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- 14+ Speakers | 50+ Atendees
- 10+ Program Hours | 8+ Networking Hours
- Refreshments & Coffee Breaks
- Business Lunches & Dinner
- Case Studies | Workshops
- Panel Discussions | Q & A

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2nd Annual DRUG/DEVICE COMBINATION PRODUCTS SUMMIT 2019

December 4-5, 2019 | Prague, Czech Republic

Venue:

Novotel Praha Wenceslas Square Hotel

Katerinska 38, 120 00 Prague

NOVOTEL
HOTELS & RESORTS

SPEAKERS BOARD

CHAIR DAY 1

Mike Wallenstein
Global Head Novartis MDR Implementation
Novartis Pharma AG, CH

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

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

James Meehan
Associate Principal Scientist
AstraZeneca, UK

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

Fayez Abou Hamad
MD Vigilance Expert – Pharmacist, Complaint & Vigilance Manager
Terumo Europe, BE

Bjørg Kaae Hunter
Regulatory Manager, Devices
GlaxoSmithKline, UK

Daniel L. Bantz
Technology Manager, Packaging & Performance
West Pharmaceutical Services, Inc., CH

CHAIR DAY 2

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

David Roe
Global Technical Steward, NTO Manufacturing Science & Technology
Novartis Pharma AG, CH

Marco Prado
Global Head Quality Medical Devices, TRD QA
Novartis Pharma AG, CH

Dr. Raphael Krampe
Scientist
Boehringer Ingelheim microParts, DE

Shruthi Vidyasagar
Device Development Lead
Device Engineering, GSK, UK

Nicholas Stones
Senior Device Manager - Human Factors
Novartis Pharma AG, CH

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

Elise Legendre
Head of PFS/LVD Late Stage Development, MED Primary Container Development
Sanofi, FR

WHO YOU WILL MEET

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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.

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 - 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

POSITIONS

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

DIVISIONS

- Combination Products
- Device Development
- Device Engineering
- Device Manufacturing
- Medical Devices
- Device Design
- Design Controls
- Design Verification
- Design Validation
- Human Factors
- Usability Engineering
- Risk Management
- Drug Delivery
- Pharmaceutical Formulation

- CMC
- Packaging
- Materials Development
- Research & Development
- QA/ QC
- Regulatory Affairs
- Business Development

INDUSTRIES

- Pharmaceutical
- Biotechnology
- Medical Devices
- CMO
- CRO

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2nd Annual DRUG/DEVICE COMBINATION PRODUCTS SUMMIT 2019

December 4 | Prague, Czech Republic

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

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

08:40 - 09:20 — **MDR and the impact on combined drug-device products - latest status.**

- Refresh the audience on the key implications of the MDR
- Identify implications for both integrated and co-packed configurations
- Share the latest status of guidance and industry discussions
- Offer advice and suggestions for May 2020 readiness

Mark A. Chipperfield | Company Director and Principal Consultant | Corvus Device, UK

09:20 - 10:00 — **Speed Networking**

10:00 - 10:40 — **MDR Art 117 advocacy update.**

- Where are we with MDR Article 117 implementation? And what has been done from an industry advocacy perspective.
- Key Industry comments/questions on EMA Q&A on MDR Article 117 implementation and interaction with EMA on this topic
- Key Industry comments on EMA draft guideline on dossier requirement for drug-device combination products. And reflections on end to end control strategy
- Industry position on clinical evaluation and labeling requirement for drug-device combination products

Bjørg Kaae Hunter | Regulatory Manager, Devices | GlaxoSmithKline, UK

10:40 - 11:10 — **Morning coffee and networking break**

11:10 - 11:50 — **Driving innovation to extend your combination product lifespan – focus on devices for self-injection.**

This presentation will start with a market overview and then cover current trends in the self-injection area including as the move towards platform-based developments and the drive for digitalization. Different options for Life Cycle Management of a device combination product will be discussed, such as the addition of further mechanical device features, updates to the industrial design and modular addition of smart / connected functionalities. The talk will end with a case study presenting usability work conducted using eye tracking on a reusable connected add-on for an autoinjector.

