STABILIZATION OF POOR GLASS-FORMING APIS WITH MESOPOROUS SILICA

FINN BAUER, Head of Solid Formulations R&D, **Merck**

Dr. Finn Bauer is Director for Solid Formulations R&D, recently launching two PVA-based excipients for sustained release and solubility enhancement through hot melt extrusion. He is a biochemist by education and holds a Doctoral degree from the University of Bayreuth, Germany. In 2016, in addition, Finn completed a Master of Business Administration at Ashridge Executive Education, Hult Internarial Business School, UK. With broad experience in managing product and application development projects, Finn has guided many programs in his 13-year career with Merck Life Sciences. During this time, Finn held positions from Quality Control to R&D and Site Manager across various countries. Most recently, Finn has assumed additional responsibility for Merck's Global Actives & Formulations Application Labs network including locations in Europe, India and China.

Ahead of our Formulation & Drug Delivery congress, we got talking to Finn Bauer from Merck KGaA about solubility developments for Solid Oral Dose developments and the outlook for sustained release medicines.

What is your current role – and what drew you to work for Merck?

I'm currently Director of Solid Formulation R&D with Merck Life Science. More than 10 years ago I was drawn to Merck as the world's oldest pharmaceutical and chemical company. In the past 13 years that I'm now with the organization (moving through different roles in quality control and research and development in Germany, US and Switzerland), I have been fortunate to witness and shape how we at Merck constantly re-focusses our activities to ensure that our products meet current and future customer needs. Today I'm excited to make Merck a vibrant science and technology company and expanding our solid formulation excipient portfolio especially for applications like solubility enhancement and controlled release of APIs.

What are you working on at the moment?

At this moment our focus is on new product developments of polymer-based excipients. This includes new solutions for solubility enhancement of small molecule APIs and sustained release from matrix tables. At the same time, we're still very much committed to our previous product innovations. Specifically, I would like to highlight our silica microcarrier for solubility enhancement. We introduced this carrier material back in 2013. Nevertheless, we're constantly optimize our technical support and service offering around this product – e.g. by scaling up the API loading process of this microcarrier material to commercial manufacturing scale (up to 150 kg loading scale).

What are the biggest challenges working with Solid Oral Dosage Form?

Solid oral dosage forms are the gold standard in patient centric drug delivery formats. However, solubility enhancement technologies, continuous manufacturing approaches and the potential of additive manufacturing techniques are about to disrupt the solid oral dosage manufacturing footprint of the future. As more and more specialized treatment approaches immerge, the need for efficient and increasingly flexible fabrication processes rises. As an excipient manufacturer we strive to support our customers to mitigate these challenges. The before mentioned drug product manufacturing scale-up know-how is just one example on how we support our customers in minimizing development risks.

There have been significant developments in targeted therapeutics – how do you see this progressing?

There have been numerous extremely interesting targeted drug delivery approaches recently – manly in the area of parenteral applications with special emphasis on implants and nanoparticle. That being said, most of these approaches, however, still must prove their economic feasibility and relevance. Therefore, one of our mail efforts is to further innovate in the area of "classical" solid oral dosage forms to further optimize solubility enhancement and controlled release of APIs.

What would you like to get out of the Formulation & Drug Delivery event?

I'm looking forward to Formulation & Drug Delivery as a platform for excellent scientific presentations and discussions along with a great networking opportunity.

Finn will be presenting on Stabilization of Poor Glass-Forming APIs with Mesoporous Silica at our Formulation & Drug Delivery congress, taking place in London on the 22-23rd of April 2020. Register to attend here.