

# **About Boehringer Ingelheim and the Challenges in Formulation Development of Biologicals in Respect to Polysorbate Analytics**

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The talk is subdivided into two parts. First, a general overview about Boehringer Ingelheim (BI) as pharmaceutical company regarding milestones, network, innovations, and research & development is provided. Secondly, challenges in formulation development of biologicals in respect to polysorbate analytics are highlighted with focus on analytical techniques.

Biologicals including monoclonal antibodies are the current flagships in pharmaceutical industry. However, they are exposed to a multitude of destabilization conditions such as hydrophobic interfaces, leading to a reduced biological activity. In formulation development excipients and adjuvants are tested to improve and ensure the stability of the biopharmaceutical products over the entire shelf life. Especially, polysorbates (PS) are used as gold standard to effectively stabilize biologicals against colloidal stress. Nevertheless, chemical instability of PS via hydrolysis or oxidation results in degradation products that can form particles via phase separation. As the number and size of particles in pharmaceutical products is strictly regulated for instance by the US Pharmacopeia or the European Pharmacopeia, PS-induced particle formation needs to be monitored upon drug storage. To mitigate and understand the cause of PS degradation, automated fluorescence detection as well as liquid chromatography coupled to charged aerosol detection or mass spectrometry were usually applied and combined with model development.