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

3rd Annual

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2021

29-30 July 2021

● VIRTUAL CONFERENCE

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

hopin

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SPEAKERS BOARD

Michael Dekner
Innovation & External Collaborations
Takeda, AT

Mostafa Nakach
Head of formulation and process development section within Bilogics drug product development
Sanofi R&D, FR

Dr. Andrea Weiland-Waibel
Managing Director
Explicat Pharma GmbH, DE

Diego Zurbriggen
Technical Account Manager
West Pharmaceutical Services, USA

Dr. Mattia Cassanelli
Technical Manager – Consultancy
Biopharma Group, UK

Ian Blackham
Business Development Executive – Instruments
Biopharma Group, UK

Dr. Simon Kervyn
Manager Materials Development
Datwyler Pharma Packaging International NV, BE

Georg Frinke, Dipl.-Ing. (FH)
Senior Manager Engineering
Ferring GmbH, 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, CN - 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

SNAPSHOT OF ATTENDEES - 2nd Annual Pharmaceutical Lyophilization Summit 2020:

Allergan - Aptar Pharma - AZBIL TELSTAR TECHNOLOGIES SLU - Baxalta Manufacturing Sàrl - Bayer AG - BB-NCIPD Ltd. - Biopharma Process Systems Ltd - BLAC-BioPharma UG - Boehringer Ingelheim - Datwyler Pharma Packaging International NV - De Montfort University - DendroPharm GmbH - Elm o Sanat University - Freie Universität Berlin - Ghent University - INDICAL BIOSCIENCE GmbH - Janssen - KSHM-Rezonanca - Lek Pharmaceuticals d.d. - Lonza AG - Martin Christ Gefriertrocknungsanlagen GmbH - Masaryk University - MSD - MSD International - Novartis Global Drug Development / Technical Research & Development - Pensatech Pharma - Pfeiffer Vacuum GmbH - Pfizer - PharmaCept GmbH - Polpharma SA - Rhine Waal University - Sanofi - SCHOTT AG - Shire Austria GmbH now part of Takeda - Surface Measurement Systems Ltd. - Takeda - Tempris GmbH - VLB Berlin - West Pharmaceutical Services Deutschland GmbH & Co KG and others.

Agenda: https://qepler.com/agendas/pharmaceutical-lyophilization-summit-2020.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

- Lyophilization
- Pharmaceutical Manufacturing, Engineering & New Technologies
- Laboratory Management
- R&D
- Formulation
- Containment
- Pharmaceutical & Processing Development
- Process Design, Technology, Analytics, Testing, Monitoring & Control
- Aseptic Production, Cleaning & Sterilisation
- Bioprocessing
- QA/QC
- Characterisation
- Regulatory Affairs
- Stability
- Standardisation
- Qualification & Validation
- Scale-up & Technology Transfer
- Cycle Management
- Facility & Site Design & Management
- PAT, QbD
- Media Fills
- Visual Inspection
- Filling & Materials
- Materials Development
- Container Development & Container Closures
- Vials, Stoppers & Dual Chamber Systems
- Devices &Application Systems
- Product Development & Control
- Parenteral Production
- Injection Systems
- Vaccines
- Corporate & Business Development
- External Supply
- Sales & Marketing
- Outsourcing
- Partnerships & Alliances
- Strategic Development
- Other

INDUSTRIES

- Pharmaceutical
- Biotechnology
- Chemical
- Medical Devices
- CDMOs
- CMOs
- CROs
- NOPs
- Regulatory Agencies
- Bioprocessing services and equipment
- Equipment suppliers
- Training providers
- Other

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PHARMACEUTICAL
LYOPHILIZATION
SUMMIT
2021

PROPOSED TOPICS

- Latest regulatory updates in lyophilisation. Preparation for the regulatory review and inspection. Regulatory considerations.
- Lyophilisation and critical quality attributes and process parameters: analysis, testing, validation and regulatory implementation.
- Media fills and regulations.
- Sterilization in place requirements and considerations.
- Fundamentals of lyophilization. Different phases of a lyophilization process. Practical example of the lyophilization use in pharmaceutical production.
- Lyophilisation process development. Process optimisation, monitoring, and control. Model-based process engineering.
- Lyophilization cycle development, optimisation and improvement: real practical examples.
- Application of a risk-based approach to lyophilization process.
- Primary packaging for lyophilization.
- Scale-up development and validation of lyophilization processes.
- Technology transfer from one lyophilization model to another. Predictive models of lyophilization Process.
- Media Fill design. Validation of lyoprocess. Requirements. Current trends.
- QbD and PAT approaches. Space design for lyophilization. QbD aspects and determination of critical process parameters.
- Continuous freeze drying.
- Strategies for GTIs analysis.
- Lyophilizer in aseptic production.
- Innovations in formulation development.
- Lyophilized formulation: prediction and optimization of stability.
- Secondary drying and residual moisture monitoring.
- IPressure and video monitoring.
- Freeze drying of novel products: mAbs, bacterial, viral or gene therapy-based products. Challenges in cycle development. New excipients.
- Lyophilization of high potent and sensitive biological material. Critical limits evaluation. Cleaning validation. Containment.
- New Developments in materials and devices. Advanced vials and novel vial identification approaches.
- Lyophilisation in dual chamber cartridges. Process challenges, design and control.
- Automatic loading and unloading technologies and robotics. Reasonable limits of automation. Upgrading possibilities.
- Controlled nucleation techniques. Recent developments. Challenges. Experimental and stability data. Impact on quality and stability of lyophilized biologics.
- Vacuum-induced surface freezing.
- Wireless Technologies. Wireless multipoint temperature sensors for lyophilization monitoring.
- Atmospheric spray freeze drying.
- Green technology and environmental considerations.
- Other new innovations in lyophilization applications.

