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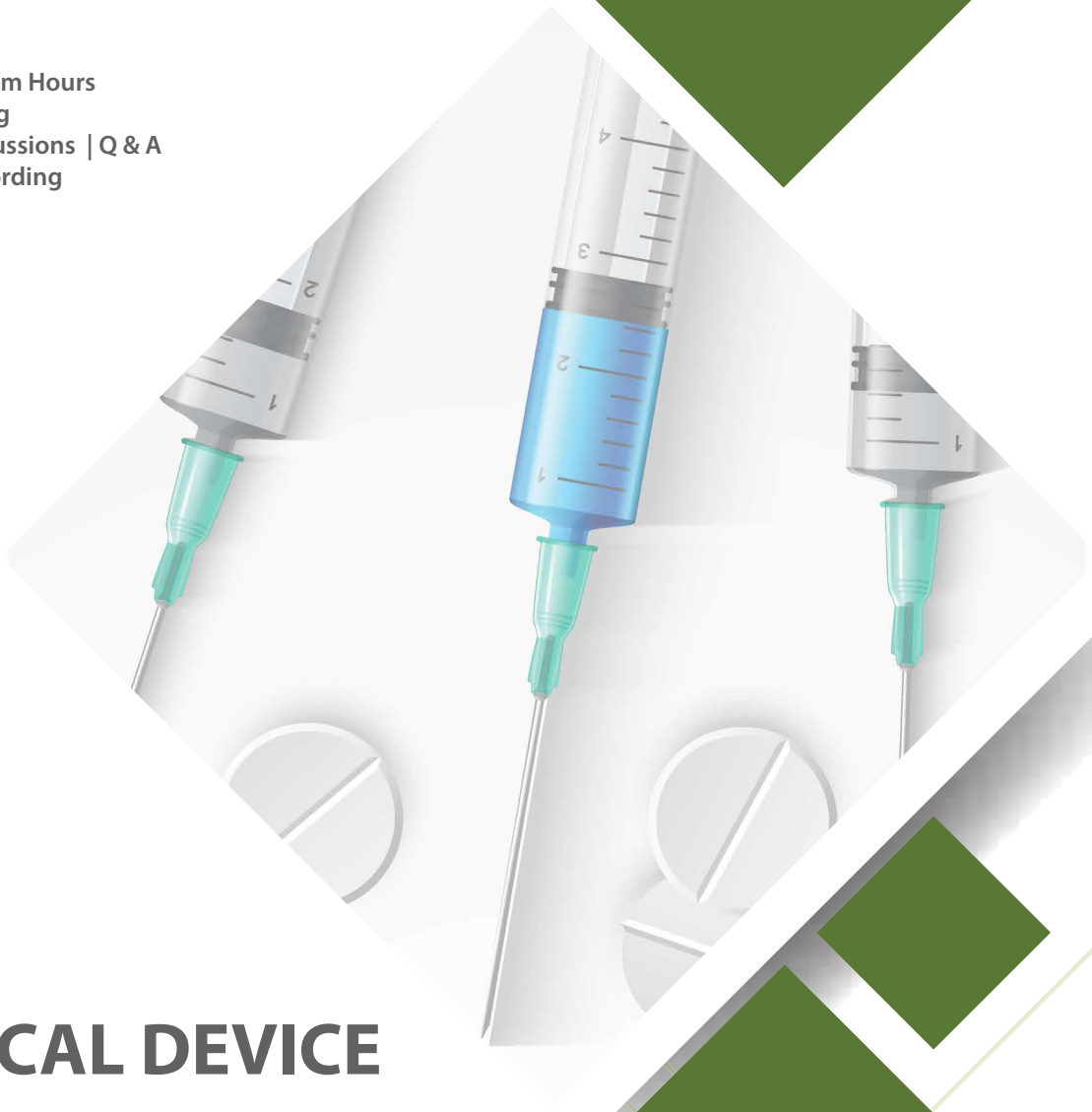
- 12+ Program Hours
- Networking
- Panel Discussions | Q & A
- Video Recording



