

## Latest Revision on FDA Combination Product Guidance Presented at Pre-Filled Syringes Boston Summit

FDA Present on Regulatory Considerations for Combination Products at Pre-Filled Syringes East Coast this Spring

LONDON, ENGLAND, UNITED KINGDOM, January 11, 2017 /EINPresswire.com/ -- SMi Group will welcome the expertise of Tina Kiang, FDA Science & Policy Acting Director, when she presents an opening keynote at <a href="Pre-Filled Syringes East Coast 2017">Pre-Filled Syringes East Coast 2017</a>.

The talk entitled 'Regulatory considerations of Combination Products' will explore key topics surrounding applicable regulatory schemes in both the US and EU; the latest revision of the FDA Combination Product Guidance; and changes in FDA's quality system requirements for pre-filled injection devices.

Working closely with a selection of handpicked PFS experts, the <u>program</u> for Pre-Filled Syringes East Coast 2017 will

offer critical updates in pre-filled technological developments and opportunities for both new and established stakeholders.

Other notable speakers joining the FDA on the agenda will include:



...we should take this opportunity to learn, develop and improve our best practice and strategy for pre-filled syringes

Conference Chair, Shire

- Dhairya Mehta, Associate Director, Shire
- Li-Chun Tsou, Global Device Technical Director, AstraZeneca
- Ronald Iacocca, Research Fellow, Delivery and Device, R&D, Eli Lilly
- Edmond Israelski, Director Human Factors, AbbVie
- David Chen, Principal Scientist, Novel Drug delivery Technologies, Pfizer
- Sudeshna Dutta Ray, Senior Engineer Advanced Device Technology, Amgen
- Stephen Barat, Executive Director, Non-Clinical and Translational Sciences Safety Assessment and Bioanalysis, Allergan
- Tiffnay McIntire, Human Factors Engineer, Eli Lilly
- Hemal Mehta, Manager, Global CMC-RA, Medical Devices and Combination Products, Janssen R&D
- Phillip Green, Executive Director, Merck
- Michael Selzer, Manager, Combination Products Engineering, Regeneron
- Toshiro Katayama, Product Manager, Zeon
- Kenchiro Usuda, Researcher, Advanced Business Development Division, Mitsubishi Gas Chemical



Further details including a full speaker line-up is available at <a href="https://www.pfsamericas.com">www.pfsamericas.com</a>

Pre-Filled Syringes East Coast 2017 4th Annual Conference: April 26th & 27th Interactive Workshops: April 25th The Colonnade, Boston, MA, USA

Sponsored by: FluentaOVLK, Mitsubishi Gas Chemical, MW Industries, Nemera, Overlook Industries, Owen Mumford, Terumo Pharmaceutical Solutions, West Pharmaceutical Services, Zeon

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