Bio Innovation Leaders Summit

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Speaker Interview

Hubert Chen
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Pfenex

What is your role at Pfenex and what experience are you bringing with you to the summit?

I am the Chief Medical and Scientific Officer at Pfenex where I am focused on leading our pipeline programs, which currently include biosimilars, therapeutic equivalents and vaccine candidates. My current role is focused on overseeing these products and leading each through the appropriate clinical and regulatory processes.

My previous experience includes serving as vice president of clinical development at Aileron Therapeutics, where I led the first IND filing and clinical investigation for the Stapled Peptide technology. While at Aileron, I also oversaw the early clinical and regulatory activities for a first-in-class MDM2/MDMX dual inhibitor for malignancies expressing wild-type p53 tumor suppressor protein. Prior to Aileron, I served as vice president of translational medicine at Regulus Therapeutics, providing preclinical and clinical strategies for microRNA-based medicines in multiple therapeutic areas, including atherosclerosis, diabetes, fibrosis, and hepatitis C infection. I began my biotech career as associate director of medical sciences at Amgen.

Your presentation will be all about "Progress of Biosimilars: Emergence, Future Development and Manufacturing" – what can our delegates expect to learn from you?

Biosimilars have moved beyond their infancy and are starting to make strides globally, however there is still more work to be done to increase total market uptake and to encourage greater US adoption. During my presentation, I will discuss where biosimilars currently stand and where we can anticipate growth in the future. Further, I will explore considerations in biomanufacturing and commercialization as a greater number of biosimilars seek to enter the market.

What are the greatest challenges currently facing biosimilars in the US?

While biosimilars have been used throughout Europe for over a decade, they are still a nascent industry in the United States. We are encouraged that there is greater attention and focus on biosimilars from the FDA, and we look forward to enhanced engagement with regulators and payors in ensuring that biosimilars have a streamlined pathway for market adoption.

What can the US learn from Europe about biosimilars integration and innovation?

We can look to Europe, with over 400 billion days of safe use of biosimilars, to see the positive impact that biosimilars can have on increasing patient access. Further, we should draw on the European experience in naming and interchangeability when creating our guidelines here in the United States.

What are the benefits of biosimilars to the healthcare / pharmaceutical industry?

Biosimilars offer the ability to open access to essential treatment options for patients across the healthcare spectrum.

What new developments are expected in the biosimilars area in 2017/2018?

I think we will see additional guidance from the FDA on interchangeability and on switching designations.

What is necessary for a successful future of biosimilars?

Education of patients, providers and payers is important in ensuring the biosimilars industry reaches its full potential within the US.

What are you looking to gain from your participation at the 11th annual Bio Innovation Leaders Summit?

I'm looking forward to engaging with other industry leaders to discuss ways that we can propel biosimilars forward both in the US and globally.

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For more information on Hubert's talk and the Bio Innovation Leaders Summit, please visit the summit website at: www.bioinnovation.co.uk

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