

Dr. James Zega

“Moving Beyond the Black Box: The Development of In-Line Measurements to Improve Pharmaceutical Process Understanding”

Thursday February 24, 2004

Join us on Thursday February 24, 2004 to hear Dr. James Zega of Merck & Co. present a talk entitled “Moving Beyond the Black Box: The Development of In-Line Measurements to Improve Pharmaceutical Process Understanding.” Historically, pharmaceutical process development relied on a black box approach. These black box approaches often use statistically designed experiments with machine operating parameters as variables. The operating variables, typically, are not directly related to the fundamental physical phenomena governing the processes. An alternative approach is to develop instrumentation and monitoring techniques or process analytical technologies (PAT) to provide more direct and physically meaningful measurements. Merck’s lab has developed a “toolbox” of these techniques for key pharmaceutical unit operations; including high shear wet granulation, roller compaction and column coating. The use of these techniques facilitates a deeper understanding of the fundamentals of pharmaceutical processes and provides a mean to reduce process development resources through more focused experimental designs

Biography: Jim Zega is Director of the Solids Pharmaceutical Development Group at Merck Research Laboratories (MRL) in West Point, PA. He manages the group that prepares clinical supply materials and develops pharmaceutical processes for tablets and capsules. In addition, his group scales up these processes and transfers the technologies to the commercial manufacturing sites. Prior to joining MRL, Jim was in

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Dr. Jim Zega is Director of the Solids Pharmaceutical Development Group at Merck Research Laboratories.

Meeting Date: February 24, 2005

Location:

Palace of Asia
285 Commerce Dr
Fort Washington, PA 19034-2406
215-646-2133

Times:

6:00-6:30 Social Hour
6:30 Dinner with speaker to follow

Cost: \$25 (\$15 for students)

RSVP: Please register by Tuesday February 22, 2005 at our website www.aiche-philadelphia.org or by contacting William Wong either by phone: 215-652-8191 or by email: william_wong@merck.com

Directions: The restaurant is located in Best Western Inn. From the Pennsylvania Turnpike take Exit 339 under bridge to traffic light, make a right turn, the Best Western Fort Washington Inn is located on the right.

VICE-CHAIR’S CHAT BY STEVEN WOOD

Some things endure. In their meeting minutes from December of 1877, the Engineers Club of Philadelphia included that their goal "...shall be the professional improvement of its members, the encouragement of social intercourse among men of practical science, and the advancement of engineering in its several branches." In 2005, our goals at AICHE-DVS remarkably similar. In order to advance the Chemical Engineering profession for our members in the Delaware Valley, AICHE-DVS provides: (1) educational programs, (2) networking opportunities, and (3) expert resources.

2004 was a terrific year for our section. We remain financially strong. New programs brought new opportunities for participants. From a winery to a waste-to-energy facility, participants learned something new and created contacts during plant tours. Participants learned of new job opportunities, created business opportunities and made new friends. We have added new members but recognize that there are many of you that we have not engaged.

You work long hours, you have families and other obligations that push participation in a professional society down the priority list. We endeavor to become more accessible to you. As active members, we have reaped the benefits of participation and hope to share those benefits with you. We are holding events closer to where you work. We are considering Trade Shows, Job Fairs, Vendor Exhibitions, and Continuing

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CHEMICAL CONSULTANTS NETWORK

January 12, 2005, Meeting

Visit our web page at www.chemconsultants.org

Date & Time: Wednesday, March 9, 2005, Meeting at the Cynwyd Club, Bala Cynwyd, PA; Networking, 5:30 PM; Dinner, 6:30 PM; Talk and Business Session, 7:30 PM.

Topic: InnoCentive® Dr. John Newport (SBDC)

Abstract: : “ InnoCentive® is an exciting web-based community matching top scientists to relevant R&D challenges facing leading companies from around the globe and provides a powerful online forum enabling major companies to reward scientific innovation through financial incentives.”

Following a brief overview of the various web sites that seek solutions to chemical and related problems, detailed information on InnoCentive®, from both company and solver perspectives, will be presented. The wide range of problems presented by InnoCentive should be of interest to Network members; some require lab work while others do not. Awards range from \$3K to \$100K.

Biography: Dr. John Newport (www.johnnewport.com), a graduate of UMIST in Chemistry (B.Sc) and Polymer & Fibre Science (PhD), came to the USA in 1967. Since retiring from Hercules Incorporated after 34 years of investigative and managerial R&D in the Fiber, Film, Reaction Injection molding and Paper Chemical businesses, he became as a registered consultant with the Chemical Consultants Network.

Location: The Cynwyd Club, 332 Trevor Lane, Bala Cynwyd, PA. If lost, call the club at 610-667-4524.

Reservation: To make or cancel a dinner reservation, e-mail CCNReservations@aol.com or call the ACS office at 215-382-1589 (leave message on voicemail if necessary). Fee, including food and beverages, is \$25 provided reservations are made before 6 PM Friday, March 4th; \$30 if made subsequently by 10 AM Monday, March 7th. If no reservation is made by the final deadline, food and beverages will not be available unless a cancellation occurs. No-shows will be invoiced

DR. JIM ZEGA*(Continued from page 1)*

Merck's Manufacturing Division (MMD) with responsibilities for in-line product support and technology transfer. He earned his BS in Chemistry from Beloit College and his Ph.D. in Chemical Engineering from Rice University.