MEDICAL DEVICE REGULATIONS SUMMIT 2021

8-9 July 2021

● VIRTUAL CONFERENCE

12:00 - 19:00 CEST (Prague - UTC/GMT +2 hours)

hopin

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SPEAKERS BOARD

Bijan Elahi
Award Winning International Medical Device Risk-Mgmt Educator, Consultant and Author
Medtronic, NL

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

WHO YOU WILL MEET

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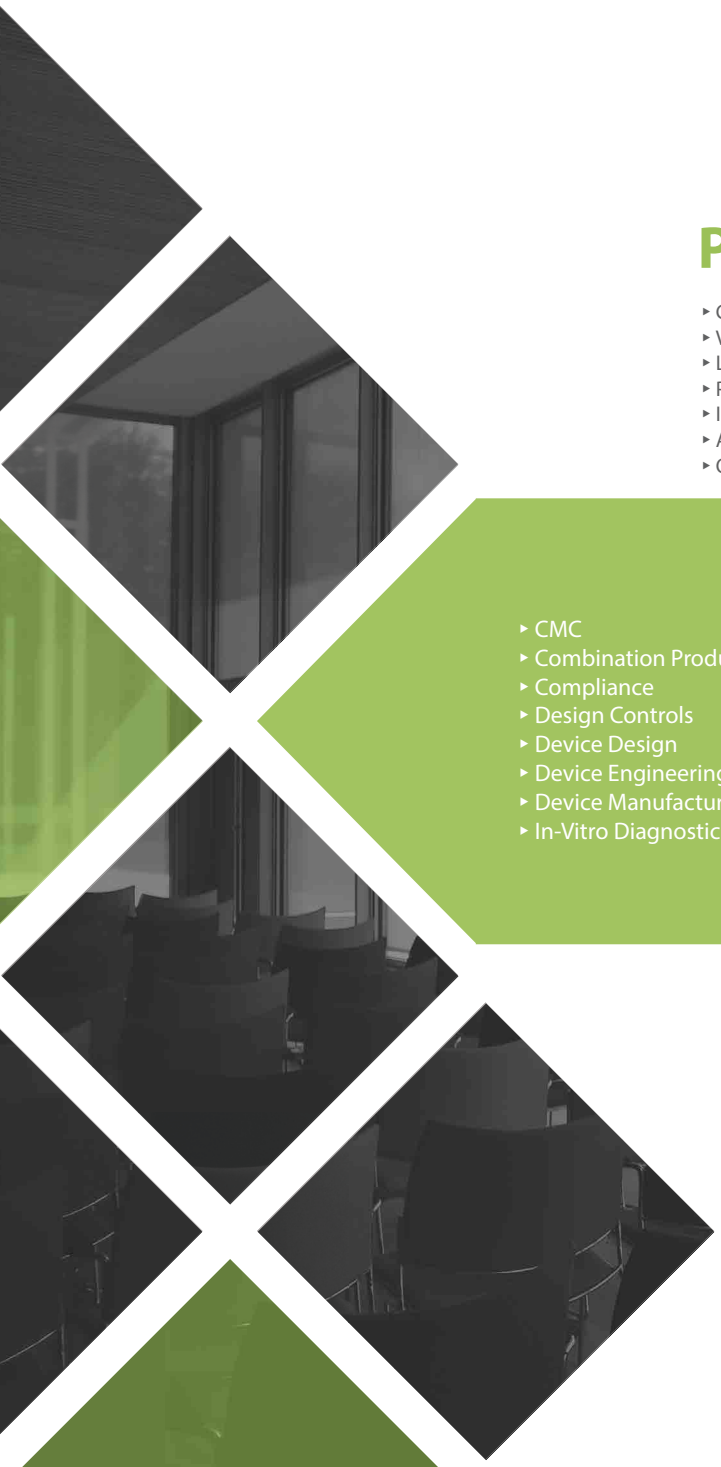
SNAPSHOT OF ATTENDEES - VIRTUAL 2nd Annual Extractables & Leachables Conference 2020:

3P Biopharmaceuticals, ES - Abbott Healthcare Products B.V., NL - Abbvie Deutschland GmbH & Co. KG, DE - Accord-UK Ltd, UK - Advent Consulting Canada, CA - ALK, DK - Alkermes Pharma Ireland Limited, IE - Alphamed Formulations PVT LTD, IN - Apotex Research Pvt Ltd., IN - Aspen Holdings, ZA - Aspen Pharmacare, ZA - B.Braun medical SA, CH - Bavarian Nordic, DK - Becton Dickinson, FR - Biogen, USA - Boston Analytical, USA - Claudia Cusa, d.i., IT - CSL Behring AG, CH - Datwyler Pharma Packaging International NV, BE - DuPont, USA - DuPont-Asahi Flash Spun Products, JP - EirGen Pharma, IE - Eli Lilly and Company, USA - EMS SA, CH - Eurofins Analytical Science Laboratories, Inc., JP - Fujifilm Diosynth Biotechnologies, UK - GSK, US - GSK Vaccines, BE - Hall Analytical, UK - Hemofarm AD, RS - HTL-Strefa S.A., PL - Intertek (Schweiz) AG, CH - Janssen, USA - Kora Healthcare, IE - LEO Pharma, IE - Maven E&L Ltd, UK - Medline Industries, USA - Merck KGaA, DE - MilliporeSigma a business of Merck KGaA, USA - Novartis, CH - Novartis Pharma Stein AG, CH - NOVAVAX CZ a.s., CZ - Orexo AB, SE - Orion Corporation - FI, Philips, NL - Polifarma İlaç San. ve Tic. A.Ş., TR - PPD, IE - Rentschler Biopharma SE, DE - Safetree Consulting e.U., AT - Sandoz Manufacturing Inc., CA - Sanofi, FR - Sanofi, DE - Sanofi Pasteur, CA - Sartorius Stedim Biotech GmbH, DE - SCHOTT AG, DE - SCIEX, UK - Selvita S.A., PL - Septodont, FR - SGS, CN-TW - SGS Institut Fresenius GmbH, DE - Solvias AG, CH - Sthree, BE - Swedish Biomimetics 3000 Ltd, UK - Takeda Pharmaceuticals, USA - Vet-Agro Sp. z o.o., PL - West Pharmaceutical Services, USA - Wockhardt Ltd, IN - and others.

Agenda: https://qepler.com/agendas/agenda-2nd-extractables-and-leachables-20.pdf



POSITIONS

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

DIVISIONS

- CMC
- Combination Products
- Compliance
- Design Controls
- Device Design
- Device Engineering
- Device Manufacturing
- In-Vitro Diagnostic
- IVDR
- MDR
- Medical Devices
- Packaging
- PFS
- Product Development
- QA
- QC
- R&D
- Regulatory Affairs
- Risk Management
- Safety Management
- Sterilization
- Traceability
- Validation
- Vigilance
- Other

