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3rd Annual

# COMBINATION PRODUCTS / PRE-FILLED SYRINGES SUMMIT 2020

**2 - 4 December**

- **VIRTUAL CONFERENCE**

# 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

Niklas Niederwieser
Business Development Manager Polymer Solutions
SCHOTT Pharmaceutical Packaging, 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

Min Wei
Director/Fellow,
Dosage Form Design and Development
AstraZeneca, USA

Tina Rees
Associate Director-Human Factors
Ferring Pharmaceuticals, USA

Bjørg Kaae Hunter
Department Manager
RA CMC & Device;
RA NextGen Drug-Device
Novo Nordisk A/S, DK

Dr. Nicolas Brandes
Director Global Product Management (PPS and Vial Containment)
West Pharmaceutical Services, DE

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

Sandro Laiso
Business Development Manager DACH Chemicals & Pharmaceuticals
Intertek (Schweiz) AG, CH

Daniel Behrens
New Business Development – Healthcare
Performance Masterbatches Germany GmbH / Clariant, DE

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

## 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

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

## INDUSTRIES

- Pharmaceutical
- Biotechnology
- Chemical
- Medical Devices
- Plastics
- Packaging
- CMOs/CDMOs
- CROs
- NOPs

## COMPANIES

- Device Design and Development
- Drug Delivery Systems
- Formulation Development
- Analytical Services
- Injection Molding
- Sterilization Technologies
- Digital Health Solutions
- Other

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# COMBINATION PRODUCTS / PRE-FILLED SYRINGES VIRTUAL SUMMIT 2020

## December 2 | 1st DAY

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

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

**08:40 - 09:20** — 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

**09:20 - 10:00** — **Speed Networking**

**10:00 - 10:40** — Case Study - RESERVED FOR

Bjørg Kaae Hunter |
Department Manager RA CMC & Device; RA NextGen Drug-Device |
Novo Nordisk A/S, DK

**10:40 - 11:20** — TBA

**11:20 - 11:50** — **Morning coffee and networking break**

**11:50 - 12:30** — TBA

**12:30 - 13:00** — Slot Reserved for Sponsors

**13:00 - 14:00** — **Business lunch**

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# COMBINATION PRODUCTS / PRE-FILLED SYRINGES VIRTUAL SUMMIT 2020

## December 2 | 1st DAY

**14:00 - 14:40**

Slot Reserved for Sponsors

**14:40 - 15:10**

### 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

**15:10 - 15:40** — Afternoon coffee and networking break

**15:40 - 16:20**

TBA

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

**16:20 -17:00**

TBA

**17:00 -18:00** — Panel Discussion

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

**19:00 - 21:00** — Business dinner

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# COMBINATION PRODUCTS / PRE-FILLED SYRINGES VIRTUAL SUMMIT 2020

## December 3 | 2nd DAY

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

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

**08:40 - 09:20** — TBA

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

**09:20 - 10:00** — **Networking Session**

**10:00 - 10:40** — **Primary container for cell and gene therapy product**

**Min Wei** | Director/Fellow, Dosage Form Design and Development | AstraZeneca, USA

**10:40 - 11:20** — **Reducing medical errors in hospital environment with use of Prefilled syringe systems**

- Drug transfer out of vials or ampules is still a major source for medical errors and contamination
- Market needs for a container – injection device
- How can a pre-filled syringe (PFS) system help to reduce those risks
- How SCHOTT solved the compatibility with broad range of IV connectors

**Niklas Niederwieser** | Business Development Manager Polymer Solutions | SCHOTT Pharmaceutical Systems, CH

**11:20 - 11:50** — **Morning coffee and networking break**

**11:50 - 12:30** — TBA

**12:30 - 13:00** — Slot Reserved for Sponsors

**13:00 - 14:00** — **Business lunch**

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# COMBINATION PRODUCTS / PRE-FILLED SYRINGES VIRTUAL SUMMIT 2020

## December 3 | 2nd DAY

**14:00 - 14:30**

**Investigation on Residual & Foreign Matter in Primary Packaging**

SPEAKER SPONSOR

Intrinsic and extrinsic particles in parts of a primary packaging could infringe the integrity of the entire prefilled syringe. The necessary investigation with analytical techniques allows a root cause analysis to optimize the processes and/or the components.