Dr. Jakob Lange | Account Director | Ypsomed, CH

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11:50 - 12:30 — **Analytical approaches for determination of Leachables and Impurities in Combination Products.**

Combination products often contain different types of polymeric construction materials and therefore they are often associated with an increased risk of the presence of Leachables. In many cases large contact surfaces of the different materials are exposed to relatively small volumes of drug formulations which further increases the risk of unwanted interactions.
Moreover, special combination products such as drug eluting stents and other devices with a functional coating are used more frequently. For such products a precise and robust determination of very small levels of coating-related impurities is essential.
In this presentation effective strategies for performing Extractables and Leachables investigations on combination products will be shown including case studies which illustrate the application of such strategies in the daily practice.
In addition, a highly sensitive determination method for volatile and semi volatile impurities will be introduced, which is directly applied to coated devices in order to determine process related impurities in a quantitative way under GMP without the need of complicated, time intensive and often error-prone sample preparation procedures.

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

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2nd Annual DRUG/DEVICE COMBINATION PRODUCTS SUMMIT 2019

December 4 | Prague, Czech Republic

12:30 - 13:30 — **Business lunch**

13:30 - 14:10

Platform selecting and engaging the right stakeholders in the product development process.

- Why a platform approach in drug combination product?
- What are patients and business needs?
- Building the platform, what does that mean?
- Outcomes & challenges

Elise Legendre | Head of PFS/LVD Late Stage Development, MED Primary Container Development | Sanofi, FR

SANOFI

14:10 - 15:30

Workshop:

This workshop will provide an overview of the journey and lessons learnt by the first company to achieve a certification of their QMS system and product against the EU MDR. The presentation will be focused in two parts – firstly an overview of the adaptation of the quality system to incorporate and address the elements required under the MDR followed by a discussion and reflection of the challenges and strategies used to successful upgrade and certify an inhaler device platform supporting both commercial and development products.

- Strategy used to adapt a quality system to the MDR
- Gap assessing your quality system and implementing a plan to adapt and upgrade to continuously improve and meet the MDR and other Global HA requirements
- What does ready look like? Key lessons learned on the transition.
- Discuss the product strategy employed and the challenges faced in adapting a legacy platform product to the MDR, which also required an up classification.
- Outcomes, challenges and strategies for transition and implementation

Marco Prado | Global Head Quality Medical Devices, TRD QA | Novartis Pharma AG, CH
David Roe | Global Technical Steward, NTO Manufacturing Science & Technology | Novartis Pharma AG, CH

NOVARTIS

15:30- 16:00 — **Afternoon coffee and networking break**

16:00 - 16:40

Combination product control strategy.

- QbD Approach to Control Strategy- Drug Product vs Device
- Design Space Exploration through Modelling and Mechanistic Understanding
- Regulatory expectations and industry trends
- Opportunities and Challenges
- Case Study- Final Product Release Tests

Shruthi Vidyasagar | Device Development Lead | Device Engineering, GSK, UK

gsk do more feel better live longer

16:40 -17:30 — **Panel Discussion**

17:30 - 17:40 — **Chairman's closing remarks and end of day one**

19:00 - 21:00 — **Business dinner**

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2nd Annual DRUG/DEVICE COMBINATION PRODUCTS SUMMIT 2019

December 5 | Prague, Czech Republic

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

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

08:40 - 09:20

The re-usable Respimat – Eco-friendly Inhaler with robust technical performance and improved usability.

- Carbon footprint as a development goal
- Optimization of the successful soft mist inhaler Respimat
- Technical performance and Usability (Human factors)
- Synergism of device and cartridge

Dr. Raphael Krampe | Scientist | Boehringer Ingelheim microParts, DE

09:20 - 10:00

Understanding a device framework - risk management, design controls, and systems complexity.