INDUSTRIES

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

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MEDICAL DEVICE
REGULATIONS
VIRTUAL SUMMIT
2021

PROPOSED TOPICS

- EU MDR overview - main regulation changes, challenges you will meet during transition.
- Switching to the EU Medical Device Regulation. Preparing company to meet the Medical Device Regulation (MDR).
- MDR transition – preparing your company and team. Adopting your technical documentation, labelling and clinical data to EU MDR. Process and conformity assessment.
- Practical case study - Steps of the successful EU MDR implementation.
- Adopting current medical devices portfolio to EU Medical Device Regulation.
- Risk management transformation and new safety measures. In-depth clinical data assurance. EU MDR and MD risk management – implementation challenges overcome.
- Medical devices reassessment for compliance and certification.
- Revisiting your QA, risk management and post-market vigilance.
- Updating quality management system to MDR. Key elements.
- Unique Device Identification (UDI) system implementation for device tracking throughout the supply chain. Labelling. Post market requirements.
- Medical Devices traceability requirements.
- Medical devices reclassification based on new requirements. New classification rules.
- MDR and IVDR. In vitro diagnostics classification.
- Drug device combination products safety.
- Biocompatibility and EU Medical Device Regulation.
- Notified Bodies and Competent Authorities.
- Authorized Representatives: EU Declaration of Conformity and technical documentation for non-EU manufacturers.

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MEDICAL DEVICE REGULATIONS VIRTUAL SUMMIT 2021

July 8 | 1st DAY

Central European Time (CEST, Prague, UTC/GMT +2 hour)

12:00 - 12:20	**Registration**
12:20 - 12:30	**Opening Address from the Chairman**
12:30 - 13:00	Case Study #1
13:00 - 13:10	**Q & A**
13:10 - 13:40	Case Study #2
13:40 - 13:50	**Q & A**
13:50 - 14:00	**Break**
14:00 - 14:30	Case Study #3
14:30 - 14:40	**Q & A**
14:40 - 15:10	Case Study #4
15:10 - 15:20	**Q & A**

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MEDICAL DEVICE REGULATIONS VIRTUAL SUMMIT 2021

July 8 | 1st DAY

Central European Time (CEST, Prague, UTC/GMT +2 hour)

15:20 - 15:50	Sponsorship presentation — **SPONSOR**
15:50 - 16:00	**Q & A**
16:00 - 16:10	**Break**
16:10 - 16:40	Case Study #5
16:40 - 16:50	**Q & A**
16:50 - 17:20	Case Study #6
17:20 - 17:30	**Q & A**
17:30 - 18:30	Panel discussion
18:30 - 18:40	**Closing remarks and end of Day 1**

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MEDICAL DEVICE REGULATIONS VIRTUAL SUMMIT 2021

July 9 | 2nd DAY

Central European Time (CEST, Prague, UTC/GMT +2 hour)

12:00 - 12:20	**Registration**
12:20 - 12:30	**Opening Address from the Chairman**
12:30 - 13:00	Case Study #1
13:00 - 13:10	**Q & A**
13:10 - 13:40	Sponsorship presentation **SPONSOR**
13:40 - 13:50	**Q & A**
13:50 - 14:00	**Break**
14:00 - 14:30	Case Study #2
14:30 - 14:40	**Q & A**
14:40 - 15:10	Case Study #3
15:10 - 15:20	**Q & A**

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MEDICAL DEVICE REGULATIONS VIRTUAL SUMMIT 2021

July 9 | 2nd DAY

Central European Time (CEST, Prague, UTC/GMT +2 hour)

15:20 - 15:50	Sponsorship presentation — **SPONSOR**
15:50 - 16:00	Q & A
16:00 - 16:10	Break
16:10 - 16:40	Case Study #4
16:40 - 16:50	Q & A
16:50 - 17:20	Case Study #5
17:20 - 17:30	Q & A
17:30 - 18:00	Case Study #6
18:00 - 18:10	Q & A
18:10 - 18:20	Closing remarks and end of summit

SPEAKER'S BIOGRAPHIES

Bijan Elahi
Award Winning International Medical Device Risk-Mgmt Educator, Consultant and Author
Medtronic, NL

Bijan Elahi has worked in risk management for medical devices for over 25 years at the largest medical device companies in the world, as well as small startups. He is currently employed at Medtronic as a Technical Fellow where he serves as the corporate expert on safety risk management of medical devices. In this capacity, he offers education and consulting on risk management to all Medtronic business units, worldwide. Bijan is also a lecturer at Delft University of Technology, and Eindhoven University of Technology in the Netherlands, where he teaches risk management to doctoral students in engineering. Bijan is a frequently invited speaker at professional conferences, and is also a contributor to ISO 14971, the international standard on the application risk management to medical devices. He is the author of the book Safety Risk Management for Medical Devices.

