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SMi presents the East Coast's Leading, 6th Annual Conference and Exhibition...

Pre-Filled Syringes East Coast

Sheraton Boston Hotel, Boston, USA

CONFERENCE:
8TH - 9TH
WORKSHOPS: 10TH
APRIL 2019

The future of injectable drug delivery: regulations, connected devices and the global push for patience centricity

2019 FEATURED HIGHLIGHTS:

- Explore the outcomes of the **EU Medical Device Regulations (MDR)** and the impact of these changes on the industry
- Evaluate key aspects of **partnering, outsourcing** and **translation of market research** for successful commercialization
- The **21st Century cures act:** defining the device
- Learn different approaches to summative **human factor validation studies**
- **Chemical compatibility** challenges and the resulting impact on drug delivery performance
- **Device design strategies** for successful implementation of **connected devices**
- Forecasting the future of pre-filled syringes with consideration of **competitive drug delivery systems**

CHAIRS FOR 2019:

- **Dhairya Mehta,** Director Device and Combination Products, **Shire**
- **Darin Oppenheimer,** Executive Director, Head Drug Device Centre of Excellence, **Merck**

KEY SPEAKERS INCLUDE:

- **Molly Story,** Head of Global Usability Engineering and Risk Management, **Sanofi**
- **Linda Ricci,** Associate Director for Digital Health, Office of Device Evaluation, **FDA**
- **Nicholas Zampa,** Senior Engineer, Human Factors and Risk Management, **Biogen**
- **John Schalago,** Head Devices, **EMD Serono**
- **Cedric Gysel,** Health Care Solutions Design Manager, **Johnson & Johnson Design**
- **Joyce Y Zhao,** Device Lead, Combination Product Development, **Takeda**
- **Michael Song,** Sr. Manager, Drug Delivery and Device Development, **MedImmune**
- **Amit Khanolkar,** Director, New Product Development Quality Engineering, **Janssen**
- **Ramin Samadani,** Senior Scientist in Dosage, Form, Design and Development, **MedImmune**
- **Hemal Mehta,** Associate Director Global CMC RA, Medical Devices and Combination Products, **Janssen**
- **Ling Lu,** Sr. Principal Scientist, **Pfizer**
- **Brian Frank Lewis,** Senior Consultant Engineer, **Eli Lilly**
- **Tina Kiang,** Acting Division Director, **CDRH/ODE/DAGRID, FDA**

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West
ZEON

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
WEDNESDAY 10TH APRIL 2019, SHERATON BOSTON HOTEL, BOSTON, USA

A: Glass and Polymer – two established materials for primary containers – identify the best option

Workshop Leaders: **Dr. Wenzel Novak,** Global Senior Director Business Development, **Gerresheimer**
Bernd Zeiss, Head of Global Technical Support, **Gerresheimer**
08.30 - 12.30

B: Preparing for a Pre-submission Meeting

Workshop Leader: **Barry Sall,** Principle Consultant, **Parexel Consulting**
13.30 - 17.00

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LETTER FROM THE CHAIRS:

Dear Participants,

We are absolutely delighted to welcome each of you to SMi Groups Pre-Filled Syringes East Coast conference.

A Pre-filled syringe – whilst it is nothing but an effective means of drug delivery, it has proven to be a strong bridge that connects the medicament and the patient. It is undoubtedly one of the greatest innovations to deliver modern medicine. Furthermore, the technological advances for pre-filled syringes don't end there. It has revolutionized many lives and given birth to several different areas including, but not limited to, drug delivery, combination products and connected delivery. The pre-filled syringe and the relevant devices have empowered healthcare providers and patients to control and manage disease conditions and treatments. As the development of pre-filled syringes, devices, and combination products are a prime example of complex, multi-disciplinary efforts - it takes a village to develop them.

This meeting will, therefore, allow for the face-to-face assembly of subject matter experts in all areas related to the development of pre-filled syringes and other related combination drug products, and thereby provide a tremendous opportunity for meaningful discourse.
We look forward to seeing you there!

