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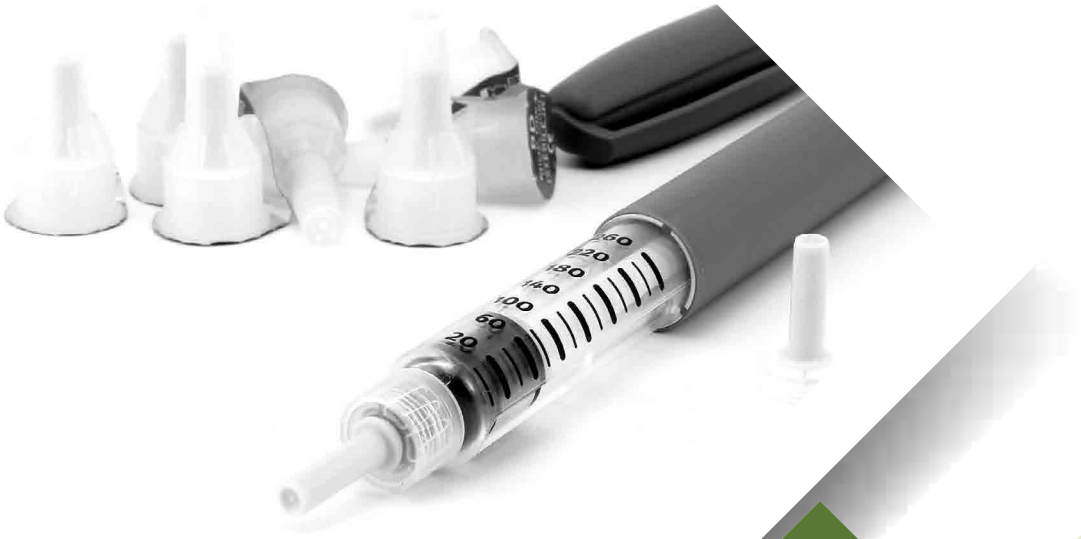

3rd Annual

PRE-FILLED SYRINGES SUMMIT 2020

May 28-29, 2020 | Virtual Conference
Start 08:30 CET (Central European Time)

SPEAKERS BOARD

Harshal Shah
Vice President, Global Medical Technology Division
Cambridge Consultants, USA

Anil Kumar Busimi
Senior Global Product Manager
SCHOTT Pharmaceutical Packaging, CH

Dr. Jakob Lange
Senior Director, Delivery Systems
Ypsomed, CH

Davide Mercadante
Sr. Associate, Product Development Quality (PDQ) – Device Development Quality (DDQ)
Biogen, CH

Cedric Gysel
Manager, Healthcare Solutions Design
Johnson & Johnson, CH

Dr. Daniel Latham
Head – Device Development & LCM
Novartis, CH

Mark A. Chipperfield, M.Sc., B.Eng.(Hons), AMIMechE, MTOPRA
Company Director and Principal Consultant
Corvus Device , UK

Dr. Robert Hormes, Ph.D.
Group Head - Packaging Technology
Novartis, CH

Tina Rees
Associate Director-Human Factors
Ferring Pharmaceuticals, USA

Natalie Abts, MS
Head of Human Factors Engineering
Genentech, USA

WHO YOU WILL MEET

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SNAPSHOT OF ATTENDEES - Pre-Filled Syringes Summit 2018:

- AbbVie - Accord Healthcare - Aptar Pharma - Aristo Pharma - Bayer - Becton Dickinson - Bespak Europe - Bioton - Bristol-Myers Squibb - Cambridge Consultants - Celanese - Corvus Device Datwyler - F. Hoffmann-La Roche - Flex - GlaxoSmithKline - Hekuma - HTL-STREFA - Intertek - Janssen - Laboratoire Aguettant - Medac - Merck Group - Novartis - Novo Nordisk - Pall Life Sciences - RAUMEDIC - Sanofi - SCHOTT Pharmaceutical Packaging - SHL Group - Solvias - Sonceboz - STADA Arzneimittel - Stevanato Group - Terumo Europe - TOPAS Advanced Polymers - West Pharmaceutical Services - Worrell - Others

Agenda: https://qepler.com/pdf/pfs.pdf

SNAPSHOT OF ATTENDEES - Drug/Device Combination Products Summit 2018:

AbbVie - Ablynx - anteris medical - AOP Orphan Pharmaceuticals - Astellas Pharma - AstraZeneca - BIOCORP - Biogen - Boehringer Ingelheim microParts - Bristol-Myers Squibb - BSI Group - Corvus Device - Cytel - Design Science - Eli Lilly - Freelancer - GSK - H&B Electronic - H&T Presspart - Hanway Associates - Janssen - LEO Pharma - Maetrics - Medac - Medtronic - Nelson Labs - Nelson Labs Europe - Novartis - Orion Corporation - Orion Pharma - Pall Life Sciences - Pharmathen - Progress - PME - Regeneron Pharmaceuticals - Sanofi R&D - Sanofi-Aventis - sfm medical devices - Sharp Clinical Services - Spiegelberg - TERUMO EUROPE - tesa Labtec - Teva - UPM Raflatac - Others

Agenda: https://qepler.com/pdf/ddc.pdf

SNAPSHOT OF ATTENDEES - Pharmaceutical Lyophilization Summit 2019:

- Bachem AG - Bayer - Bayer Pharmaceuticals - BIOCAD - BioTestLab, Ltd - Boehringer Ingelheim - Boehringer Ingelheim Animal Health - CONTIPRO a.s. - CSL Behring AG - CSLBehring GmbH - Datwyler Pharma Packaging International NV - De Montfort University - Ghent University - GOETHE Biotechnology GmbH - iQ-mobil solutions GmbH/Tempris - Janssen Pharmaceutica NV - Kingston University London - Laboratoire Aguettant - Lonza AG - Lyofal - Martin Christ Gefriertrocknungsanlagen GmbH - MediWound - MSD International - Novartis - oncomed manufacturing a.s. - Patheon - PIGO srl - Sanofi Pasteur - sfm medical devices GmbH - Shire - Skan AG - SP Scientific - Takeda - Takeda GmbH - Takeda Vaccines - UCL School of Pharmacy - Vaxxinova Int. - Weibo Hi-tech Group - Others

Agenda: http://qepler.com/pdf/lyo.pdf

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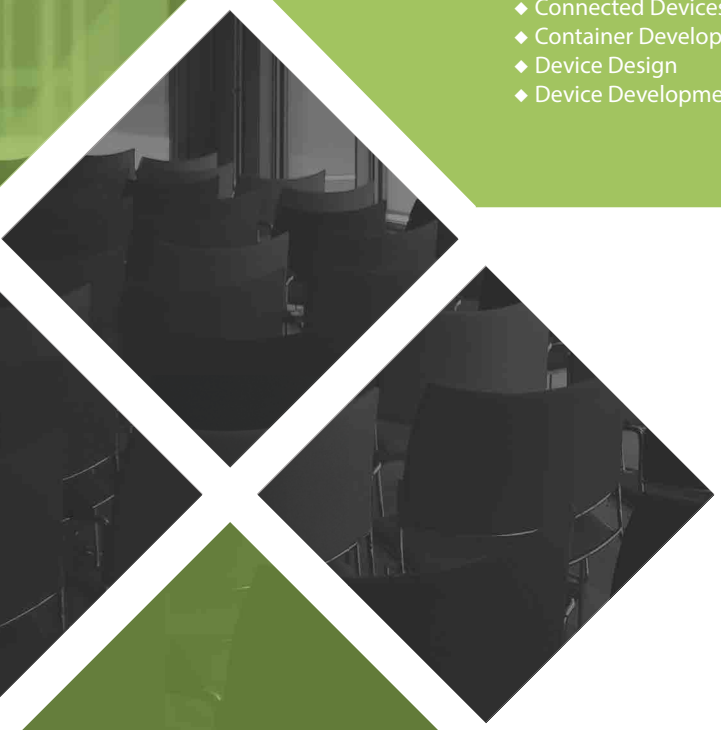
- C-Level, Presidents, Chairs, Members of the Board & VPs
- Vice presidents, Directors, & Heads
- Leaders & Managers
- Principals, Engineers, Analysts & Scientists
- Instructors & Trainers & Teachers
- Advisors, Coordinators, Auditors & Consultants
- Other Professionals, Experts & Specialists

