Q&A SESSION WITH MERSHID ALAI-SAFAR

MERSHID ALAI-SAFAR, Senior Director, Regulatory Affairs, **Baxter**

Mehrshid Alai works for Baxter as Senior Director of Regulatory Affairs, involved with new product development and life cycle management of variety of products, including biosimilars. She has extensive experience in licensing and management of post-approval changes. Prior to moving to regulatory affairs she was part of the Quality organization with extensive experience in multiple areas. Mehrshid also worked in R&D as a protein characterization scientist and managed a group of scientists prior to moving into the Quality organization. She has more than 23 years of experience in biologics development and production, biological product life cycle, quality and regulatory affairs. Prior to joining Baxter, she was an assistant professor at Simon Fraser University. She holds a PhD from Johns Hopkins School of Medicine.

Despite having to overcome tight regulatory challenges the biosimilars industry is rapidly moving. In your opinion, what is the key driving force behind this rapid growth?

The opportunities are immense and there are different paths to the finish line. Healthcare should be made more affordable to patients and healthcare providers.

How are the current biosimilars regulations affecting the industry and are there some new regulations researchers should be aware of?

The field is evolving very rapidly. The regulatory requirements – although different – are converging to some degree. The quality and analytical biosimilarity assessment requirements will be something to keep an eye on. For example, the sensitivity of analytical methods to detect differences vs. clinical results will become more and more evident. I personally think that the regulators will be asking for a much more extensive analytical comparison; the tools are there and becoming more sophisticated.

At our 3rd Annual Biosimilars & Biobetters Congress you will be sharing with us your experience in different regulatory guidelines, primarily FDA and EMA. Could you highlight some of the most important differences to these two guidelines? How do the different guidelines affect the industry in different locations?

Interchangeability is the first thing that comes to my mind. That is in the FDA's guidance documents but not something that is regulated by the EMA, and this can potentially impact the design of clinical trials. Also, there are differences in clinical requirements for certain types of biosimilars. In the past few months we have seen some differences in extrapolation of indication between EMA and Health Canada. We are all interested to see how the FDA evaluates the same product.

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