Dhairya Mehta, Associate Director of Device and Combination Products, **Shire**

Darin Oppenheimer, Executive Director Head of Drug Device, **Merck**

08.30 **Registration & Coffee**

09.00 **Co-Chairs opening remarks**
Dhairya Mehta, Director of Device and Combination Products, **Shire**
Darin Oppenheimer, Executive Director Head of Drug Device, **Merck**

UPDATE ON NEW AND EXISTING REGULATORY PROCESSES

09.10 **Regulatory Processes and challenges within the constantly evolving Pre-filled syringes market**
- Thorough update on new regulatory guidelines and how to successfully comply
- Strategy control for combination products
- Drug and device requirements for innovative designs
- Challenges in applying device software regulation
- Incorporating patient centricity into regulatory requirements

Tina Kiang, Acting Division Director, **CDRH/ODE/DAGRID, FDA**

09.40 **The Impact of EU Medical Device Regulation on combination products and the industry challenges**
- Overview of EU Medical Device Regulation (MDR), which becomes effective 26 May 2020
- Impact of EU MDR Article 117, which requires Notified Body review of the device constituent of single-entity combination products
- Challenges in interpreting Article 117 requirements, industry's approach to addressing this uncertainty, and recent developments

Hemal Mehta, Associate Director Global CMC RA, Medical Devices and Combination Products, **Janssen**

10.10 **Morning Coffee Sponsored by ZEON**

INTEGRATION OF COMBINATION PRODUCTS AND EVALUATION OF NEW LAWS AND TECHNOLOGY TRENDS

10.40 **Comparing radiation modalities:**
- Differences with electron beam, gamma and x-ray with case studies
- Irradiation of the product with gamma
- E-beam advantages - less colouration and less degradation
- Disadvantages of e-beams. Gamma has better penetration and can penetrate dense products
- Introduce own research

Larry Nicolas, CEO, **Steri-Tek**

11.20 **Challenges of integrating combination product development into the drug development process**
- Life cycle management of products and common hurdles at each step
- Troubleshooting the big technical challenges in development and manufacturing
- Successful integration of human factor studies

Amit Khanolkar, Director, New Product Development Quality Engineering, **Janssen**

12.00 **Partnering in the development and commercialization of combination products**
- Not all handheld injectors need to look and feel the same
- Satisfying the need for a platform of wearable on-body injection systems
- Integrated Solutions: Focus on what you're good at and let your partner do the rest
- Your partner's engagement shouldn't end when the product is launched

Carl Dabruzzi, Director, Product Management, Self-Injection Systems, **West Pharmaceutical Services**

12.40 **Networking Lunch**

13.40 **21st century cures act and how this new law has transformed digital health**
- The fine line as to what is and what is not a device and how to interpret the law
- Examples of developments that are not classed as devices
- Connectivity, Regulations and Prediction of tighter manufacturing controls

Linda Ricci, Associate Director for Digital Health, **Office of Device Evaluation**

14.10 **Evolution of regulatory strategy - creating a roadmap to define strategy and mitigate risks**
John Schalago, Head Devices, **EMD Serono**

HUMAN FACTORS AND PRIORITISING PATIENT SAFETY

14.40 **Human factors considerations throughout pre-filled syringe development**
- Early human factors techniques and tools for understanding user perspective and user needs
- How to ensure a human factor study is representative of use in everyday life, certifying that studies are truly patient centric
- Linking risk management and compliance with good design for the end user
- Approaches and applications of different types of human factor studies throughout development with successful case-studies

Nicholas Zampa, Senior Engineer, Human Factors and Risk Management, **Biogen**

15.20 **Afternoon Tea Sponsored by ZEON**

15.50 **Medical apps: The user interface is the product**
- Identifying the primary users
- Identifying the use cases and controlling the use-related risks
- Iterative (Agile) formative testing to ensure the app satisfies the user needs
- Final (summative) human factors validation testing

Molly Story, Head of Global Usability Engineering and Risk Management, **Sanofi**

16.20 **Translation of user research to actionable product specification**
- Conducting contextual inquiry and exploratory human factors studies
- Translating the data into quantifiable and measurable requirements for product development
- Collaboration between design, marketing, and human factors
- How to bridge aesthetics, psychology and user satisfaction to engineering

Sara Waxberg, Director of User Centered Design – Delivery, Device & Connected Solutions, **Eli Lilly**

16.50 **PANEL DISCUSSION:**
Evaluation of the Medical Device Single Audit Program (MDSAP) – who has joined and what are the implications for the medical device industry
Moderator: Dhairya Mehta, Director of Device and Combination Products, **Shire**
Panel participants to be confirmed