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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2021

July 29 | 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

A 2020 hindsight look at how COVID-19 has affected the freeze drying industry and what we have learned from it.

Dr. Mattia Cassanelli | Technical Manager – Consultancy
Biopharma Group, UK

13:00 - 13:10 Q & A

13:10 - 13:40

Freeze drying-Scaling up

Mostafa Nakach | Head of formulation and process development section within Bilogics drug product development | Sanofi R&D, FR

13:40 - 13:50 Q & A

13:50 - 14:00 Break

14:00 - 14:30

Aseptic Process Simulation for Lyophilization – Best Practice, an Industry Opinion

Michael Dekner | Innovation & External Collaborations
Takeda, AT

14:30 - 14:40 Q & A

14:40 - 15:10 Case Study #4

15:10 - 15:20 Q & A

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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2021

July 29 | 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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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2021

July 30 | 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 - 15:00 WORKSHOP: Role and measurement of mechanical properties in lyobeads technology.

Ian Blackham | Business Development Executive – Instruments
Dr. Mattia Cassanelli | Technical Manager – Consultancy
Biopharma Group, UK

biopharma group
intelligent freeze drying

15:00 - 15:10 Q & A

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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2021

July 30 | 2nd DAY

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

15:10 - 15:40	Sponsorship presentation **SPONSOR**
15:10 - 15:20	Q & A
16:00 - 16:10	Break
16:10 - 16:40	Case Study #2
16:40 - 16:50	Q & A
16:50 - 17:20	Case Study #3
17:20 - 17:30	Q & A
17:30 - 18:00	Case Study #4
18:00 - 18:10	Q & A
18:10 - 18:20	Closing remarks and end of summit

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PHARMACEUTICAL
LYOPHILIZATION
SUMMIT
2021

SPEAKER'S BIOGRAPHIES

Dr. Mattia Cassanelli
Technical Manager – Consultancy
Biopharma Group, UK

Mattia joined Biopharma Group in February 2018 and he currently works as a Technical Manager of the Consultancy Division, providing support through desktop study, cycle audit, characterisation of the material pre- and post- process, formulation development, optimisation of the freeze drying cycle and tech transfer/scale-up.
Mattia's background includes a PhD focussed on drying mechanisms of hydrocolloids in the food industry from a microstructural point of view at the University of Birmingham.
He also gained a Master's Degree in material engineering, and a Bachelor's Degree in industrial engineering completed at the University of Trento, Italy.

Michael Dekner
Innovation & External Collaborations
Takeda, AT

10/2017 – present: Head Fill&Finish Life Cycle Management support. Leading a team of senior manufacturing scientists responsible for process monitoring, technical product stewardship and process development, audit support, knowledge brokers, risk management (QbD) and linking to industrial and academic networks.
04/2015 – 10/2017: Shire (Baxalta), Innovation Manager, Lead Enhanced Process Control establishing innovation management process, communication, development of technology strategy and roadmap for real time release, technology scouting, linking to industrial and academic networks.
02/2014 - present: Lecturer for University of applied sciences Campus Wien, Downstream Processing - Lyophilization.
10/2011 – 04/2015: Baxter Bioscience AG, Supervisor Lyophilization and Crimping LA24B, aseptic processing, lyophilization, crimping, material flow, trouble shooting and maintenance, change management, NCR, leading 26 FTEs, coordination of an internal community of practice (Lyophilization), SME in projects on lyophilization and crimping, presenting at audits (FDA,…), continuous improvement.
06/2006 – 09/2011: f-star Biotechnologische Forschungs und Entwicklungs Ges.m.b.H; Scientist - screening, selection, expression and purification of binding antibody fragments, cell culture, protein engineering, immunology, analytics, microbial cultivation, cell sorting, molecular biology, fire safety, biological safety.
04/2006 - 05/2006: University of Natural Resources and Life Sciences, Vienna / Department of Biotechnology, Scientist - strain improvement
09/2004 - 03/2006: Biomin Gesunde Tierernährung International Ges.m.b.H, Scientist - enzyme production, fluidized bed coating, large scale cell cultivation, enzyme analytics, scientific support of master students
05/2004 - 05/2006: Lecturer for University of applied sciences Wiener Neustadt / Tulln, Biotechnology and Applied Microbiology.

Dr. Simon Kervyn
Manager Materials Development
Datwyler Pharma Packaging International NV, BE

Simon Kervyn graduated as a PhD in organic chemistry and materials from the University of Namur, Belgium in 2012. After research stays at National Institute of Materials Sciences in Tokyo and at UCLA, Los Angeles, he worked at the Coatings Research Institute in Belgium.
He is now working for Datwyler as manager materials development. In this position he performs customer's dedicated research to optimize the selection of rubber components to their applications. Furthermore, he works on the development of coated products for the Datwyler portfolio.

Georg Frinke
Senior Manager Engineering
Ferring GmbH, DE

Georg holds an Engineering degree (Technical University/Cologne). He works as facility & process engineer at Bayer Pharma and with responsibility responsible for the technical operation of the parenteral facility. Previously, he worked as Process Engineer for Optima (Klee) and GEA Lyophil / Steris. Among others, he is specialized in the development of customized Freeze-Drying processes (particularly upscaling with PAT) and in the qualification (FAT, SAT, IQ, OQ, PQ) of pharmaceutical freeze dryers.

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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 - 3rd Annual Pharmaceutical Lyophilization Summit 2021

REGISTRATION DATE:

PACKAGE NAME	Standard price	
Individual ticket - 1st Day (29th July 2021) - (*includes 1st Day's post-event conference materials distribution)	€195	☐
Individual ticket - 2nd Day (30th 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:

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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
REGISTRATION IS OPEN
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CONTACTS

Please send your session title and summit name to:

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