- Autoinjectors
- Business Development
- CMC
- Combination Products
- Connected Devices
- Container Development
- Device Design
- Device Development
- Device Engineering
- Drug Delivery
- Human Factors
- Injectables
- Materials Development
- Medical Devices
- Packaging Development
- Parenterals

DIVISIONS

- Pharmaceutical Formulation
- Pre-Filled Syringes
- Primary Packaging
- Quality Engineering
- R&D
- Regulatory Affairs
- Sterile Manufacturing
- Usability Engineering
- Other



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- Other

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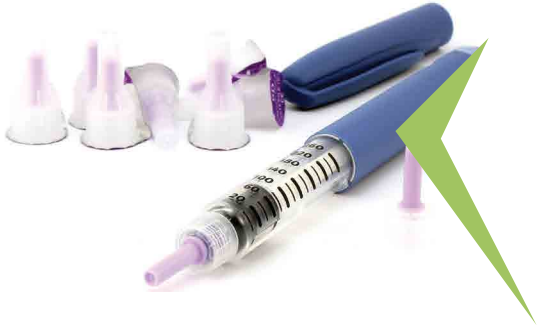

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PRE-FILLED SYRINGES SUMMIT 2020

May 28 | Prague, Czech Republic

08:30 - 09:00 — Registration

09:00 - 09:10 — Opening Address from the Chairman

09:10 - 09:50 — Refresher on the regulatory, quality and technical expectations for PFS in EU/US

- Regs: 21CFR4, 21CFR820, MDR
- QMS: 21CFR820, ISO 13485, MDSAP
- Tech: ISO, Agency requests

Mark A. Chipperfield, M.Sc., B.Eng.(Hons), AMIMechE, MTOPRA | Company Director and Principal Consultant | Corvus Device , UK

09:50 - 10:30 — Case Study - RESERVED FOR

GlaxoSmithKline

10:30 - 10:45 — Morning coffee break

10:45 - 11:25 — TBA

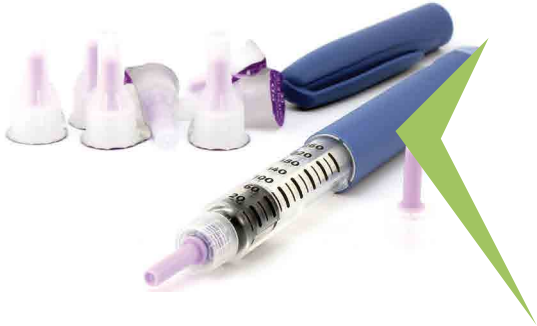
Dr Jakob Lange | Senior Director, Delivery Systems | Ypsomed, CH

11:25 - 12:05 — TBA

Harshal Shah | Vice President, Global Medical Technology Division | Cambridge Consultants, USA

12:05 - 12:35 — Slot Reserved for a Sponsor

12:35 - 13:35 — Lunch break



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May 28 | Prague, Czech Republic

13:35 - 14:15 TBA

Davide Mercadante | Sr. Associate, Product Development Quality (PDQ) – Device Development Quality (DDQ) | **Biogen, CH**

14:15 - 14:45 Slot Reserved for a Sponsor

14:45 - 15:25 TBA

Dr. Daniel Latham | Head – Device Development & LCM | **Novartis, CH**

15:25 - 15:40 Afternoon coffee break

15:40 -16:20 The interface of formulation and application - syringe and device functionality challenges.

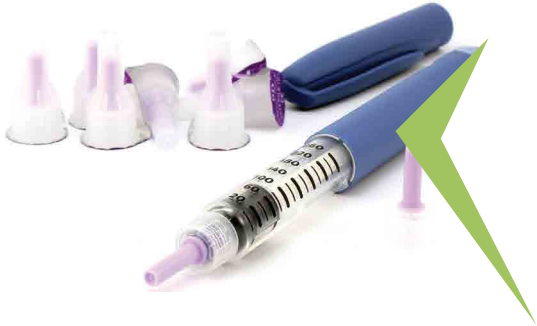
Dr. Robert Hormes, Ph.D. | Group Head - Packaging Technology | **Novartis, CH**