- Combination Product Definition and Regulations on Design Control and Risk Management
- Risk Management as Central pillar to guide the Development of Combination Product
- Integrated development Approach
- Design Validation and Post Marketing

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

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

10:30 - 11:10

Case studies on utilizing human factors in combination products risk management.

- Discussion of how human factors and risk management link through-out the development process
- Practical examples of this for products from early development through to release onto the market
- Current regulatory expectations for the linkage between these two disciplines
- Identification and discussion of various tools that support the generation of this information
- Discussion around managing this for products with digital elements

James Meehan | Associate Principal Scientist | AstraZeneca, UK

11:10 - 11:50

Can a "platform approach" support Human Factors activities?

- What is a "platform approach" ?
- Opportunities of using a "platform approach" to support the Human Factors/Usability activities
- Advantages of implementing a technology platform approach
- Challenges / unknown when applying a platform approach for Human Factors

Nicholas Stones | Senior Device Manager - Human Factors | Novartis Pharma AG, CH

11:50 - 12:50 — **Business lunch**

12:50 - 13:30

Medical Device Vigilance system under MDR - Basics and Approach for Implementation

- Change in definitions of serious incident and FSCA
- Change in the vigilance and FSCA reporting criteria
- Change in vigilance reporting time-frame
- Change in the route of submission for both of vigilance reporting and FSCA.
- Trend report requirement and implementation approach
- Vigilance reporting implementation approach – EU decision tree

Fayez Abou Hamad | MD Vigilance Expert – Pharmacist, Complaint & Vigilance Manager | Terumo Europe, BE

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December 5 | Prague, Czech Republic

13:30 -14:10

Development of Drug Device Combination Products: Nonclinical safety requirements.

- Understanding the complexity of nonclinical safety requirements
- How to select an appropriate test strategy
- How to perform biocompatibility testing according to ISO-10993
- How to avoid potential pitfalls

Dr. Clemens Guenther | Director Nonclinical Safety CC | Bayer, DE

14:10 - 14:50

Beginning with the end in mind – Combination Product Testing.

- Fundamental Product Performance
- Navigating the Standards
- Risk vs Resources Prioritization
- Effective Risk Assessments
- Forthcoming Standards
- Key Takeaways

Daniel L. Bantz | Technology Manager, Packaging & Performance | West Pharmaceutical Services, Inc., CH

14:50 - 15:00 Chairman's closing remarks and end of day two

15:00 - 15:30 Afternoon coffee and networking break

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2nd Annual DRUG/DEVICE COMBINATION PRODUCTS SUMMIT 2019

December 4-5 | Prague, Czech Republic

BIOGRAPHIES

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'.

Bjørg Kaae Hunter
Regulatory Manager, Devices
GlaxoSmithKline, UK

Bjorg Hunter holds a BSc in Design and Innovation Engineering from Technical University of Denmark and an MSc in Biomedical Engineering from Aarhus University, Denmark.
Bjorg has been with GSK since graduating and has held different roles within the Device Engineering Group.
In 2015 Bjorg moved into the late stage parenterals area as device lead for key GSK parenteral devices, working closely with internal GSK project teams and external partners.
She progressed into leading a device management team in January 2017, where she has had the accountability of project management and regulatory compliance for parenteral devices.
In February 2019 Bjorg moved into a key management role in CMC regulatory where she is responsible for the global regulatory and advocacy strategy for GSK's portfolio of devices across modalities and lifecycle.

Dr. Jakob Lange
Account Director
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 Account Director in M&S Delivery Systems, overseeing a team of Product Managers with focus on managing customer relationships in device development projects as well as for marketed device products.

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.