17.30 **Chairs closing remarks and close of day one**

18.00 -21.00 **Sponsored dinner – only available to pharmaceutical companies**

Engage with top pharma scientists and engineers in our PFS focused conference


Hear the very latest plans for drug-device development in the injectables industry

Network with industry and pharma leaders in the exhibition area

08.30 Registration & Coffee

09.00 Chairs opening remarks
Dhairya Mehta, Director Device and Combination Products, Shire
Darin Oppenheimer, Executive Director, Head Drug Device Centre of Excellence, Merck

A REGULATORY EXPLORATION

09.10 Exploring the Regulatory Environment for Combination Products
- Understand the evolving regulatory landscape for combination products
- Explore best practices for regulatory filings of combination products
- Identifying post market safety reporting requirements for the US and EU
- Understand evolving requirements for digital technology, such as mobile apps
- Highlight the direction that combination products are heading

Suraj Ramachandran, Director, Regulatory Affairs Drug-Device Centre of Excellence, Merck

CHEMICAL COMPATIBILITY AND DESIGN CONTROL STRATEGIES

09.40 Cyclo Olefin Polymer (COP) – technical data update
- Key properties of COP
- Case study. Biologics formulation for COP syringe optimized to eliminating use of surfactant
- Case study. Study on protein adsorption/aggregation – COP vs glass
- Case study. Study on delamination with glass syringe vs COP syringe
- Leachable data on COP syringes with various chemicals

ZEON Toshiro Katayama, Product Manager, Zeon

10.20 Morning Coffee Sponsored by ZEON

KEYNOTE ADDRESS

10.50 Control strategy and design transfer for pharmaceutical delivery device combination products
- Establish control strategy (CS) for PFS manufacturing including device constituent parts
- Develop CS for delivery device during design transfers to identify critical quality attributes (CQAs) for device constituent parts
- Generate a set of controls, e.g. incoming, in-process, release and/or stability specifications for delivery device manufacturing
- Promote communication between device and drug development groups, development and manufacturing groups, pharma company and device component suppliers
- Recognize the difference between delivery device and drug: drug focused more on process parameter (e.g. CPP) and device focused more on material attributes (e.g. CMA)

Ling Lu, Sr. Principal Scientist, Pfizer

11.20 The best plastic syringe for biologics
- Multilayer plastic vial & syringe
- Excellent oxygen and UV barrier contribute to stability of drugs
- Very low extractables contribute to stability of drugs
- Minimized silicone-oil contributes to preventing protein aggregation

Shota Arakawa, Business Development Researcher, Mitsubishi Gas Chemical Company, Inc.

12.00 Networking Lunch

13.00 PFS / autoinjector compatibility – impacts to manufacturing and drug delivery performance
- What is the PFS/Autoinjector compatibility
- Challenges to manufacturing and drug delivery performance
- Proposed solutions

Joyce Y Zhao, Device Lead, Combination Product Development, Takeda

13.30 Design the container around the device – benefits of primary container customization with cyclic olefin copolymers for large volume injectors
- Different wearable device options on the market and their primary container requirements
- The benefits of cyclic olefin copolymer primary container customization for devices
- A few case studies on primary container customization

SCHOTT glass made of ideas Patrick Gallagher, Head of Business Development – Polymer Solutions, SCHOTT AG

14.10 Challenges in developing high concentration formulations for combination products
- Importance of viscosity on injection force
- Excipients used to reduce intermolecular interactions
- Effect of shear thinning on injection time

Ramin Samadani, Senior Scientist in Dosage, Form, Design and Development, MedImmune

PRODUCT INTEGRITY, KEY TROUBLESHOOTING TECHNIQUES AND SUCCESSFUL OUTSOURCING

14.40 Advance Prefilled Syringe Development and Robust Development Approach
- Reducing patient risks with innovative elastomeric components
- Minimizing design verification failures, using extreme sterilization conditions and advanced simulation tools
- Ensuring product robustness via a probabilistic approach

LONSTROFF Douglas Cusato, Director of Medical Rubber Business, Sumitomo Rubber Industries

15.10 Afternoon Tea Sponsored by ZEON

15.40 Effects of aging and transportation of pre-filled syringes on device performance
- Establishing initial component and system injection functionality behaviour
- Elucidating the effects of component and system aging on syringe glide force and device performance
- Understanding the physical effects of transportation on prefilled syringes