16:20 -17:00 Case Study

- Innovations in Manufacturing and Processing . Robotics and Augmented Reality implementation. Modular assembly, testing equipment, scalability and flexibility. OR
- Prefilled Syringes and New Therapeutics: Challenges Overcome Recommendations, Formulation and Design Considerations. OR
- Designing syringe able biopharmaceuticals. Protein stability challenges OR
- Delivery of high concentration formulations. From molecule to device design. OR
- The interface of formulation and application. Device functionality challenges

17:00 -18:00 Panel Discussion

18:00 - 18:10 Chairman's closing remarks and end of day one



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PRE-FILLED SYRINGES SUMMIT 2020

May 29 | Prague, Czech Republic

08:30 - 09:00 — Registration

09:00 - 09:10 — Opening Address from the Chairman

09:10 - 09:50 — A holistic Approach to Pharmaceutical Product Development

- Addressing the needs of a changing world
- How design creates value
- A care centered design approach
- A proactive device portfolio strategy
- Case Studies

Cedric Gysel | Manager, Healthcare Solutions Design | Johnson & Johnson, CH

09:50 - 10:30 — Root Cause Analysis Best Practices

- Recommended techniques for conducting root cause analysis in a human factors study
- Interpreting root cause analysis data
- Using results to identify design improvement opportunities
- Determining impact on residual risk

Natalie Abts, MS | Head of Human Factors Engineering | Genentech, USA

10:30 - 11:00 — Slot Reserved for a Sponsor

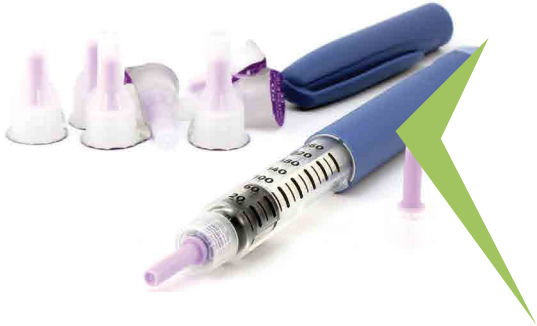
11:00 - 11:15 — Morning coffee break

11:15 - 11:55 — Human Factors Considerations for Pre-Filled Syringes

Tina Rees | Associate Director-Human Factors | Ferring Pharmaceuticals, USA

11:55 - 12:35

12:35 - 13:35 — Lunch break



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PRE-FILLED SYRINGES SUMMIT 2020

May 29 | Prague, Czech Republic

13:35 - 14:05

Slot Reserved for a Sponsor

14:05 -14:45

TBA

Anil Kumar Busimi | Senior Global Product Manager | SCHOTT Pharmaceutical Packaging, CH

14:45 - 15:00

Afternoon coffee break

15:00 - 15:40

Case Study 6

- Risk Management for Combination Products.
- Glass or polymer? Strategies for selecting an appropriate primary container
- Rubber components to guarantee highest compatibility with injectable drugs OR
- Elastomeric closures for sensitive injectables

15:40 - 17:20

Case Study 7

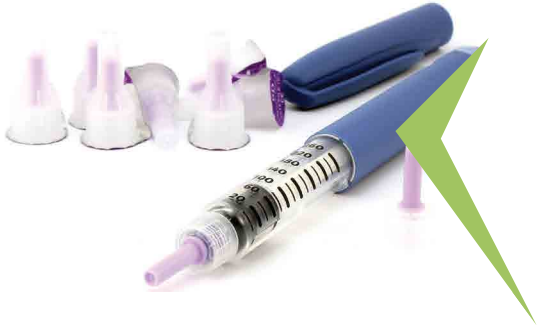
- Syringe siliconization process selection and optimization. Assessment of particles OR
- Particle challenges associated with delivery systems and devices
- Assembly of syringes into devices. Needle bonding and adhesives OR
- Stoppering methods. Selection criteria for filling and stoppering

17:20 - 18:00

Q&A

18:00 -18:10

Chairman's closing remarks and end of day two



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PRE-FILLED SYRINGES SUMMIT 2020

May 28-29 | **Prague, Czech Republic**

BIOGRAPHIES

Harshal Shah
Vice President, Global Medical Technology Division
Cambridge Consultants, USA