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.

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REGISTRATION FORM

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

SUMMIT NAME: VIRTUAL - Medical Device Regulations Summit 2021

REGISTRATION DATE:

PACKAGE NAME	Standard price	
Individual ticket - 1st Day (8th July 2021) - (*includes 1st Day's post-event conference materials distribution)	€195	☐
Individual ticket - 2nd Day (9th July 2021) - (*includes 2nd Day's post-event conference materials distribution)	€195	☐
Individual ticket - 2 Days - (*includes complete post-event conference materials distribution)	€295	☐
Group ticket - 2 Days (*2-3 delegates) - (*includes complete post-event conference materials distribution)	€215	☐
Group ticket - 2 Days (*4+ delegates) - (*includes complete post-event conference materials distribution)	€145	☐
Documentation package - (*if you have no plans to join the live conference)	€495	☐
Promotional materials distribution	€445	☐
SPEAKER SPONSOR - €995 ☐	PARTNER SPONSOR - €1295 ☐	GOLD SPONSOR - €1695 ☐

CONFERENCE MATERIALS:
All participation tickets, already contains complete conference materials distribution package, including - slides, list of participants, stream and video recording. You don't need to order an additional «Documentation Packages».
Documentation package will be sent to the attendees within 72 hours after the event. The presentation content is subject to speaker's companies approval for distribution.

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 ☐

TERMS & CONDITIONS:

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

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

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

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

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

PARTICIPATION PACKAGES

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ONLINE PACKAGES:

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

PACKAGE NAME	PRICE
DOCUMENTATION (*if you have no plans to join the live conference) Post-event presentations with video records, list of participants and other materials. The presentation content is subject to speaker's companies approval for distribution.	€495
PROMOTIONAL MATERIALS DISTRIBUTION Distribution of your company's promotional materials to all attendees	€445

SPONSORSHIP PACKAGES:

BENEFITS	SPEAKER €995	PARTNER €1295	GOLD €1695
Number of passes included	1	2	3
Registration fee for additional company representatives	€195	€145	€95
Link to Landing Page/Video Presentation trough the live event translation.		•	•
Link to Virtual Exhibition Page trough the live event translation.			•
Opening keynote presentation			15 min
Speaking slot	20 min	30 min	30 min
Workshop slot			40 min
Recognition in chairman's opening address		•	•
Opening & closing speech			•
Chairman of Day 1			•
Chairman of Day 2		•	
Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•
Recognition on Qepler social media channels (LinkedIn/Facebook/Twitter/Instagram)	•	•	•
Color advert placed on agenda		1/2 Page	1 Page
Online distribution of your company's promotional materials to all attendees		•	•

MARKETING CAMPAIGN

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

PARTICIPATION FEE

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

TRANSLATION

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

POST-EVENT DOCUMENTATION

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

DISCOUNTS

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

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WAYS TO REGISTER

EVENTS CALENDAR 2021

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

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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

Highly Potent APIs Webinar Day ..... June 25, 2021
- VIRTUAL

Enhance expertise sharing in developing pre-filled syringes and provide attendees with ample networking opportunities.
https://qepler.com/pdf/vhpapi21.pdf
REGISTRATION IS OPEN
AGENDA WEB

Medical Device Regulations Summit ..... July 8-9, 2021
- VIRTUAL CONFERENCE

Exploring EU MDR and IVDR updates and preparing company for new requirements implementation.
https://qepler.com/pdf/vmdr21.pdf
REGISTRATION IS OPEN
AGENDA WEB

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

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

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

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

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

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

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

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

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

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

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

Get up to date with the regulatory and quality compliance strategies for combination product development.
https://qepler.com/pdf/v3ddcp21.pdf
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CONTACTS

Please send your session title and summit name to:

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