Brian Frank Lewis, Senior Consultant Engineer, Eli Lilly

THE FUTURE OF PRE-FILLED SYRINGES

16.20 Design device strategy for successful implementation of connected devices
- Case study of i-smart, a smart blister tracking device
- Connectivity and data strategy for choosing the right programs
- Setting up the all-important device development programs
- Process of reorganising funding and financing for device development platforms

Cedric Gysel, Health Care Solutions Design Manager, Johnson & Johnson Design

16.50 Early stage device development and understanding cyber security
- De-risk evaluation in terms of early stage device development
- Digital estimations in terms of challenges for patience use and product integrity
- Case study evidence to advise against rushing digital tools to the market and how to ensure they are robust enough
- Advice on cyber security with new devices and the challenges within field

Michael Song, Sr. Manager, Drug Delivery and Device Development, MedImmune

17.20 PANEL DISCUSSION:
GDPR and its implications on digital health
Moderator: Darin Oppenheimer, Executive Director Head of Drug Device, Merck
Sudeshna Detta Ray, Senior Engineer Advanced Device Technology and Innovation, Amgen
Further panal participants to be confirmed

17.50 Chairs closing remarks and close of day two

SMI'S UPCOMING EVENTS IN THE PRE-FILLED SYRINGE SERIES:

PRE-FILLED SYRINGES & INJECTABLE DRUG DEVICES
16TH -17TH JANUARY,
LONDON, UK

PRE-FILLED SYRINGES WEST COAST
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3RD - 4TH JUNE 2019

PRE-FILLED SYRINGES EAST COAST 2018 ATTENDEE LIST

- Abbott Laboratories
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- Amgen
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- Aurobindo Pharma USA Inc.
- Baumann Springs Usa Inc
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- Bemis Healthcare Packaging
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- Connecticut Spring & Stamping
- Cook Pharmica LLC
- Daicel Corporation
- Datwyler Schweiz AG
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- Eli Lilly
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- Pfizer
- Philips - Medisize
- Plastibell DTP Holding
- rap. ID, Inc.
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- Topas Advanced Polymers
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- W.L. Gore & Associates, Inc.
- Weidmann Medical Technology AG
- West Pharmaceutical Services, Inc.
- Zeon Chemicals L.P.

HALF-DAY POST-CONFERENCE WORKSHOP A
WEDNESDAY 10TH APRIL 2019 | 08.30 - 12.30
SHERATON BOSTON HOTEL, BOSTON, USA

Workshop Leaders:
Dr. Wenzel Novak, Global Senior Director Business Development, **Gerresheimer**
Bernd Zeiss, Head of Global Technical Support, **Gerresheimer**

GLASS AND POLYMER – TWO ESTABLISHED MATERIALS FOR PRIMARY CONTAINERS – IDENTIFY THE BEST OPTION

GERRESHEIMER

Workshop Overview
Glass and Polymer, two established materials for pharmaceutics packaging will be compared to identify limitations of the usability correlated to the drug, storage, environment and other factors. Case studies will highlight the different advantages and drawbacks on each solution in "real life". A risk-based decision matrix will be created by the group to allow further a fast and fact based "to do" list on the evaluation of new products. Case studies will talk on critical factors and give some view into issues and solutions for in market products.

Why you should attend
The workshop will provide attendees the information to identify needs, advantages and drawbacks of different materials used for pharmaceutical primary packing containers. It will allow attendees to make knowledge-based decisions on the individual, best option for containers and troubleshot issues with existing products.

About the workshop leaders

Wenzel Novak has 20 years' experience in the pharmaceutical packaging environment. Holding positions in production, R&D and business development with glass and polymer packaging manufactures and fill-finish equipment suppliers. Focusing on system integration, functionality and GMP relevance.


Bernd Zeiss is biologist by education. After several years working as a biostatistician, he works today in the Gerresheimer Centre of Excellence for pre-fillable syringes. His main areas of work are technical customer support with regard to syringe systems, e.g. investigating interactions between syringe components and drug substance. He evaluates innovations like COP syringes.

About the organisation
Gerressheimer is a well-established supplier for glass and polymer-based packaging material in the cosmetic and mainly pharmaceutical business. With worldwide-located plants, strong R&D and long-term experience in process- / product development focused on customers' needs. Offering glass and polymer syringes, vials, cartridges, specialities and medical devices. Gerresheimer can help to identify the best option out of both worlds. **www.gerresheimer.com/en/home.html**

Programme

8.30 **Registration & Morning Coffee**

9.00 **Workshop Leaders' Introduction**

9.10 **Market overview**
- Syringe formats used in different applications
- Reasons for an increased demand on polymer and still much higher demand on glass
- Is COP the new trend?

