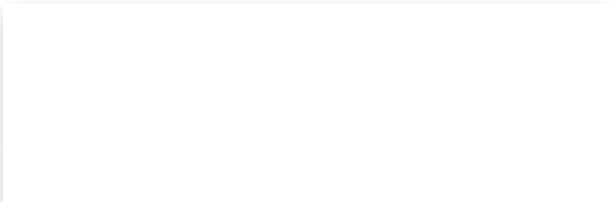
Dr. Clemens Günther
Director Nonclinical Safety Consumer
Care
Bayer AG, DE



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



Dr. Simone Biel
Field Marketing Single Use Technology
Merck Millipore, DE



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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.

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 - ◆ Chief Executives
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 - ◆ Vice Presidents
 - ◆ Department Heads
 - ◆ Leaders
 - ◆ Managers
 - ◆ Scientists
 - ◆ Engineers
 - ◆ Other Specialists
- ◆ 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

DIVISIONS

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- ◆ Product & Process Development
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- ◆ Risk Management & Assessment
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- ◆ Safety Assessments
- ◆ Scientific Affairs
- ◆ Single Use Systems
- ◆ Standardisation
- ◆ Toxicology
- ◆ Validation
- ◆ Other

GEOs

- ◆ Central and Eastern Europe
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- ◆ Middle East and Africa
- ◆ Asia-Pacific
- ◆ Other



INDUSTRIES

- ◆ Pharmaceutical
- ◆ Biotechnology
- ◆ Medical Devices
- ◆ Chemicals
- ◆ Plastics
- ◆ Glass
- ◆ Other

EXTRACTABLES & LEACHABLES

October 15 | Berlin, Germany

07:50 - 08:30

 Registration and Welcome Coffee

08:30 - 08:40

 Opening Address from the Chairman

08:40 - 09:20

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. Simone Biel | Field Marketing Single Use Technology | Merck Millipore, DE



09:20 - 10:00

 Speed Networking

10:00 - 10:40

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 | Former Vice-President Global Preclinical Development & Management | Fresenius Kabi Deutschland GmbH, DE

10:40 - 11:10

 Morning coffee and networking break

11:10 - 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

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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



EXTRACTABLES & LEACHABLES
October 15 | Berlin, Germany
12:45 - 13:45
 **Business lunch**
13:45 - 14:10
RESERVED FOR SPONSOR
14:10 - 14:50
Setting up effective E & L Studies: extraction and right conditions selection, leachable study monitoring and compounds selection, leachable study design.

Andrew Feilden | Technical director | Smithers Rapra Ltd., UK

14:50 - 15:30
Comparative Extractables Study of Autoclavable Polyethersulfone Filter Cartridges for Sterile Filtration

Dr. Roberto Menzel | Laboratory Supervisor and Manager Extractables | Sartorius Stedim Biotech, DE
15:30 - 16:00
 **Afternoon coffee and networking break**
16:00 - 16:40
Session 9

- ◆ Practical implementation of E & L strategy: study design for multicomponent/single container closure systems. Creating analytical laboratory based on regulatory requirements. Studies' data evolution.
- ◆ Best practices of Extractables & Leachables assessments: study organisation and design. Analytical methods. Sterilization methods. Materials qualification and selection. OR
- ◆ E & L research excellence: analytical techniques implementation, sample preparation, targeted compounds identification and classification. New methodologies.

16:40 - 17:20
Session 10

- ◆ Building effective leachables study: mapping activities for the development phase, techniques for the quality control, information identification and effective use. OR
- ◆ Excelling leachables strategies: analytical methods and validation, strategy development, chemical profiles. Single-use process equipment. Risk-based evaluation.
- ◆ Extractables testing: criteria for the profile, quality control, change management. OR
- ◆ Setting up effective E & L Studies: extraction and right conditions selection, leachable study monitoring and compounds selection, leachable study design.

17:20 - 17:50
 **Panel Discussion**
17:50 - 18:00
 **Chairman's closing remarks and end of day one**
19:00 - 21:00
 **Business dinner**

EXTRACTABLES & LEACHABLES
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
Session 2

- ◆ Medical device: E & L point of view, regulatory updates, packaging, testing. OR
- ◆ Large volume injections: E & L testing challenges, primary and secondary packaging.