Harshal Shah is part of Cambridge Consultant's Global Medical Technology Division. He primarily focuses on novel drug delivery systems and innovations in the field of Oncology.
Harshal has deep commercial understanding of the scientific and engineering innovations in the field of administration of biologics through advance delivery devices and systemic delivery of biologics, proteins and peptides through inhalation route. He has significant domain expertise in oncology patient journey, economics of cancer care, latest industry trends in R&D, and commercialization strategy. His current and past projects include end-to-end drug-device combination product development, manufacturing tec-transfer, life cycle management, commercial launch, technology innovation and device focused regulatory strategy.
He has 12+ years of progressive strategy and management consulting experience in pharmaceutical, biotech and medical device industry. Past experiences include working with Bristol-Myers Squibb, Johnson & Johnson, Merck and over 15 other major companies in consulting role while working with PRTM Management Consultants and as principal of Labyrintheus Consulting.
He has Bachelor of Mechanical Engineering from Nirma Institute of Technology, India and MBA in Supply Chain and Finance from Syracuse University, New York.
He is avid traveler and has been to 50+ countries on adventure, photography and cultural expeditions. He lives in Boston. He can be reached at +1.609.529.2891 / Harshal.Shah[at]CambridgeConsultants.com.

Anil Kumar Busimi
Senior Global Product Manager
SCHOTT Pharmaceutical Packaging, CH

Anil Busimi started his professional career in 2003 at SCHOTT AG in Germany. He worked in different positions including business development manager for microarrays, project manager for new business, and consultant in corporate strategy and development. In 2005, he moved to the business segment Pharmaceutical Packaging and played a key role in building long-term business strategy, market intelligence, product management and innovation for pharmaceutical systems business. From August 2009 until June 2016, he held various positions in global product management for pre-fillable syringe business (glass and polymer). Currently, he is in the strategy & innovation team as senior global product manager for Cartridges and leads the iQ™ Platform market launch. He holds M.Sc degree in Agriculture and Genetics and a MBA.

Dr. Jakob Lange
Senior Director, Delivery Systems
Ypsomed, CH

Jakob is an Engineer and Materials Scientist by training with an MSc degree in Chemical Engineering from the Royal Institute of Technology in Stockholm, Sweden and a PhD in Polymer Science from the Swiss Federal Institute of Technology in Lausanne, Switzerland. He has written and published more than 30 peer-reviewed papers on medical devices, packaging materials and polymers and is a regular contributor to technical and scientific conferences.
Jakob started his professional career as a Research Scientist in packaging R&D with Nestlé at the Nestlé Research Centre in Lausanne, Switzerland. He then worked in R&D Management with GE Healthcare Biosciences in Uppsala, Sweden, before joining Ypsomed in Burgdorf in 2006.
With Ypsomed he has held different positions within Marketing and Sales as well as in R&D Project Management. Currently he has the role of Senior Director, Delivery Systems, overseeing two teams of Product Managers, one managing Ypsomed's autoinjector platforms and the other focusing on customer relationships for device development projects and marketed device products.

Davide Mercadante
Sr. Associate, Product Development Quality (PDQ) – Device Development Quality (DDQ)
Biogen, CH

Davide Mercadante is a medical engineer with 10+ years of experience within multiple areas of device and combination product development, including design & development, design quality assurance, verification & validation engineering, quality control and supply chain quality. He received his bachelor's and master's degree in medical engineering from the Second University of Rome, where is focus was on medical device design and development.

Davide has a Lean Six Sigma Green Belt and he currently works at Biogen in the Device Development Quality group where he is the quality project lead for both the Risk Management Continuous Improvements and Combination Product DHF 21CFR Part 4 Final Rule enhancement projects. He also has been instrumental with the integration of software as a medical device into the existing Quality Management System.

Dr. Daniel Latham
Head – Device Development & LCM
Novartis, CH

Daniel Latham is Head of Device Development Operations in Global Drug Development, Novartis, where he leads an organization responsible for developing delivery systems for combination products for new biologic entities, biosimilars and small molecules.
During the past 10 years at Novartis he has overseen significant device and primary packaging developments and launches and has significantly supported the growth of device development and combination products within the organization.
Prior to Novartis he working in a variety of roles in consumer healthcare focusing on the development of OTC medicines, transdermal patches and medical devices.
He has a PhD in controlled drug delivery from Queen Mary's, University of London and Bachelor and Master's degrees in Engineering from the University of Sheffield.

