DEVELOPING PROTEIN THERAPEUTICS

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Bernardo is a Senior Scientific Director in the Global Pharmaceutical Development Biologics Department at Sanofi. He is responsible for development of drug products for therapeutic proteins, due diligences, life cycle management strategies, and platform technology evaluation. He also serve as the US-based Drug Device Integrator for Sanofi's North American portfolio. Prior to joining Genzyme/Sanofi, he was Laboratory Head of Formulation and Process Development at Genetics Institute/Wyeth Biopharma (now Pfizer).

Dr Perez-Ramirez holds a BS degree in Biology a M.S. degree in Biochemistry from the Medical College of Virginia and a Ph.D. in Chemistry/Biochemistry from the University of Missouri. He did postdoctoral research in physical biochemistry of proteins at Brandeis University, MA. He is a member of several scientific societies including the New York Academy of Sciences; The American Society for Biochemistry and Molecular Biology, Sociedad Espanola de Bioquimica y Biologia Molecular. He is a fellow of the Royal Society for the Arts (RSA) of England and he also serves as adjunct professor in the Department of Biomedical Engineering at Tufts University in Boston.

What will your presentation be covering?

In the meeting I will be presenting on the challenges and opportunities in developing drug products for therapeutic proteins. In particular, I will integrate the concepts of developing convenience to patients while creating stable dosage forms for different type of monoclonal constructs. This necessitates strong integration with discovery research as well as with the groups working on the upstream process and the ones designing the final container closure. The need to have an early device ability criterion for biologicals to predict the behavior of the final drug product is an imperative.

What are the emerging trends that you are seeing in formulation and drug delivery?

There is a continuous evolution of different type of protein scaffolds that has prompted an in depth evaluation and optimization of platform approaches. The promises of brain delivery and the challenges of gene therapy applications for brain delivery continue to be important. Taking in consideration the patient experience to develop dosage forms is a critical point that is becoming to be integrated in the target product profile early on.

What are the main challenges that you are facing in formulation and drug delivery?

In order to develop protein therapeutics we need a very diverse expertise including pharmaceutical scientists with experience in drug substance and drug product development, engineers, protein chemists, pharmacologists, compliance specialists, etc. Talent is in great demand and training and retaining talent is a high priority and a challenge in a very competitive environment. This is one of the reason that I decided to teach a graduate course at Tufts University on formulation and drug product development so we can expose students to real work examples to better prepare them for a career in the biopharmaceutical industry .

Why are conferences like this [the 4th Formulation & Drug Delivery Congress and co-located 3rd Inhalation & Respiratory Drug Delivery Congress, May 2018] important to you?

In the industry we have common technical challenges so these type of forums are important to learn from our respective experiences and see how others have approached or come out with solutions for similar situations. There is also lot of opportunities to chat with colleagues and networking with others.