

# Device innovations, connected delivery and regulatory guidance for advanced parenteral systems

*This agenda offers you networking with Global Product Managers, Senior PFS Engineers, Device Testing Managers, Heads of Late-Stage PFS Development and many more*

BOSTON, MASSACHUSETTS, UNITED STATES, January 25, 2022  
/EINPresswire.com/ -- SMI's 9th Annual Conference

[Pre-Filled Syringes East Coast](#)

Main Conference: April 25 - 26, 2022 |

Workshops: April 27, 2022

Sheraton Boston Hotel, Boston, MA, USA

[www.pfsamericas.com/](http://www.pfsamericas.com/)

Sponsors are: SCHOTT, ZEON

“

it looks as though this years event could be the biggest ever. The bookings we are receiving show that people want to return to live events”

*Richard Jones*

Exhibitors: Owen Mumford Pharmaceutical Services, PHC Corporation, POLYPLASTICS- TOPAS, Weiss-Aug Group

The global [pre-filled syringes](#) market was valued at \$1139.6 million in 2020 and with the rapid growth of the industry, is expected to grow at a CAGR of 8.95% up to 2027. With that in mind, the 9th annual Pre-Filled Syringes East Coast conference will bring together leading industry experts

representing big pharma and device developers to discuss the key drivers accelerating the expansion of the industry.

The past year has seen significant developments in the injectables landscape with the rapid introduction and development of vaccines in response to the pandemic, updates in regulations including the EU MDR and FDA guidance on bridging studies, and increasing industry acceptance



SMi Group Proudly Presents the 9th Annual...

## Pre-Filled Syringes East Coast

25 - 26 April 2022  
Boston, USA

Device innovations, Connected Delivery & Regulatory Guidance for advanced parenteral Systems

Register at: [www.pfsamericas.com](http://www.pfsamericas.com) Visit: @SMIPharm | #smipfsusa

Pre Filled Syringes East Coast 2022

of connectivity to aid the user experience. As part of SMI's leading injectable series, the 2022 conference will provide an exclusive insight into the latest developing technologies for device design, advances in parenteral device platforms and development, insights into growing integration of digital health and deep dives into recent case studies on novel delivery systems.

This two-day agenda offers you peer-to-peer networking with Global Product Managers, Senior PFS Engineers, Device Testing Managers, Heads of Late-Stage PFS Development and many more.

Visit the website at: [www.pfsamericas.com/](http://www.pfsamericas.com/)

Chair for 2022:

Gretchen Vandal, Sr. Director, Head of Global Regulatory Affairs – Devices and Combination Products, Takeda

Guest FDA Speaker:

- John Barr Weiner, Associate Director for Policy and Product Classification Office, Office of Combination Products FDA

Featured 2022 Speakers Include:

- Joyce Zhao, Associate Director, Combination Product, Takeda
- Suzette Roan, Associate VP and Head of Global Device Regulatory Affairs, Sanofi US
- Christine Lynn Ianning, Distinguished Scientist, Device Area Leader, Merck
- Heather I. Guerin, Associate Director, Regulatory Affairs – CMC, Janssen
- Tieming Ruan, Senior Director of Device Development, Alexion Pharmaceuticals
- John Schalago, Executive Director, Senior Global Program Director Regulatory Affairs, Novartis
- Gretchen Piwinski, Manager, Combination Product Laboratories, Regeneron
- Michael Song, Associate Director, Takeda
- Deep S Bhattacharya, Senior Scientist, Drug Product Development and Design, Pfizer

BENEFITS OF ATTENDING:

- Explore the latest developments in innovative technologies for device design accelerating the path to self-administration
- Assess the evolving regulatory landscape for pre-filled syringes and discuss approaches to work with regulators as guidance is updated
- Engage in panel discussions with industry leaders to navigate the accelerating digital health landscape for combination products and drug delivery systems
- Understand the landscape of delivery for novel drug products and key considerations to overcome challenges in CCI

View the full agenda and speaker line-up online: [www.pfsamericas.com/](http://www.pfsamericas.com/)

Who should Attend:

- Drug-delivery developers

- Medical Device Engineers
- Primary Packaging material designers
- Secondary packagers
- Smart device developers
- Training device developers
- Device-safety solution providers
- Drug developers

#### EARLY-BIRD RATES:

- ☐ BOOK BY 31st JANUARY AND SAVE \$200
- ☐ BOOK BY 28TH FEBRUARY AND SAVE \$100

Registrations can be made on the event website at: [www.pfsamericas.com/](http://www.pfsamericas.com/)

#### POST CONFERENCE WORKSHOP A: EU MDR 2017/745 Article 117 Requirements

Workshop Leader: Theresa Jeary, Technical Specialist & Scheme Manager, BSi  
08.30 - 12.30

#### Overview of the workshop:

The workshop is aimed to provide an introduction to the key elements of the Medical Device Regulation that Companies affected by article 117 need to consider.

#### Why you should attend:

- Be able to determine if Article 117 is applicable to your products
- Understand and be able to interpret the requirements of Article 117
- Understand the impacts on your marketing authorization application or post-market variation
- Gain an appreciation and understanding of the MDR Annex I, General Safety & Performance Requirements
- Understand requirements to facilitate the documentation preparation needed to obtain a NB Opinion

#### POST CONFERENCE WORKSHOP B: Developing User-Centric Next Generation Combination Products

Workshop Leaders: Marty Coyne, Principal & Co-Founder, Matchstick and Chris Franzese, Principal & Clinical Leader, Matchstick  
13.00 - 17.00

#### Overview of the workshop:

This interactive workshop will explore approaches for developing innovative drug delivery device combination products offering tools for optimal device development with the user in mind. Workshop leaders will provide insights into effective strategies for concept generation, product testing and validation for the future of device design.

Why you should attend:

- Discover innovative concept generation approaches for device development
- Understand how to utilise user feedback and experiences in early stages of development
- Walk through unique examples assessing effective testing to ensure an optimal product
- Engage in interactive discussions to assess opportunities for enhanced devices ensuring the patient is kept at the forefront

Visit the website here to find out more and to download the full agenda:

[www.pfsamericas.com/](http://www.pfsamericas.com/)

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