

Dr. James Zega

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

Tuesday, May 10th, 2005

Join us on Tuesday, May 10th, 2005 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 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.



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

Meeting Date: Tuesday May 10th, 2005

Location: Best Western

Times:
6:00-6:30 Social Hour
6:30 Dinner and speaker to follow

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

RSVP: Please register by May 3rd 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: Take Route 476 to Lansdale Exit, turn left after tolls and Best Western is on the right.

Chair’s Chat: DVS ON MOVE & THANK YOU & GOOD BYE!

Your Chair: Dr. Ajit Ghorpade

"Time flies when you are having fun! (When bad weather cooperates!)" How true when it come to being the chair of AIChE-DVS this year. We had to reschedule a meeting due to bad weather and lower the guaranteed attendance due to bad weather! First, I thank all of you to give me this opportunity to be the helm and in the same breath I would like to thank all of you who attended planning meetings from the first one at my Grand Conference Center at home office, assisted in monthly meeting co-ordination as well as attended most.

We have an excellent crew of regular members on the board that made my job as chair extremely easy, with the systems and personnel in-place, it was almost on “auto Pilot”. So, please do not hesitate to VOLUNTEER! Especially, I have to thank our VICE-CHAIR (incoming Chair), Mr. Steven Wood who conducted meetings for me when I had to leave town on a short-notice and contribute to the newsletter; our EDITOR, Mr. Doug Kriebel and his staff for making sure that I remembered the deadlines and providing me slack; our SECRETARY Mr. Scott Smith for taking minutes at all planning meetings even though sometimes they got too long and most importantly to our TREASURERS, Mr. Carl Watters and Mr. Karl Saydlowski for keeping books balanced and keeping those delicious WAWA HOGIES coming for the planning meetings! There are two other individuals who really worked their magic behind the scenes, but on your computer screens, they are our Webmaster, Mr. Charles Rudolph and advertising co-coordinator, Dr. David Lee. My thanks go out to Mr. Richard Kral without whose database and membership management skills none of us would have received the monthly newsletter or at least to the correct address!

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TECH TIPS - BENCHMARK FOR CHANGE

Process improvement in the Asphalt industry by John Rockwell

Summary:

How do you put a process on paper known only in the minds of operators? How can you identify key parameters to serve as benchmarks for future process improvements?

An asphalt company had a polymer modified asphalt (PMA) process at three different plants. Basically the process consisted of mixing base asphalt from refineries with polymers at certain temperatures for certain periods of time. Batches were made and combined in one single tank named the "sales tank". The final product was tested for quality in the sales tank, and then pumped into trucks to be delivered to customers.

The company was a small family operation with about 125 employees. Naturally, they were interested in growth and desired to optimize the process that manufactured their key product. The problem was, nobody knew exactly how much time was required to make these batches with a reasonable confidence at any plant. How could the process be improved without having a previous benchmark?

The project commenced with four different steps:

1. Identify key process parameters used for the benchmark.
2. Gather appropriate data for confidence levels.
3. Measure and prepare schematics of all equipment at the three plants.
4. Analyze results and present report to management.

The parameters chosen were cycle time, tank temperatures, and quality characteristics of the finished product. For every plant, a minimum of two batch processes were recorded, 3 or more were preferred. The data was input into a statistical software program, and the parameters were control charted to 2 and 3 sigma levels. Also the equipment varied with the plants, schematics were prepared showing which plants had more heating capacity, or a different way of adding chemicals into the tanks. Lastly a report of all the data was prepared and presented to management.

The results included a cycle time to the 95% confidence level for all three plants, and also graphs showing key parameters of the major equipment. Shortly after the results were presented to management, a new process was tested, and also compared. In the end a benchmark was available upon which to improve the PMA process.

*Results are confidential to protect company interests. John Rockwell holds a BS ChE from the University of Idaho, and is currently seeking employment in the Allentown, Philadelphia area. He can be reached at (208)-859-3085 (cell).

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CHEMICAL CONSULTANTS NETWORK

May 11, 2005, Meeting

Visit our web page at www.chemconsultants.org

Date & Time: Wednesday, May 11, 2005 at the Cynwyd Club, Bala Cynwyd, PA; Networking, 5:30 PM; Dinner, 6:30 PM; Talk and Business Session, 7:30 PM.