9.55 **"Battle" Glass vs. Polymer**
- Is cost and breakability all differentiation?
- Permeability a no-go or just a niche restriction?
- Customization opportunities
- Technical standards, component integration and regulatory perspectives will be highlighted to support decisions

10.40 **Morning Coffee**

11.10 **Case studies**
- Protein absorption
- Permeability / Migration

11.55 **Group: Create a decision matrix**
- Heparin - BioTech - Ophthalmic- Vaccines- Aesthetic
- Summarize needs and decide for the best system

12.30 **Q&A / wrap up**
- Identify the best container material option for YOUR product

HALF-DAY POST-CONFERENCE WORKSHOP B
WEDNESDAY 10TH APRIL 2019 | 13.30 - 17.00
SHERATON BOSTON HOTEL, BOSTON, USA

Workshop Leader:
Barry Sall, Principle Consultant, **Parexel Consulting**

PREPARING FOR A PRE-SUBMISSION MEETING

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Workshop Overview
Participants will evaluate an innovative drug delivery system and work to identify key issues requiring early coordination. Effective approaches and questions will be prepared during the workshop. Issues will be considered from both medical device and pharmaceutical perspectives with a goal of crafting an approach that minimizes regulatory risk and creating an efficient development process.

Why you should attend
You will gain an understanding of key regulatory considerations for the development of a drug delivery system and a variety of approaches to address those points.

About the workshop leader

Mr. Sall is a Principal Consultant with PAREXEL Consulting in Waltham, MA. PAREXEL provides clinical trial, clinical data management, medical and regulatory services to the pharmaceutical and medical device industries. Mr. Sall's areas of responsibility include strategic regulatory consulting involving medical devices and combination products including a wide variety of drug delivery devices and companion diagnostics. He also manages the preparation of FDA marketing applications for medical devices and provides regulatory assistance related to the conduct of clinical trials and Quality Systems compliance. He also regularly participates in public and private training activities, including a joint effort with FDA held twice in Israel. He is also an Adjunct Assistant Professor at the Massachusetts College of Pharmacy, teaching in the Graduate Program in Regulatory Affairs and Health Policy. He has been Regulatory Affairs Certified by the Regulatory Affairs Professionals Society (RAPS) since 1991 and a RAPS Fellow since 2010. In 2008 he was named one of the 100 Notable People in the device industry by MD&DI. Mr. Sall joined PAREXEL in 1989.

About the organisation
PAREXEL is the world's leading innovator of biopharmaceutical services. We simplify our clients' journey of transforming scientific discoveries into new medical treatments for patients with high-quality Phase I-IV clinical research, regulatory, consulting and market access services. PAREXEL develops breakthrough innovations and solutions by leveraging its comprehensive therapeutic, technical, and functional expertise.
www.PAREXEL.com

Programme

13.30 **Registration and Coffee**

14.00 **Workshop leaders Introduction**
- Description of the delivery system
- Overview of the meeting process and goals

14.10 **Breakout session**
- Identifying key issues related to both pharmaceutical and medical device components
- Categorizing these issues with relation to regulatory, technical and business risks

14.25 **Discussion of key issues and their relative priorities**

15.10 **Afternoon Tea and Networking Break**

15.40 **Breakout session**
- Formulate approaches

16.10 **Group discussion**
- Questions from industry and regulator perspectives

17.00 **Final Discussion and close of workshop**

PRE-FILLED SYRINGES EAST COAST PROUDLY SPONSORED BY:

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Harro Höfliger is located in Southern Germany with over 1250 employees. With an extensive portfolio of technical platforms, Harro Höfliger offers customer specific, special solutions for growing market segments, innovative products and new drug delivery systems. Its technology platforms and turnkey system solutions are always precisely tailored to the needs of the customer. This 100% customer focus and a high level of innovation have earned the company a leading market position. With a worldwide sales and service network. A member of Excellence United. **www.hoefliger.com**

Lonstroff is a partner that offers all services related to elastomeric solutions from a single source. We advise our customers not only in the new development and optimization of materials, but also in their applications and in value analysis. Thanks to our experience, we are also able to provide valuable support with the registration and approval of the products. **www.lonstroff.com**

