

Hear from Amgen speaking at SMI's 4th annual Conference and Exhibition: Pre-filled Syringes West Coast 2019

Hear from Amgen as they will be presenting the Keynote Address:

LONDON, UNITED KINGDOM, April 25, 2019 /EINPresswire.com/ -- Platform approach for combination products and devices on day one by Ronald Forster, Executive Director, Amgen and Kesley E. Gallagher, Director of External Engagement, Combination Products, Amgen at the 4th annual conference and exhibition taking place June 3rd - 4th in San Diego, USA.

Below is a summary of Ron Forster and Kesley Gallagher's presentation:

A promotional poster for the SMI Group's 4th Annual Conference and Exhibition, titled "PRE-FILLED SYRINGES WEST COAST". The poster features a close-up image of two pre-filled syringes, one yellow and one white, on the left. The text on the right reads: "SMI Group Presents the 4th Annual Conference and Exhibition...", "PRE-FILLED SYRINGES WEST COAST", "HYATT REGENCY MISSION BAY, SAN DIEGO, CA, USA", "3RD - 4TH JUNE 2019", and the website "www.prefilled-syringes-westcoast.com". The SMI logo is at the bottom left of the poster.

SMI Group Presents the 4th Annual Conference and Exhibition...

**PRE-FILLED
SYRINGES WEST
COAST**

HYATT REGENCY MISSION BAY, SAN
DIEGO, CA, USA

3RD - 4TH JUNE 2019

www.prefilled-syringes-westcoast.com

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PR

Opening Keynote Address: Overcoming the challenges in development of injectable protein formulations - Day 1 | 09:10

- IFE assessment considerations
- Challenges in biocompatibility
- The balance between volume and viscosity
- The future of the platform approach for devices

Kesley Gallagher is the Director of External Engagement, Combination Products, at Amgen in Thousand Oaks, CA. She has worked in the pharmaceutical and medical device arenas for over 20 years in both Quality Assurance and Regulatory Affairs. Her prior responsibilities include Medical Device Regulation (MDR) implementation for both CE marked devices and products that will require notified body opinion. She led teams for the global submissions and approvals for the Repatha Pushtronex and managed the regulatory aspects of the Neulasta OnPro; these are Amgen's first on-body injectors. Prior to joining Amgen, Kesley was an RA Manager at Abbott Medical Optics, specializing in new product development for eye care products and

ophthalmologic surgical femtosecond lasers. Kesley has an MS in Regulatory Science from the University of Southern California and an BA in Biology/Chemistry from Bowdoin College.

Ronald Forster, Executive Director, Amgen will also be moderating a panel discussion on the future regulatory trends and covering the following:

- The European Medical Device Regulation
- The emerging market in China
- Brexit and how it will affect the device industry
- Regulatory strategies for wearables, software-based medical devices and integrated devices

Dr. Forster is the Executive Director, Device Final Drug Product Technology department at Amgen Inc. Responsible for all Container Closure Systems, their integration into combination products, devices and drug substance systems. His team has developed and published numerous standards for Biological Packaging systems, lead multi-company teams to establish guidance's in Biological Packaging development, and serves on numerous customer advisory boards for packaging suppliers.

He is also a Board of Director member as well as head of the Technical Advisory Committee for the Suzhou Industrial Park Biologics and Pharmaceutical Packaging institute (Upon accreditation this facility will become the Chinese National Biological Packaging Testing Laboratories)

Prior to joining Amgen, Ron was with Merck Inc. where he was Senior Principle Engineer leading a group that implement Quality by Design for primary packaging systems from early clinical development through commercial supply chain systems. He was a key leader in advancing the Merck Commercialization process and served as a global manufacturing lead on a key product franchise board.

Ron has an Interdisciplinary Ph.D. from Rutgers University in Chemical Engineering, Ceramic Engineering, and Mechanics and Materials Science.

For those looking to attend there is currently \$100 early-bird saving, ending April 30th.

Further information is available at: www.prefilled-syringes-westcoast.com/einpr6

SMi presents the 4nd Annual Conference:

[Pre-filled](#) Syringes – [West Coast](#) 2019

Date: June 3-4, 2019

Workshops: June 5 21019

Location: Hyatt Regency Mission Bay, San Diego, California, USA

Website: www.prefilled-syringes-westcoast.com/einpr6

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About SMi Group:

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