An update on combination product device development discussed at Pre-Filled Syringes San Francisco 2021

As part of SMi's leading Injectables series, this year's event will address the key drivers of the pre-filled syringes and combination products industry

Pre-Filled Syringes San Francisco 2021

LONDON, LONDON BRIDGE , UNITED KINGDOM, June 2, 2021 /EINPresswire.com/ -- Delegates stand to gain many valuable insights from Pre-Filled Syringes San Francisco with case studies highlighting developing approaches to device development and strategic platform approaches, design controls and applications and an insight into the evolving landscape of connected devices.

Visit the event website to learn more and download the brochure at www.prefilled-sanfrancisco.com/einpr3

An update on combination product and injection device regulatory guidance
•A review of current guidance for pre-filled syringes and what is new from the past year
•How has COVID-19 impacted regulatory submissions and processes?
•An update on expectations for regulatory submissions – common pitfalls and how to ensure you are meeting requirements
•A future outlook of changes to regulatory requirements and guidance in the coming years
Alan M. Stevens, Acting Director - Division of Drug Delivery, General Hospital, and Human Factors, CDRH, FDA

Strategic platforming for combination products
•Optimising development time, costs and reducing risks through platforming
•How do you select your platform device and key lifecycle management considerations?
•Challenges in a one size fits all approach

•Platforms for novel drug products and new device technologies
Scott Surrette, Manager Combination Product Development, Regeneron

Developing on-body delivery devices with the user in mind
•An outlook on the need for large volume injectors and high viscosity drug products
•Delivery device technologies for sustained delivery
•An outlook of evolving delivery devices for novel drug products
Nicholas Mandala, Senior Director, Medical Device and Combination Product Technology, Pfizer

Regulatory standards and guidance for combination product Instructions for Use (IFUs)
•Types of User Documentation
•Regulatory Requirements for Instructions for Use
•Special Considerations: accommodating colorblindness, folding, font size
•Case Study: People with Parkinson's User Manual Comprehension Research
Shannon Clark, CEO, UserWise

Register online: www.prefilled-sanfrancisco.com/einpr3

Early bird offer register by 30th June and save $100
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About SMi Group:
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