

# 9<sup>th</sup> World Drug Delivery Summit

June 30-July 02, 2016 New Orleans, USA

## Prediction and prevention of protein aggregation in multi-dose products

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One of the major challenges in development of biotherapeutics is protein aggregation. Proteins tend to aggregate in solutions. These aggregates are often more immunogenic and less bioactive. Protein aggregation affects the quality attributes of the drug and has to be prevented throughout the shelf-life of the product. There are different mechanisms behind protein aggregation and appropriate formulation strategies can be employed to address this issue. Multi-dose formulations containing biotherapeutics often use phenolic compounds to ensure sterility. However, these preservatives are known to destabilize the protein and may cause aggregation. In this presentation, the interaction between phenolic preservatives and proteins was investigated using isothermal calorimetry in a TAM instrument in the presence and absence of different stabilizers. The effect of different additives on the enthalpy of binding of phenol to protein was evaluated and thereby phenol induced aggregation of protein could be predicted. The initial aggregation of the protein in the presence of phenol was studied by size exclusion chromatography in the absence and presence of stabilizers. It was shown that aggregation was prevented using the found excipient as predicted by this novel strategy.

### Biography

Mitra Mosharraf has over 15 years of experience in biotech drug development. She is the Chief Scientific Officer and partner at HTD Biosystems, a CRO in the San Francisco Bay Area. Prior joining HTD, she has served in different scientific positions at Pharmacia Corporation and at Pfizer Global Manufacturing. She has received her MSc in Pharmacy and PhD in Pharmaceutical Sciences from Uppsala University. She has authored several scientific papers in peer reviewed journals and proceedings. Her scientific interest lies in material sciences, molecular interactions and their impact on drug development. In her free time, she volunteers for the American Association of Pharmaceutical Scientists.

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