

Thursday, February 16, 2006

Vaccines Symposium

Presented by Brian H. Lange, P.E.

The presentation will provide a brief overview of the biology related to vaccines, what are vaccines and who uses them. The process for manufacturing vaccines will be presented (and compared to other biotech processes such as brewing). The rationale for using vaccines will be explored. A glimpse of the future of vaccines will also be provided.

Brian H. Lange, P. E. is Director of Engineering in Sterile & Packaging Operations for Merck & Co., Inc. in West Point, Pennsylvania. His responsibilities include capital management, maintenance and operations for facilities and utilities supporting barrier, liquid and lyo manufacturing along with packaging operations. Previous to his current position, Lange was Associate Director – Lyo Operations where he was responsible for lyo filling and packaging of biological and pharmaceutical products. Lange was also Manager of Sterile Filling and responsible for liquid filling of sterile biologicals and pharmaceuticals. Before moving into vaccine manufacturing, he spent a great deal of his 18 year career with Merck providing engineering support to all facets of Research including facilities, solid and sterile clinical manufacturing and utility generation and distribution. Brian is highly active within ISPE as a Chairman of the International Board of Directors (2003-2004), a Past President of the Delaware Valley Chapter and a member of the Society's Facility of the Year Judging Committee. He has served the ISPE as a course leader and speaker on many occasions and has been published in Pharmaceutical Engineering. Lange is a graduate of Villanova University with a Bachelors of Mechanical Engineering and is a registered Professional Engineer in the state of Pennsylvania.



*Brian H. Lange, P.E.
Director of Engineering
Sterile & Packaging Operations
Merck & Co., Inc.*

Meeting Date: February 16, 2006

Location: Iron Hill Brewing
The Shoppe's at English Village
1460 Bethlehem Pike
North Wales, PA 19454.

Times : 6:00 Reception
7:00 Dinner & Speaker
9:00 Adjourn

Price, members & nonmembers:
\$20.00 per person & \$10.00 per student
Cash Bar

RSVP: Monday, Feb. 13, 2006
Please **RESERVE ONLINE** or contact **Chuck Clerecuzio** at cclerecuzio@ipsdb.com or 610-828-4090 x238 with your name, company, number attending, and telephone number.

No shows will be billed unless cancelled prior to meeting.

Directions: For more information about the Iron Hill Brewing Company please visit www.ironhillbrewery.com

Chair's Chat

by Steve Wood, CFM

As most around Philadelphia know, January marked Benjamin Franklin's 300th birthday. In February, AICHE-DVS plays homage to Ben by celebrating one of his best loved quotes: "God gave us beer because he wants us to be happy." Coupled with a discussion of vaccine development, the brewery tour on February 16th will be terrific event and we hope you will join us.

Remarkably, our 2005 - 2006 campaign of events is rapidly coming to close. In March, we host a tour of the Rohm & Haas Bristol facility. In April, we close the year in our traditional manner with our Student Awards banquet at Drexel. We hope that you have noticed a difference this year in our programs. We sure have. Our average attendance to events has more than doubled. In addition to events, we have worked hard to improve the quality of our newsletters and increase our electronic communication to members. We will continue to work on these through the coming year and hope that you will help us via your feedback. We are working hard to create a "community of colleagues" to help you be connected -- connected to opportunities for professional development and growth. I, personally and professionally, have benefited from this connectivity and invite you to do the same. For this organization to truly serve you and your colleagues, we need your help. Please contact a member of the planning committee to see how you can help build the community. We have a strong (and fun) group of people and are looking for more.

"Ask not what AICHE can do for you...."

Tech Tips – Charles A. Clerecuzio, P.E.

Since our February meeting will focus on the production and use of Vaccines, it is timely to discuss the growth in the use of disposable technology for the manufacture and finishing of biologics. Although disposable components have been used in the BioPharma industry for many years (filter cartridges, single use tubing, etc.), there has been increased interest over the last few years in the use of this technology for larger process systems. This has been driven by the following factors: a greater number of multi-product facilities, increased cost pressure (particularly capital cost) on the manufacturing of these products and the expansion in the devices and solutions based on disposable technology.

The benefits that disposable technology offers include lower risk of cross-contamination, reduced cleaning requirements (and therefore cleaning validation) and reduced capital costs related to fixed tanks and piping. As more production scale plants implement this technology, better data will become available comparing the overall lifecycle costs of disposables to the savings realized in capital costs.

Disposable technology holds great promise for the Bioprocess industry, but a number of areas of concern need to be addressed in effectively applying this technology:

1. Material compatibility with the process streams
2. Aseptic connections between the components (reliability, reproducibility)
3. Practical limitations on the size of the units (including transportation and handling)
4. Mixing of materials within units
5. Validation / qualification of these units (approach and testing)



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2005 – 2006 AICHe- DVS Event Schedule

March 16, 2006
Plant Tour:
Rohm & Haas -- Bristol
Cost: \$20/\$10

April 11, 2006
Student Awards Banquet:
Drexel University
Cost: \$20/\$10

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Tech Tips Continued

6. Facility Layout to support the use of disposables and ancillary equipment (containers, dollies, etc.)

There are a number of vendors that supply equipment and systems in this technology. They have taken unique approaches to the issues concerning mixing and connections. The validation issues can be addressed through a vendor audit program. Material compatibility will be addressed through traditional material compatibility testing during development. Facility layout will be addressed during programming, once the decision to utilize disposable technology has been made.

Progress in addressing these areas has been steady and the more these solutions are implemented and the body of knowledge surrounding them is increased, the better we will get at utilizing them. Disposable technology will play a significant role in Bioprocessing in the years to come and will deliver strong benefits to our industry.

Chuck Clerecuzio is Senior Director, Process & Technology for Integrated Project Services (IPS) and can be reached at cclerecuzio@ipsdb.com.

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inside...

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DVS Chair's Chat**

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