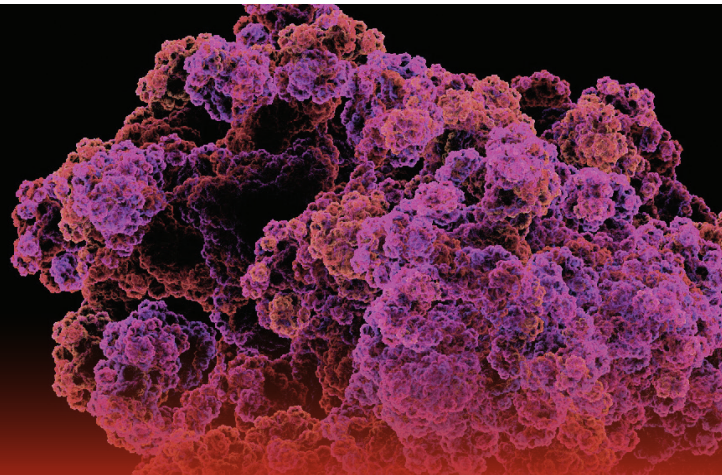


Cambridge Healthtech Institute's  
**16th Annual**  
**PEPTALK**  
THE PROTEIN SCIENCE WEEK

January 9-13, 2017 | San Diego, CA  
Hilton San Diego Bayfront



## New Case Studies and Strategies for Manufacturing, Scale-Up and Tech Transfer

**Alexander P. Herbert**, Senior Process Engineer, Process Engineering and Pilot Plant, West-Ward Pharmaceuticals

Cambridge Healthtech Institute recently spoke with Alexander Herbert of West-Ward Pharmaceuticals, about his upcoming presentation "New Case Studies and Strategies for Manufacturing, Scale-Up and Tech Transfer", at the **10th Annual Lyophilization and Emerging Drying Technologies** 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**.



### Q Can you tell us a little about yourself and your work?

I've been working in the field of sterile injectables within the generic industry for eight years. I was introduced to lyophilization as a bench chemist and pilot plant technician, and my experiences built my approach to the science from the ground

up. I am now the subject matter expert within my company for all facets of lyophilization process design, from evaluation of the initial formulation through submission of the final production process. I am also heavily involved in equipment design, maintenance and event investigation.

### Q Why are you attending the PepTalk and what are you looking forward to at 2017's gathering?

The roll of speakers for 2017 represents an excellent cross-section of the industry - I'm both appreciative and humbled to have been invited to speak. I'm looking forward to stretching myself in areas of protein science that I'm not usually exposed to.

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

I have a deep personal interest in increasing availability of much-needed medicines to patients. The work I'll be presenting involves the return

of two legacy products to commercial manufacture, and the transfer strategy between production sites through our pilot plant facility. Lifecycle management of lyophilized products is often difficult (and to me, interesting) due to the balance between differences in the manufacturing sites and the complications of the established regulatory filings.

### Q What are the major obstacles and what's revolutionizing your field of research?

There's a phenomenon in the field of forensic science known as the "CSI Effect", in which high-level exposure to forensic science can lead to an over-emphasis on its place in the criminal justice system at the expense of traditional investigative techniques. I've frequently encountered similar misconceptions regarding computational modeling and its role in process design.

Theoretical modeling and the supporting equipment and formulation characterization techniques are invaluable tools for guiding projects and increasing the efficiency of the development pathway. That being said, models cannot stand on their own without real-world evaluation and implementation. Hard data is still a firm requirement for confident process design. Appropriate integration of emerging technologies into the process development workflow has been a challenging but very rewarding role in my career.

## Speaker Biography: **Alexander P. Herbert**, Senior Process Engineer, Process Engineering and Pilot Plant, West-Ward Pharmaceuticals



Alex Herbert is a Senior Process Engineer for West-Ward Pharmaceuticals. He serves as global subject matter expert (SME) for thermal characterization, QbD lyophilization cycle development, technology transfer/scale-up and event investigation. His experience includes the lyophilization of over 100 product presentations, including small molecules, proteins, liposomes, and both deactivated and live attenuated vaccines, across seven manufacturing facilities around the world. He also serves on the Speakers Committee of the International Society for Lyophilization – Freeze Drying (ISL-FD) and continues to collaborate with academic institutions and equipment vendors in new lyophilization technologies.

TO LEARN MORE ABOUT HIS  
PRESENTATION AND PEPTALK, VISIT:

[CHI-PepTalk.com/lyophilization-drying-technologies](http://CHI-PepTalk.com/lyophilization-drying-technologies)