Mike Wallenstein
Global Head Novartis MDR Implementation
Novartis Pharma AG, CH

Mike Wallenstein holds the position as Head Novartis MDR Implementation since April 2019. In this role, Mike oversees all activities related to the EU MDR implementation for Medical Devices & Combination Products at Novartis globally.
Prior to this position Mike was functioning as Executive Director QA / Senior Compliance Officer (GCA) since 2015 to oversee all compliance activities related to Medical Devices & Combination Products at Novartis globally.
He is leading the Medical Device and Combination Product Expert Network at Novartis, and member of several US and EU Expert Committees and Interest Groups on Combination Products. Mike joined Novartis in 2010 as Global Auditor in Group Compliance and Audit. Mike has over 25 years of experience in QA, R&D, and Manufacturing within the Medical Devices & Pharmaceutical Industry. Before joining Novartis, he was Head Global Audit Systems at Gambro Renal Care (today Baxter) and European Head Quality Systems & Audits at 3M. He studied Chemical Engineering and Plastic Technologies, in Münster, Germany.

Dr. Raphael Krampe
Scientist
Boehringer Ingelheim microParts, DE

Raphael Krampe is a pharmacist by training.
After his studies he joined the department of pharmaceutics at the university of Florida for a research stay. He received his Ph.D. in pharmaceutics and biopharmaceutics from the Heinrich Heine University at Düsseldorf.
In 2016 he joined Boehringer Ingelheim microparts in Dortmund. His work focusses on device development, life cycle management and design verification of the Soft Mist Inhaler Respimat®.

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December 4-5 | Prague, Czech Republic

BIOGRAPHIES

Elise Legendre
Head of PFS/LVD Late Stage Development, MED Primary Container Development
Sanofi, FR

With 15 years of experience across pharma, Elise currently serves as Head of late stage development of primary container in medical device at Sanofi.
She is responsible of leading the drug integrated product development for both biologics and small molecules on prefilled syringe based delivery system. Her group is mainly leading the technical operation of the PFS development and the transfer of the developed container and safety system to R&D center and manufacturing groups.
Prior joining Sanofi, Elise was GSK's packaging head on an industrial site in Normandy. She was managing the LCM activities on primary, secondary packaging.
Before this, Elise worked in Aseptic and Packaging manufacturing area as operational manager where she served in various roles focusing on Total cost of ownership, manufacturing, product commercialization and operational excellence.

Marco Prado
Global Head Quality Medical Devices, TRD QA
Novartis Pharma AG, CH

Marco is the appointed Management Representative and accountable for the ISO 13485 certification for Medical Devices for the global Head Quarters at Novartis Pharma AG, Basel. This connects as well with the lead and coordination of the implementation of the ISO strategy as it expands across Novartis.
Marco's team is responsible also for the medical devices input into QMS; global projects e.g. EU MDR and support to other line functions.
Marco started his career as a microbiologist in research and commercial antibiotic production. His 27 year journey with the Novartis group companies started in Brazil as head of sterile production, later expanded to oral liquids and semi-solids production.
Since 2003 Marco has been at the headquarters in Basel in Quality roles ranging from global roles for manufacturing sites and country organization oversight to Head of TRD QA Switzerland.
He obtained his diploma in Pharmacy-Biochemistry at the University of São Paulo (Brazil) followed by a MBA at Fundação Getúlio Vargas (São Paulo, Brazil).

David Roe
Global Technical Steward, NTO Manufacturing Science & Technology
Novartis Pharma AG, CH

Dave has been the Global Technical Steward for Combination Products and Medical Devices since October 2013. In this role, Dave oversees all global operational and maintenance activities related to Medical Devices & Combination Products at Novartis globally and his team supports multiple development programs and projects containing medical devices and or combination products.
He is also the operational representative for the Medical Device and Combination Product Expert Network at Novartis, as well as member of several other cross-functional boards.
Dave joined Novartis in 2009, through the acquisition of Nektar Therapeutics and has contributed to the industrialization and commercialization of several programs in that time.
He has over 25 years of experience in R&D, and Manufacturing within the Consumer electronics, Medical Devices & Pharmaceutical Industry.
Before joining Novartis, he held several roles in fortune 100 companies including West Pharmaceuticals, Apple and General Electric focusing on the development and commercialization of pharmaceutical delivery systems and consumer electronics.
He studied Engineering and holds both a Bachelors and Masters of Science in Plastics Engineering, from the University of Massachusetts, USA. He is aslo a gradute of the General Electric Chemicals and Materials Leadership program and is a certified Six Sigma Black Belt.