CHAIR'S CHAT

(Continued from page 1)

Education Programs. We are working hard and welcome your ideas.

A suggestion: resolve to participate in one AIChE event this year. For some, participation in just one event a year is enough to create lasting and growing contacts. The power of email and the telephone enables a single face-to-face contact to create a lasting conversation. Often a single contact is all it takes to create a powerful opportunity. Consider adding our website to your favorites and keep an eye on our schedule of events. We look forward to meeting you soon.

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AIChE members brave snow/ice storm to attend January 19th Meeting

Despite one of the year's worst storms a large group attended the dinner meeting at the Union League of Philadelphia to hear Mr. Andy Signore's talk on "Delivering Affordable Innovation in Pharmaceutical Projects".

Mr. Signore is a Chemical Engineer, MBA, PE, past national president of ISPE, and several other professional organizations, and founder and president of IPS.

Cocktails and hors d'oeuvre were served in the Lincoln Memorial Room under the eyes of a full size statue of President Lincoln. Much of the conversation centered on the adventure of arriving on time in one piece.

Dinner was served in the Library Room and was followed by Mr. Signore's talk.

It covered:

What is Affordable Innovation, why is it important, what are the challenges, what is the current status of the Pharmaceutical Industry, and what's new in Pharmaceutical Manufacturing?

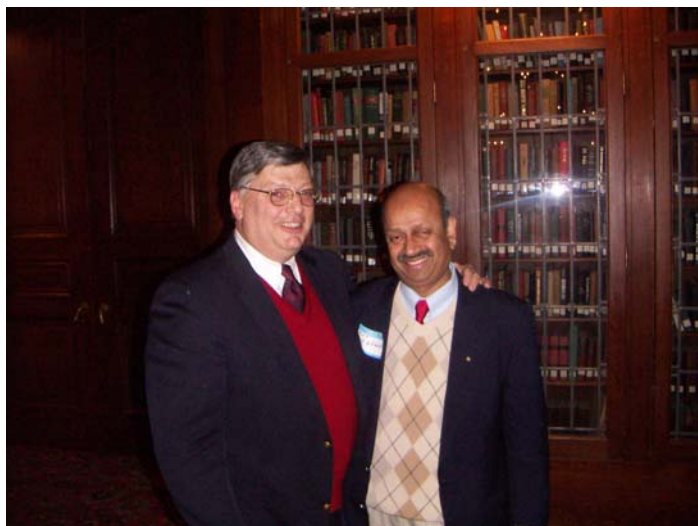
He discussed manufacturing issues, R&D spending, pricing and government policy, quality, drug development cycles, new manufacturing technologies and PAT, and how engineering/project management can help delivery Affordable Innovation. A spirited Q&A session followed the talk.

A number of people called to cancel prior to the meeting and we received emails the next morning telling of traffic jams lasting for miles. Since the Union League was kind enough to reduce our dinner count at the last minute, and we do not believe we should have people put themselves into danger, we have lifted our cancellation policy for this meeting. Those unable to attend will not be billed and those of you who have mailed payment are having their checks returned.

Doug Kriebel and Carl Walters receive awards for decade long service to the AIChE DVS.



Guest Speaker Andy Signore with AIChE Chair Ajit Ghordade



Professional Development - By Mark DeLuca

Things are looking up! The number of job seekers fell from 27 to 17. I received several encouraging emails from people with positive news about developments at their companies.

While production jobs are still moving off shore, new product development is an area where local jobs look promising.

The European Union is flexing its muscle as a unified market place and American companies have a new regulatory body to contend with in order to sell products into that large market. Unlike local regulations that drive business out of our area, the EU regulations affect all our competitors around the world. Because we have endured the toughest regulations (outside of California) Delaware Valley and Jersey Chemical Engineers are quite adept at compliance. Regulatory Compliance is again becoming an employment growth area. Our section has talent.

An improving job market may not prevent your specific company from having a layoff, but it will decrease the amount of time it takes you to find an equivalent position.

It's great to be writing a positive column again.

Until next month . . .

Future Events

February 9, CCN meeting, "How the Small Business Development Centers Can Help Your Business Grow, see www.chemconsultants.org for details

February 18, Engineers week Proclamation Luncheon, Union League of Philadelphia, meet Donald Dalessandro, 2005 DV Engineer of the Year, contact Dick Mulford at the Engineers Club, info@engrclub.org or 215-985-5701

February 23, ACS Delaware Section, talk on the Premcor Refinery, contact susan.fallers@astrazeneca.com for details.

March 15, AIChE Meeting, joint with IPSE, plant tour of AppTec Bio-Pharma labs, Details to follow.

April 19, AIChE Meeting, Student Awards, held at Villanova University, details to follow.

May AIChE Meeting TBA



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