

Sanofi Joins the Speaker Line-up for SMi's Launch, Injectable Drug Delivery 2018

LONDON, UNITED KINGDOM, March 20, 2018 /EINPresswire.com/ -- The launch of [Injectable Drug Delivery](#) will take place on the 16th - 17th May 2018, in London, UK. Hear from Sanofi as they will be presenting: Advancements of Fill & Finish Process, on day 1.

Biopharmaceutical manufacturers are under increasing pressure from regulators to ensure the safety and quality of their products. Protein aggregation presents a key challenge in the development of biologic formulations as it can have an impact on product quality in terms of efficacy and immunogenicity. Proteins have a natural propensity to aggregate due to the dynamic nature of their structure, which is held together by a combination of Van der Waals forces, hydrogen bonds, disulfide linkages, and hydrophobic interactions.

Jean-René Authelin, Global Head, Pharmaceutical Engineering, Sanofi will be presenting the Keynote Address: 'Protein Aggregation and Oxidation During Processing' on Day 1 @13:20.

Below is an overview of the session:

- Proteins are known to be sensitive to many stresses, including oxidation and shear stress, leading to potentially immunogenic aggregates
- Examine the theoretical aspects together with real-life industrial examples that illustrate the possible traps that may be found in the fill & finish processing
- Learn which experiments need to be performed in order to understand and predict risks associated with this process
- Discover the practical industrial solutions
- Hear how to implement these solutions accordingly

Fill-finish processing comes after upstream bioprocessing, formation of the active agent by cell culture or fermentation, and downstream purification; this is when the final product has the greatest value, and, thus, the most to lose to a product failure. So at these later stages of development, tried-and-true processes tend to be what's used. Innovation can introduce elements of risk, expense and regulatory work into bioprocess operations. This includes the formulation, mixing or other preparation of the active agent into its final form, e.g., liquid or lyophilized powder, and filling and sealing within final



SMi is Proud to Launch their Conference on...

Injectable Drug Delivery 2018

Holiday Inn Kensington Forum
London, UK

16 - 17 MAY

www.Injectable-drug-delivery.com



containers, which increasingly include prefilled syringes and other delivery systems.

Mostafa Nakach, Head of Pharmaceutical Engineering, Sanofi will also be presenting 'Fill and Finish of Biotech Products and Hazards Associated: Derisking Approach' on Day 1 @14:00

Below is an overview of the session:

- Basic data acquisition focusing on the main physical chemistry properties of the drug product.
- Preliminary calculations of process parameters based on prior knowledge using simulation tools in order to anticipate process parameters of freezing, thawing, mixing, filtration and filling parameters.
- Set-up of Design space using Lab scale tests for each operation units in order to fine tune the calculation results.
- Set-up of robust and efficient scale-up that can lead to stable products in the monitored quality attributes

The presentation outlines the description of the scientific methodology that consists of several steps. Download the agenda for more info on both sessions. www.injectable-drug-delivery.com/ein

For those looking to attend there is currently a £100 [early-bird](#) saving, ending March 29th

SMi presents the Launch of:

Injectable Drug Delivery

Date: 16th – 17th May 2018

Workshops: 15th May 21018

Location: Holiday Inn Kensington Forum, London UK

Website: www.injectable-drug-delivery.com/ein

Sources: <http://bit.ly/2sehtvT> | <http://bit.ly/2FTfW0q>

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