Shruthi Vidyasagar
Device Development Lead
Device Engineering, GSK, UK

Shruthi is a Device Lead at GSK (Ware, UK) managing late stage parenteral projects.
Prior to GSK, she worked at Pfizer in North Chicago on differentiated drug delivery systems. She has device development and regulatory experience across multiple platforms - combination products, electromechanical devices and consumable products.
Her recent focus has been on parenteral combination products- syringes, injectors, closed transfer devices, etc supporting all activities from development to launch.
Shruthi holds a BE in Electrical Engineering (VTU, India) and an MS in Biomedical Engineering (University of Michigan, Ann Arbor).

James Meehan
Associate Principal Scientist
AstraZeneca, UK

James Meehan, Associate Principal Scientist within AstraZeneca Device Development, holds a BEng in Medical Mechanical Engineering and an MSc in Ergonomics (Human Factors).
James provides specialist Human Factors support to development and on market products.
This includes leading and designing human factors programs for products, managing external vendors and reviewing/ updating AstraZeneca's internal human factors processes.

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.

Fayez Abou Hamad
MD Vigilance Expert – Pharmacist, Complaint & Vigilance Manager
Terumo Europe, BE

Fayez is a pharmacist with more than 15 years experience in the quality assurance within the pharmaceutical and medical device industry. Since 2008, Fayez joined Terumo Europe where he held roles of increasing responsibility in maintaining quality, risk management and clinical evidence systems. In his current position, he is responsible for global complaint handling and vigilance systems. Fayez is also a certified lead auditor for medical device quality system regulations.

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BIOGRAPHIES

Nicholas Stones
Senior Device Manager - Human Factors
Novartis Pharma AG, CH

Nick holds bachelors and masters degrees in engineering from the University of Oxford in the UK. Since 1998, he has worked in research, development and commercialization of drug delivery systems for various medical device and specialty Pharma companies in the UK, US and Switzerland. Nick joined Novartis in 2009 and was responsible for establishing the Human Factors Engineering process within device development. He has supported the development of several marketed products including the LUCENTIS® pre-filled syringe for intra-vitreal injection as well as the COSENTYX® Sensoready Pen for home use.
Nick works within the human factors team with a focus on HFE strategy, health authority communication, HFE process and platforming as well as the translation of user needs into design inputs.

Daniel L. Bantz
Technology Manager, Packaging & Performance
West Pharmaceutical Services, Inc., CH

Daniel Bantz has over 25 years practical experience in medical and analytical instrumentation development and testing. He's competent in fluid metering product development and testing, combination product testing and device reliability testing.
Additionally, he has been trained in FMEA best practices and has developed product risk mitigation strategies and platforms across multiple organizations.
Daniel implements testing strategies meeting ever-changing regulations in conjunction with customer needs and the competitive landscape.
He earned an MBA in Operations and Technology from Aurora University in Illinois.

Dr. Clemens Guenther
Director Nonclinical Safety CC
Bayer, 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.

REGISTRATION FORM

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

SUMMIT NAME: 2ND ANNUAL DRUG/DEVICE COMBINATION PRODUCTS SUMMIT 2019

REGISTRATION DATE:

TOTAL PRICE:

PROMOCODE:

PACKAGE NAME:

PACKAGE NAME	Register by 04.10.2019	Register by 31.10.2019	Register by 15.11.2019	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)	€1095 (save €600) ☐	€1295 (save €400) ☐	€1395 (save €300) ☐	€1695 ☐
Group ticket (4+ delegates)	€995 (save €700) ☐	€1095 (save €600) ☐	€1195 (save €500) ☐	€1695 ☐
Non-profit organizations	€795 (save €200) ☐	€845 (save €150) ☐	€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.