10:00 - 10:30
 **Morning coffee and networking break**
10:30 - 11:10
Session - Reserved

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

11:10 - 12:00
Leachables strategies for finished biopharmaceuticals

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**

12:00 - 13:00
 **Business lunch**
13:00 - 13:40
Session 5

- ◆ Leachables in biopharmaceuticals: leachables role in the manufacturing process, influence on the stability, storage and administration. Bioproduction view on the E & L evaluation: practical examples. materials approaches. OR
- ◆ Lyophilized products: primary packaging, leachable studies design and evaluation. Regulations impact on combinations products in administration procedures: 21CFR Part 4.

EXTRACTABLES & LEACHABLES

October 16 | Berlin, Germany

13:40 - 14:20

Session 6

- ◆ Single-Use Systems and E & L testing: risks classification, regulations implementation in study design.

14:20 - 14:50

☕ Afternoon coffee and networking break

14:50 - 15:30

Session 7

- ◆ Extractables & Glass: extractables types, glass composition, risk evaluation, extractables minimalization strategies. Challenges related to glass use in parenterals. OR
- ◆ Extractables & Plastics: plastics and additives classification and types, chemical and physical characteristics.
- ◆ CCS & materials: practical examples of use of different types of polymers. Polymers composition. OR

15:30 - 16:10

Session 8

- ◆ Extractables & Elastomers in parenteral packaging: elastomers composition, E & L minimalization, E & L studies for parenterals.

16:10 - 16:20

🗣️ Chairman's closing remarks and end of day two

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EXTRACTABLES & LEACHABLES

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 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.



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



Prof. Dr. Johannes Harleman
Former Vice-President
Global Preclinical
Development &
Management
Fresenius Kabi
Deutschland GmbH, DE

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 Tieraertztliche 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.



Andrew Feilden
Technical director
Smithers Rapra Ltd., UK

Dr Andrew Feilden is the Technical Director at Smithers Rapra and Smithers Pira where he leads the technical aspects of the chemistry department. Prior to that he was the Chemistry Operations Director, for 6 years, where he lead the chemistry group at the Shawbury site in the UK. The Shawbury site carries out extractable and leachable testing, GPC analysis and food contact testing. He has delivered numerous international podium presentations on Extractables and leachables.

Andrew has been with Smithers for over 7 years, prior to that he worked for AstraZeneca, specialising in Extractables and Leachables. He has a degree and D Phil from the university of York, is a Fellow of the Royal Society of Chemistry and is a Scientific advisor to IPAC-RS

EXTRACTABLES & LEACHABLES

BIOGRAPHIES



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

Dr. Andreas Nixdorf. Business Development Manager at SGS Life Science Services in Germany. He studied organic chemistry at the University of Bielefeld in Germany with a main focus on mass spectrometry and computational chemistry. Since the date of his Ph.D./doctorate in 1997, he worked in different managerial positions in life science industry; prior to his move to 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 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 the pharmaceutical and medical industry.



Dr. Simone Biel
Field Marketing Single
Use Technology
Merck Millipore, DE

Simone Biel is the European Field Marketing Consultant Single Use Technology at Merck. In her role she investigates the market needs in product performance, regulatory compliance, and quality of single-use systems. Simone holds a PhD from the University of Frankfurt in Microbiology.



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 Novartis 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 project 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 toxicological societies (DGPT & SST).



Dr. Simone Biel
Field Marketing Single
Use Technology
Merck Millipore, DE

Simone Biel is Field Marketing consultant of Merck Life Science's single-use business. In her role she investigates the market needs and trends of single-use technology used in final filling or other process application to ensure product performance meets all quality and regulatory requirements.

Simone joined Merck in 2006 to support the implementation of single-use systems in customer's manufacturing processes. With this experience she acts as a subject matter expert to align Merck's single-use systems and E&L strategy with drug manufacturer's expectations.

Simone holds a PhD from the University of Frankfurt in Microbiology. She is an active member of the BPSA European Advisory Council.

REGISTRATION FORM

This registration form is editable.
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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
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Title:						
Name:						
Surname:						
Company:						
Country:						
Job Title:						
Direct phone:						
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Special Requirements: (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: _____

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Signature:

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

TERMS & CONDITIONS

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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.

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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.



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◀ WAYS TO REGISTER