Mark A. Chipperfield, M.Sc., B.Eng.(Hons), AMIMechE, MTOPRA
Company Director and Principal Consultant
Corvus Device , UK

Mark serves as an independent consultant to the Pharma and Medical Device industries via his company Corvus Device Ltd.
He has over twenty years of experience in Medical Device, Drug Delivery Device and Combination Products across Development, Operations, Regulatory/ Quality Compliance and product maintenance – from a range of roles with GSK, sanofi-aventis, Novartis and F. Hoffmann-La Roche.
Through his career to date he has been heavily involved in development of medical devices for combination products in several forms: syringes, pen injectors, auto-injectors, patch injectors, solution/suspension inhalers, multi-dose disposable and reusable dry powder inhalers, convenience kits, dispensers and special purpose applicators.
He has performed numerous due diligence and technical evaluations of novel delivery technologies; developed products through the full design control phases to market; and maintained marketed products.
Mark is a veteran of several successful IND/CTA/NDA/BLA/MAA submissions and approvals that have included drug delivery devices.
He has experienced many of the challenges associated with delivery device development and device product maintenance within large pharmaceutical companies and implemented Medical Device development guidance, quality systems and business processes.
Qualified with a Master's Degree in Engineering Management from Loughborough University and a Bachelor's Degree in Mechanical Engineering from London South Bank, he has maintained Continuous Professional Development with supplemental and progressive training in areas such as Technical, Manufacturing, Risk Management, Quality & Compliance, Technical Authorship, Project Management and Leadership.
He is an active presenter in the field and has co-authored a case study chapter for PDA's 2013 publication 'Combination Products: Implementation of cGMP requirements', and worked with RAPS to co-author the introduction for their 2016 publication; 'Global Medical Device Strategy'.

Tina Rees
Associate Director-Human Factors
Ferring Pharmaceuticals, USA

Tina Rees is the Associate Director of Human Factors at Ferring Pharmaceuticals, where she is responsible for the development and implementation of Human Factors and Usability Engineering processes into the overall product development process. Prior to her move to Ferring, she was a Principal Research Scientist in Human Factors at Eli Lilly, focusing on human factors usability within the diabetes division. She has conducted many formative and summative usability studies and has participated in a number of submissions to regulatory authorities resulting in clearance of medical devices and approval of combination products. She received her Ph.D. in Biomedical Research from the Mayo Clinic in Rochester, MN. She is a strong proponent of human centered design processes and incorporating human factors early into the device development process.

Natalie Abts, MS
Head of Human Factors Engineering
Genentech, USA

Natalie Abts is the Head of Human Factors Engineering at Genentech, where she manages the team that conducts all human factors activities for Genentech's drug delivery devices. Prior to joining Genentech, Natalie worked in medical device consulting for seven years with the National Center for Human Factors in Healthcare. Natalie has specialized experience in planning and executing both formative stage usability evaluations and validation studies for medical devices and combination products on the FDA approval pathway. Natalie holds a master's degree in industrial engineering with a focus on human factors and ergonomics from the University of Wisconsin, where she was mentored by Dr. Ben-Tzion Karsh.

REGISTRATION FORM

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

SUMMIT NAME: Pre-Filled Syringes Summit 2020

REGISTRATION DATE:

TOTAL PRICE:

PROMOCODE:

PACKAGE NAME:

PACKAGE NAME			Register by 24.04.2020	Standard price
Individual ticket (2 Days)			€495 (save €100) ☐	€595 ☐
Individual ticket (1 Day)			€245 (save €50) ☐	€295 ☐
Group ticket (2-3 delegates)			€395 (save €100) ☐	€495 ☐
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Documentation €499 ☐	Promotional materials distribution €699 ☐	Speaker €2495 ☐	Pop up stand €3495 ☐	Bronze €4095 ☐
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ATTENDEE DETAILS	1ST ATTENDEE	2ND ATTENDEE	3RD ATTENDEE	4TH ATTENDEE	5TH ATTENDEE	6TH ATTENDEE
Title:						
Name:						
Surname:						
Company:						
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Job Title:						
Direct phone:						
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Special Requirenments: (If you have any special dietary requirements or other needs that would enhance your enjoyment of this summit, please specify)						

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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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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

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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
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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.