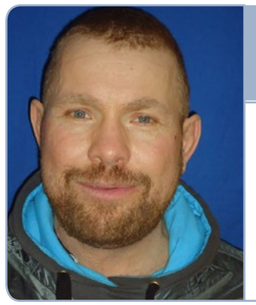
BIOLOGICS & DIGITALIZATION: THE FUTURE OF FORMULATION



JONAS FAST, Principal Scientist, Pharmaceutical Development at Roche

Jonas Fast has worked for Roche since 2009 in parenteral pharmaceutical development with a focus on biologics. He has a postdoctorate degree from the University of Colorado at Boulder after earning his PhD from Lund University, Sweden.

We discuss the burgeoning biologics formulation market with Jonas Fast, who describes the exciting potentials of technical progress and digitalization for the biopharmaceutical industry.

Please describe your current role at F. Hoffmann-La Roche AG.

I am a senior scientist in the department of pharmaceutical development for parental dosage forms in Basel, Switzerland. We develop all modalities for parental administration such as small molecules, LNAs, peptides but mainly monoclonal antibody-based formats. My role involves being part of global product development projects to conduct formulation and process development studies, coordinate preclinical and clinical drug product supplies, support clinical studies with in-use studies as well as co-authoring regulatory and clinical documents. In addition, there are always many project-independent activities and initiatives ongoing. For instance, I am part of a global in-use team that develops best share practices for clinical compatibility studies and related in-use topics, collaborates with clinical operations on various topics such as site guidance templates and recently challenges for micro-dosing.

Large molecule and biologics products occupy a growing percentage of the market – what is the driving force behind this growth, and what is your outlook on the future of the industry?

The large molecule (LM) increase as contribution of the available medications comes down to various reasons:

- Technical progress and financing: Development and maturation in research tools and kits and production technology of LMs has enabled not just big companies with vast resources but also many small companies to work in the LM area often with help of more CROs and CMOs offering services. Increased venture capital access is probably contributing and reflecting the prospects
- Large scale initiatives and digitalization: Public and private efforts to map out the blueprints of life starting with human genome 20 years ago with proteomics, epigenetics etc., together with more and more powerful computer hardware and software to parse and analyze large data sets have opened up a vast space to discover new disease pathways and targets for medical intervention, benefiting any drug modality
- Integration of new biological knowledge: The harnessing of immunotherapy finally opens up, after years of dead ends and dismissal, the scope for using the immune system to treat disease has energized the field

As for future developments, what I see is further progress in immunotherapy-based treatments by increased understanding of the immune system and its interactions in health and disease. This will include new or maturing modalities such as cell, gene therapy maturing, microbiome-based therapies. In addition, more personalized treatments based on integrating physiological, genetic and microbiome information and also preventive personalized treatments based on the same information. The key is to integrate it better in people´s lives, incentivize good habits and improve compliance to see positive public health effects. To this end, it would be helpful to see some breakthrough of oral administration of biologics.

What are the biggest opportunities in biologics formulation?

By working cross-functionally closer and seamlessly with support of the digitalization tools and actively using the large amounts of historical data to model and predict outcomes, it can potentially soon be possible to get comprehensive knowledge-based risk assessments for molecules that need more attention and resources during development that can be put in, e.g. platform formulations and demand minimal resources and enable accelerations. This would ideally increase output and flexibility while still fulfill all quality demands for successful development.

What is particularly interesting in the bioanalysis area, and what do you see as the future developments?

I would like to see real time, or close-to-real time, release of drug substance and drug product batches to shorten the time between production and patient access.

What would you like to achieve at our Formulation & Drug Delivery congress?

Meet colleagues, learn about their experiences, particularly on in-use challenges, and share my experiences.

*Jonas Fast will be presenting on 'In-Use Challenges For Low Dose Administration Of Biologics' at our **Formulation & Drug Delivery UK congress**, taking place in London, UK on the 22-23rd of Aptil 2020.* ***Register to attend here***