Mitsubishi Gas Chemical is a leading company in the field of oxygen barrier and absorbing technologies. Based on these technologies and experiences, we have successfully developed multilayer plastic vial and syringe having excellent oxygen and water vapor barrier. The products make it possible to replace glass with plastic for injectable drugs.
www.mgc.co.jp/eng/products/abd/oxycapt.html

Owen Mumford offer an integrated design and build service from a broad base of proven self-injection and blood-sampling platform devices and intellectual property. Find out more at **omdevicesolutions.com** or contact us at devicesolutions@owenmumford.co.uk. **www.owenmumford.co.uk**

SCHOTT is a leading international technology group in the areas of specialty glass and glass-ceramics. With more than 130 years of outstanding development, materials and technology expertise we offer a broad portfolio of high-quality products and intelligent solutions that contribute to our customers' success. SCHOTT Pharmaceutical Systems is one of the world's leading suppliers of primary packaging and specialized analytical lab services for the pharmaceutical industry. We provide our customers quality solutions while meeting their highest demands with our expertise and broad product portfolio; including ampoules, cartridges, vials and syringes made of glass and COC polymer. Our state-of-the-art production facilities and our products comply with the highest international quality standards for pharmaceutical needs. **www.schott.com/uk/english/index.html**

Steri-Tek is a high-volume E-beam/X-Ray contract sterilizer and R&D innovation center serving the medical device, biotech, pharmaceutical and other industries. Steri-Tek is a ISO 11137 and ISO 13485 certified, FDA registered, DEA registered as well as State of California Medical Device and Drug Manufacturing licensed facility. Particularly with sensitive materials and complex devices, Steri-Tek has developed a proprietary system for optimizing E-beam/X-Ray sterilization of drugs/biologics in combination devices, pre-filled syringes, implantables, bioabsorbables and other complex products. **www.steri-tek.com**

Since our founding in 1909 as the first modern rubber factory in Japan, we at **Sumitomo Rubber Industries** have strived to produce advanced, environmentally friendly products based on the latest innovations in rubber technology. Within the medical rubber group, we are focused on providing the highest quality products, and ultimately dedicated to improving the lives of people around the world. Utilizing the latest in material and process innovations and our global manufacturing footprint, our team members work diligently to ensure we deliver consistent high performing products and provide strong assurance of supply.
http://hybrid.srigroup.co.jp/en/products/cleanrubber/

Polyplastics, is the leading maker of TOPAS COC (cyclic olefin copolymer), a glass-clear, incredibly pure, break-resistant plastic for drug delivery, including syringes and vials. The benign COC medical polymer presents a nonreactive surface for advanced molecules. Additionally, TOPAS COC offers high moisture and chemical resistance, barrier and UV transmission.
https://topas.com/

West Pharmaceutical Services, Inc. is a leading manufacturer of packaging components and delivery systems for injectable drugs and healthcare products. Working by the side of its customers from concept to patient, West creates products that promote the efficiency, reliability and safety of the world's pharmaceutical drug supply. West is headquartered in Exton, Pennsylvania, and supports its customers from locations in North and South America, Europe, Asia and Australia. West's 2017 net sales of $1.6 billion reflect the daily use of approximately 112 million of its components and devices, which are designed to improve the delivery of healthcare to patients around the world. **www.westpharma.com**

ZEON's Zeonex® and Zeonor® cyclo olefin polymer (COP) allow for advanced, break-resistant syringes, vials and lyophilization containers for protein-based biopharmaceuticals, high viscosity drugs, and contrast media. They also offer high purity, "glass-like" transparency, sterilization, low water absorption, and superior moldability, as well as overcome protein adsorption and ph shift concerns. **www.zeonex.com**

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SMi PHARMACEUTICAL EVENT PLANNER 2019

JANUARY 2019
Pre-Filled Syringes & Injectable Drug Devices
16th -17th January, London, UK

Pharmaceutical Microbiology
21st - 22nd January, London, UK

Social Media in the Pharmaceutical Industry
21st - 22nd January, London, UK

FEBRUARY 2019
Parallel Trade
5th - 6th February, London, UK

3D Cell Culture
20th - 21st February, London, UK

RNA Therapeutics
20th - 21st February, London, UK

MARCH 2019
Superbugs & Superdrugs
18th - 19th March 2019, London, UK

Drug Discovery Chemistry
18th - 19th March 2019, London, UK

APRIL 2019
Adaptive Designs
1st - 2nd April 2019,London, UK

Pre-Filled Syringes East Coast
8th - 9th April 2019, Boston, USA

Microbiology East Coast
10th - 11th April 2019, Boston, USA

MAY 2019
Highly Potent Active Pharmaceutical Ingredients
13th - 14th May 2019, London, UK