Sandro Laiso | Business Development Manager DACH Chemicals & Pharmaceuticals | Intertek (Schweiz) AG, CH

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**14:30 - 15:10**

**New fully coated plungers**

- Presentation of NeoFlex, new coating, new designs
- Advantages of fully coated plungers
- Gliding behaviour after gamma and steam sterilization

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

DATWYLER

**15:10 - 15:40** — **Afternoon coffee and networking break**

**15:40 - 16:20**

**Polymer syringes and how unmet industry needs impact these developments**

Dr. Nicolas Brandes | Director Global Product Management (Polymer Prefilled System and Vial Containment) | West Pharmaceutical Services, DE

West By your side for a healthier world

**16:20 -17:00**

**TBA**

**17:00 -18:00** — **Roundtable Discussion**

**18:00 - 18:10** — **Chairman's closing remarks and end of day two**

**19:00 - 21:00** — **Business dinner**

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# COMBINATION PRODUCTS / PRE-FILLED SYRINGES VIRTUAL SUMMIT 2020

## December 4 | 3rd DAY

**08:00 - 08:30** — Welcome Coffee

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

**08:40 - 09:20**

**User-driven specifications and requirements for self-injection devices: Insights from two simulated use studies**

- Introduction to devices for self-injection with market overview
- The platform approach
- Usability in device development
- User-driven setting of performance requirements and specification limits
- Case study 1: Determination of acceptable use forces for device handling
- Case study 2: Avoiding medication errors: How do users differentiate between similar (platform-based) device variants?

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

YPSOMED SELFCARE SOLUTIONS

**09:20 - 10:00** — TBA

**10:00 - 10:40**

**Human Factors Considerations for Pre-Filled Syringes**

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

FERRING PHARMACEUTICALS

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

**11:10 - 11:50**

**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

Genentech A Member of the Roche Group

**11:50 - 12:30** — TBA

**12:30 - 13:00** — Slot Reserved for Sponsors

**13:00 - 14:00** — Business lunch

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# COMBINATION PRODUCTS / PRE-FILLED SYRINGES VIRTUAL SUMMIT 2020

## December 4 | 3rd DAY

**14:00 - 14:30**

Slot Reserved for Sponsors

**14:30 -15:10**

### Smart Injection Devices - Use of highly specialized Plastics

- Anti counterfeit Plastics – Full service concept realized with "intelligent" Plastics
- Improvement of Patient convenience with MEVOPUR Additive products
- Shelf life extension with Plastic Solutions
- Flexible Serialization via Laser marking

Daniel Behrens | New Business Development – Healthcare | Performance Masterbatches Germany GmbH / Clariant, DE

CLARIANT

**15:10 - 15:50**

TBA

**15:50 -16:00** Chairman's closing remarks and end of the summit

**16:00 - 17:00** Afternoon coffee and networking break

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# COMBINATION PRODUCTS / PRE-FILLED SYRINGES VIRTUAL SUMMIT 2020

**December 2-4**

## 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.

**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.

**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'.

**Min Wei**
**Director/Fellow, Dosage Form Design and Development**
**AstraZeneca, USA**

Min is a Director and Fellow at Astrazeneca. He has over 15 years of drug/device combination product development experience. During this time, he has worked at BD, Eli Lilly and Johnson&Johnson on projects from concept phase through commercialization. His experience spans device engineering, formulation development, process engineering and packaging. Currently, Min is focusing on delivery systems for new therapeutic modalities, as well as primary container R&D. Min received his Ph.D. in Materials Science and his MBA from US. His MS degrees are in Biotechnology and Computer Science. Min is an inventor of more than 50 patents and patent applications. He is also a certified Six Sigma Black Belt from American Society for Quality (ASQ).

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| PACKAGE NAME | Standard price | |
|---|---|---|
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| Speaking slot | | 30 min | 60 min |
| Facilitated 1:1 meeting with 7-8 attendees | | | • |
| Recognition in chairman's opening address | • | • | • |
| Opening & closing speech | | | • |
| Chairman of Day 1 | | | • |
| Chairman of Day 2 | | • | |
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Fees are inclusive of the complete summit materials, online post-event documentation/presentation package, list of participants, video records, and certificate of participation.

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

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- VIRTUAL CONFERENCE (**FREE** for **Pharmaceutical** and **Biotechnology** Companies)

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## CONTACTS

Please send your session title and summit name to:

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