

# Impact of Interfacial Interactions on the Formation of Particles, Aggregation of Proteins, and Their Prevention:

Role of Surface Energetics and Their Application to Container Compatibility and Protein Purification

Jinjiang Li, Ph.D., Senior Principal Scientist, Drug Product Science & Technology, Bristol-Myers Squibb Co.

Cambridge Healthtech Institute recently spoke with Dr. Jinjiang Li of Bristol-Myers Squibb, about challenges in studying protein aggregation and his upcoming presentation "Impact of Interfacial Interactions on the Formation of Particles, Aggregation of Proteins, and Their Prevention", at the 8th Annual Protein Aggregation and Emerging Analytical Tools conference, taking place **January 10-11, 2017** as part of the **16th Annual PepTalk** event which runs from **January 9-13, 2017 in San Diego, CA.** 



## What are the biggest challenges in studying protein aggregation in biopharmaceuticals?

There are many challenges in studying aggregation which is the significant concern of physical stability for biologics products. Fundamentally there is lack of mechanistic understanding in protein aggregation, which makes prediction very difficult. In addition, accurate detection

of aggregates has always been a formidable task although the progress of technology has made our job much easier. Additionally the correlation between immunogenicity and particle size/particle morphology is not established yet. Overall, it is one of the biggest challenges in dealing with biologics.

## Can you tell us a little about your work and why you chose to tackle this topic?

Another challenge in dealing with biologics is to understand the impact of interfacial forces to proteins as we all know proteins are very surface active, which makes them very different from other macromolecules. Because of this, proteins would like to move to interfaces if they are all allowed to. Also noted, the free energy for folding/unfolding transition of proteins is very small. At interfaces, depending on interfacial energy and structures, proteins can be easily denatured and subsequently form aggregates. Unfortunately during manufacturing, storage, and delivery, proteins encounter many types of interfaces, from typical air/water to water/plastics. Therefore, it is very important to understand the impact of interfacial interaction to protein stability, which will lead to effective mitigation strategies.

### Where is the field headed in coming years?

Interfacial investigation has been a very active field in other academic disciplines. Regarding to its application to product development of biologics, there are a few things to be watched for. There will be more collaboration work between academics and industry. Additionally instrument maker will facilitate this process significantly by introducing low sample volume and short run-time equipment. Consequently, a better understanding of effect of interface energy on protein stability will be there.

#### What can people expect from you talk?

In my talk, I will introduce some fundamental principles of interfacial science related to applications of drug product development for biologics. In addition case studies will be provided.

## Why did you choose to present at Eighth Annual Protein Aggregation and Emerging Analytical conference?

This conference covers both fundamentals and applications in dealing with aggregate formation, aggregate detection, and instrumentation.

# What are you looking forward to at 2017's program and gathering?

Good discussions with colleagues from other companies and scientific progress in investigating aggregation of proteins and current mitigation strategies.

## SPEAKER BIOGRAPHY: Jinjiang Li, Ph.D., Senior Principal Scientist, Drug Product Science & Technology, Bristol-Myers Squibb Co.



Jinjiang Li received his Ph.D. in physical chemistry from McGill University in Canada, in 1997. The focus of his doctoral research was on the interfacial and colloidal behavior of biopolymers. After spending two years as a postdoctoral research fellow with Prof. George Zografi of University of Wisconsin at Madison, he joined pharmaceutical industry, first with Boehringer Ingelheim and now with Bristol Myers Squibb. He is currently senior principal scientist working on product development of biologics. Dr. Li published extensively in a variety of journals and spoke in many conferences. He has been a reviewer for many journals.