Pain Therapeutics
13th - 14th May 2019, London, UK

Injectable Drug Delivery
15th - 16th May 2019, London, UK

JUNE 2019
Prefilled Syringes West Coast
3rd - 4th June 2019, San Diego, USA

Lyophilisation
3rd - 4th June 2019, London, UK

Microbiology West Coast
5th - 6th June 2019, San Diego, USA

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PRE-FILLED SYRINGES EAST COAST 2019

Conference: Monday 8th & Tuesday 9th April 2019, Sheraton Boston Hotel, Boston, USA
Workshops: Wednesday 10th April 2019, Sheraton Boston Hotel, Boston, USA

4 WAYS TO REGISTER

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ACCOUNTS DEPT

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Surname:

Email:

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Payment: If payment is not made at the time of booking, then an invoice will be issued and must be paid immediately and prior to the start of the event. If payment has not been received then credit card details will be requested and payment taken before entry to the event. Bookings within 7 days of event require payment on booking. Access to the Document Portal will not be given until payment has been received.

Substitutions/Name Changes: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. Two or more delegates may not 'share' a place at an event. Please make separate bookings for each delegate.

Cancellation: If you wish to cancel your attendance at an event and you are unable to send a substitute, then we will refund/credit 50% of the due fee less a £50 administration charge, providing that cancellation is made in writing and received at least 28 days prior to the start of the event. Regretfully cancellation after this time cannot be accepted. We will however provide the conferences documentation via the Document Portal to any delegate who has paid but is unable to attend for any reason. Due to the interactive nature of the Briefings we are not normally able to provide documentation in these circumstances. We cannot accept cancellations of orders placed for Documentation or the Document Portal as these are reproduced specifically to order. If we have to cancel the event for any reason, then we will make a full refund immediately, but disclaim any further liability.

Alterations: It may become necessary for us to make alterations to the content, speakers, timing, venue or date of the event compared to the advertised programme.

Privacy policy / Opt Out: For full details on our privacy policy please go to http://smi-online.co.uk/privacy-legals/privacy-policy. If you no longer wish to receive email updates you can opt out by going to the following webpage http://www.smi-online.co.uk/opt-out

EARLY BIRD DISCOUNT

- ☐ **Book by 14th December to receive $400 off the conference price**
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I would like to attend: (Please tick as appropriate)	**Fee**
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☐ Distribution of your company's promotional literature to all conference attendees	**$1598**	**+ VAT**	**$1917.60**

The conference fee includes refreshments, lunch, conference papers, and access to the Document Portal. Presentations that are available for download will be subject to distribution rights by speakers. Please note that some presentations may not be available for download. Access information for the document portal will be sent to the e-mail address provided during registration. Details are sent within 24 hours post conference.

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I cannot attend but would like to Purchase access to the following Document Portal/Paper Copy documentation.

	Price		**Total**
☐ Access to the conference documentation on the Document Portal	**£499.00**	**+ VAT**	**£598.80**
☐ The Conference Presentations – paper copy (or only £300 if ordered with the Document Portal)	**£499.00**	**-**	**£499.00**

PAYMENT

Payment must be made to **SMi Group Ltd**, and received before the event, by one of the following methods **quoting reference P-284 and the delegate's name. Bookings made within 7 days of the event require payment on booking, methods of payment:**

- ☐ **UK BACS** Sort Code **30-00-09**, Account **11775391**
- ☐ **Wire Transfer** Lloyds TSB Bank plc, 39 Threadneedle Street, London, EC2R 8AU
  Swift (BIC): **LOYDGB21013**, Account **11775391**
  IBAN **GB75 LOYD 3000 0911 7753 91**
- ☐ **Cheque** We can only accept USD checks Drawn on a US Bank.
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SMi Group will apply surcharges to commercial cards
Please tick here ☐ if the card provided is not a commercial card

Card No: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Valid From ☐☐/☐☐ Expiry Date ☐☐/☐☐

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If you have any further queries please call the Events Team on tel +44 (0) 870 9090 711 or you can email events@smi-online.co.uk