NEW interview released with GSK in run up to their keynote presentation at Lyophilisation Europe 2015

SMi's Lyophilisation Europe conference will open its doors on 29th and 30th June 2015 in London, UK

Lyophilisation Europe

LONDON, UNITED KINGDOM, May 15, 2015 /EINPresswire.com/ -- Following on from the well-received US show, part 2 of SMi Group's Global Lyophilisation series, Lyophilisation Europe, will open doors on 29th and 30th June.

Highlights will include a keynote address on the implementation of QbD in Lyophilisation by Yves Mayeresse from the science-led global healthcare leader, GSK.

In his 20 years of experience author and industry expert, Yves Mayeresse, has managed activities such as aseptic production, set-up of new freeze-drying facilities, design of freeze-drying cycle and development of new stabilizers for freeze-dried products. Now a Director at GlaxoSmithKline Vaccines, his current work focuses on providing support, learning and guidance settings in the global industrial operations department.

SMi group caught up with him to discuss his presentation and hear about the latest developments in the implementation of QbD principles.

Interview Snippet

Q. Although a common terminology in the pharmaceutical industry, what can be learnt from implementing QbD?

A. Qbd assesses that the quality should be embedded in the product development and not only controlled afterwards. This approach is a concept giving more discipline in the development of a new product, to generate more product knowledge/understanding and help improve the robustness of the commercial manufacturing operation. It should not be opposed to the inherent creativity needed for discovery in early stage. As it's a structured approach this will end-

up with a product having the right level of quality during commercial qualification and lifecycle. Using tools such as design of experiment (DOE), the product and process knowledge will be improved.

Q. In terms of conducting a quality risk analysis, what are the main misconceptions to approaching this and how should one best approach this in order to identify the top critical attributes and devise a control strategy around the high risk items?

A. Quality risk analyses are commonly conducted for security aspect of equipment in different industries, meaning the concept is not new, but has now been applied to pharmaceutical industry. A quality risk analysis is a lengthy operation mobilizing specialized resources in an organisation. The value of such a document is of paramount importance for product/ process development. The misconception comes from the result of the operation. Either the resources are not engaged during the process or the level of expertise is not adequate, ending with a document of average value. As this document is the basis of the next validation operations, some failure can occur giving discredit to the risk analysis.

Q. What new developments do you envision for 2015?

A. Today, the approach does not provide the full potential of its added value. In 2015, we have to continue implementation of this approach in the whole product development pipeline and on the legacy products to improve the product/process robustness. In term of freeze-drying, we are still looking for tools allowing us to better understand what goes on, inside the black box commonly called freeze-dryers. In a good QbD approach those tools target an increase in process/ product knowledge. At the same time scale-up model of the process will be reinforced in order to leverage the information generated at early stage showing their relevance for commercial stage

To read the full interview and to access further featured event contact, visit the "download" tab at www.lyophilisationconference.com/EIN

Lyophilisation Europe
29 - 30 June 2015
Holiday Inn Regents Park Hotel, London UK
www.lyophilisationconference.com/EIN

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leaders and visionaries, allowing us to bring our communities together to Learn, Engage, Share and Network. More information can be found at http://www.smi-online.co.uk

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