Speaker Topic:

Government Contracting – How to Write Winning Proposals

Abstract: David deLesdernier will present *Proposal Development for Federal Government Solicitations*. He will address the Federal Government acquisition process focusing on responding to solicitations. Topics covered in the presentation will include: different types of solicitations, how to read an RFP, proposal structure and use of storyboarding. Mr. deLesdernier will provide additional insight into the Department of Defense (DoD).

Biography:

David deLesdernier: Currently David is assisting several businesses develop and increase their government business base. He is drawing on his 30+ years experience including 18 years at Science Applications International Corporation, a \$6B professional services corporation with over 60 percent in the government market. At SAIC his customer list included DoD (Army, Navy, Air Force, USMC, DARPA, DNA), DOE, DoTreasury, EPA and NASA as well as numerous prime contractors. His projects ranged from individual consulting assignments to managing multi-million dollar development and production projects. His responsibilities grew from being a senior engineer to managing a \$25 M business unit with 6 P&L centers. After SAIC, David worked for two NASDAQ corporations in the SEMI industry as their VP of Engineering before starting Dernier Technologies, Inc.

Location: The Cynwyd Club, 332 Trevor Lane, Bala Cynwyd, PA 19004. From City Line Ave. (Route # 1) drive north on Conshohocken State Road (Route # 23 West) about 3 long blocks. Continue north on Trevor Lane instead of following Route #23 left. At "Y" in road one block north on Trevor Lane turn left where clubhouse and parking are on the left side of the road. Please park in lot if space is available; otherwise park on Trevor Lane. 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, May 6th; \$30 if made subsequently by 10 AM Monday, May 9th. 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.



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THANK YOU TO LONZA

AIChE's Delaware Valley Section Thanks Lonza Inc. for donating \$ 100 towards the Student Award Dinner. Their contribution is appreciated! This will go towards the cost of dinner of some of the award recipients.

Member News

We recently learned that **Bernard Leber** of Cherry Hill, NJ passed away on May 17th 2004 at age 79. Bernie was a chemical engineer retiring in 1986 after 37 years with FMC Corp and a longtime member of AIChE.

Otto Pfefferkorn playfully writes to us, "I have just moved to MOSCOW....that is Moscow PA!". Otto, a longtime member of AIChE, served our local section as Professional Development Chair in the late 1990's. We googled Moscow PA and found it up in the Poconos. The AIChE section officers and planning board members wish Otto all the best in his retirement.

"Position Wanted"

Chemical Engineer EIT: 1 yr exp. – Asphalt Industry, Spanish, Pending Security Clearance, 3.10 gpa. Seeking technical sales, process position in Allentown, Philly area. Reside in Quakertown.

John Rockwell (208)-859-3085 (cell)



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Annual AIChE-DVS Plan-
ning Meeting
Tuesday, June 14th at
6:30pm
White Hall, Room 311
Dinner will be served

Please join us as we plan out the 2005 - 2006 season of events. This will be a great opportunity for section members to participate in your section. You will provide input and ideas about what events should be on the schedule for the upcoming year. This will also provide an opportunity for you to help to plan and organize a section event. If interested, please contact Steven Wood, Incoming Chair, at steven_wood@ml.com.

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Chairs Chat by Dr. Ajit Ghorpade

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I thank a group of members who have really stepped up to the plate this year and contributed in a big way to DVS by contributing their time and efforts. Mr. Eric Swanberg coordinated all efforts on Student Award function and Mr. Chris Gillman took initiative and followed through on two monthly meetings (including the one that needed rescheduling). Mr. David Salas and Mr. Richard Kral championed the Process Safety meeting from DVS side with Professor Mafia of Widener taking the lead. The CEO series meeting coordinated by Mr. Charles Clerecuzio and Mr. Doug Kriebel was a great success in spite of a miserable weather! Chuck is additionally spear heading new ideas for newsletter, membership training and joint meetings with ISPE in coming years. Mr. William Wong has contributed to new ideas as well as helped in meeting planning. I would like to thank all area Universities for their active participation in chapter events and hope that in future they will promote AICHE-DVS even more as student participation at minimal cost will be one of our future goals!

I know that all in all I had a wonderful and fun filled year. My desire to improve member attendance at meetings through better programming, resulted in ONLY partial success and I hope that the next year will see much higher participation due to excellent planning that incoming chair has already started! Once again I thank all of you for this wonderful opportunity. I will continue to assist and participate in future in any capacity that the board desires.

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