



Central Jersey Section

October Dinner Meeting

Current Good Manufacturing Practice

by Timothy Flanigan

Tuesday, October 22, 2002

One area of considerable discussion in the healthcare industry is Current Good Manufacturing Practice (CGMP). There are almost as many questions as there are answers today regarding CGMP. The one area of universal recognition is the fact that CGMPs are extremely general and opened to all sorts of interpretation.

Invariably industry has chosen the most conservative approach when it comes to addressing CGMPs. It is felt that this is not necessarily the best course of action. In fact it can be argued that industry is its own worst enemy when it comes to regulatory requirements. After all it is industry that is responsible for establishing most of the "rules" that are currently enforced.

Perhaps what is needed is a better understanding of how we got to where we are. The purpose of this presentation will attempt to clarify where we are, how we got there and how to work within the given framework of CGMP. It will also

address the future. The intent is to provide basic understanding of the regulations so that we can better work with them.

Tim Flanigan is Director of Validation and Regulatory Affairs for Lockwood Greene in Somerset, New Jersey. He has over 22 years of experience in the pharmaceutical and biotech industries having spent the last 12 years in validation management.

Within these industries he has held responsible positions in quality control, quality assurance and manufacturing as well as validation. In addition to validation Mr. Flanigan's department is responsible for providing CGMP consulting services to internal and external clients, developing and presenting CGMP training programs and conducting audits for regulatory compliance for laboratory's and manufacturing facilities.

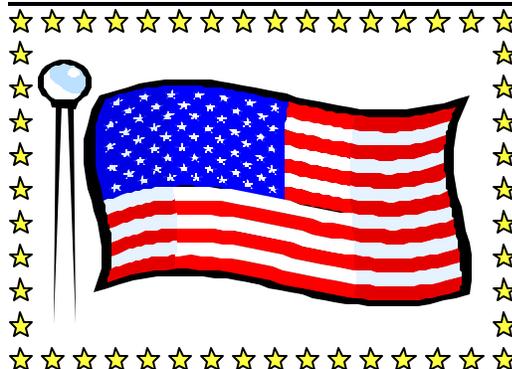
Mr. Flanigan is a member of ISPE and PDA, he has authored papers on CGMP for the Journal of CGMP Compliance, presented papers for ISPE, The Association of Membrane Separation Technology of Japan and the Institute of International Research. He chaired the Process Validation for the Pharmaceutical & Biotechnology Industries segment of the Validation Forum '99.

Mr. Flanigan is an instructor for the Ste-

(Continued on page 3)

Inside this issue:

Section Officer's Contact Information	2
Advertisement Rates	2
Special Insert – Fall Lecture Series	–
Meeting Location, Times & Costs	3
Professional Development	3



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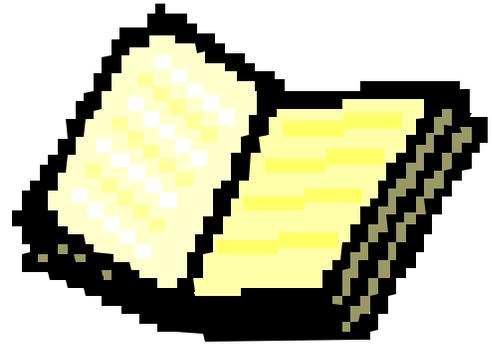
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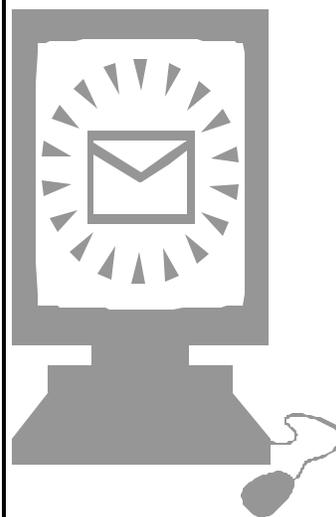
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Things are finally turning around for Chemical Engineers. The number of people looking has dropped from a high of 16 this summer to 6 people looking right now. The number of job leads is finally increasing. Some of it is in anticipation of new work, but at least businesses are thinking about new projects again.

I'd like to say that our local area is heating up, but many of the leads are from out of the area. New England and California are two areas that seem to have the most jobs. They also have the highest cost of living.

I am trying to maintain my list of local employers, but the marketplace is more dynamic than ever before. So many small companies are one time wonders, thrown together to serve a one time project, and never to be seen again when the project is finished.

Even in tough times, there are over 1000 chemical engineers working in the NJ, PA and DE area. I tend to get the bad news about people being laid off, because they are the ones that contact me. If things are different where you are working, I'd really like to hear from you, especially if your company is hiring. It would be great to start writing about the growth areas in chemical engineering again.

Until Next Month . . .

Mark DeLuca P.E (engineer@del-engineering.com)

(Continued from page 1)

vens Institute presenting CGMP and Validation related topics for Good Manufacturing Practice in Pharmaceutical Facilities Design as part of a Masters Certificate Program in Pharmaceutical Engineering. He received his BS in Public Health from the University of Massachusetts and his MBA from James Madison University.

SEE BELOW FOR TIMES

The meetings will be held at Princeton University with dinner at the Prospect House & the talk at the Friend Engineering Center - Room 108.

This will require a leisurely 5 minute walk between dinner and the presentation. Be prepared for all weather conditions.

Call Amanda Meyer at 609 258-4572 or email at (ameyer@princeton.edu) for dinner reservations.

Social hour.....5:30 - 6:00 PM
Dinner.....6:00 - 7:30 PM
Presentation.....7:30 - 9:00 PM

Cost: Members & Guests.....\$20
Unemployed & Retired....\$10
Students w/ ID.....\$10

No cost if coming for the speaker only.

Cash or check made out to Central Jersey AIChE will be collected before dinner.

For Directions to the University go to <http://www.princeton.edu/cgi/map> or look under Travel and Weather on the Princeton University main website and you can find directions to Princeton and a detailed campus map. Or call 609 258-2222 for general directions to Princeton University.

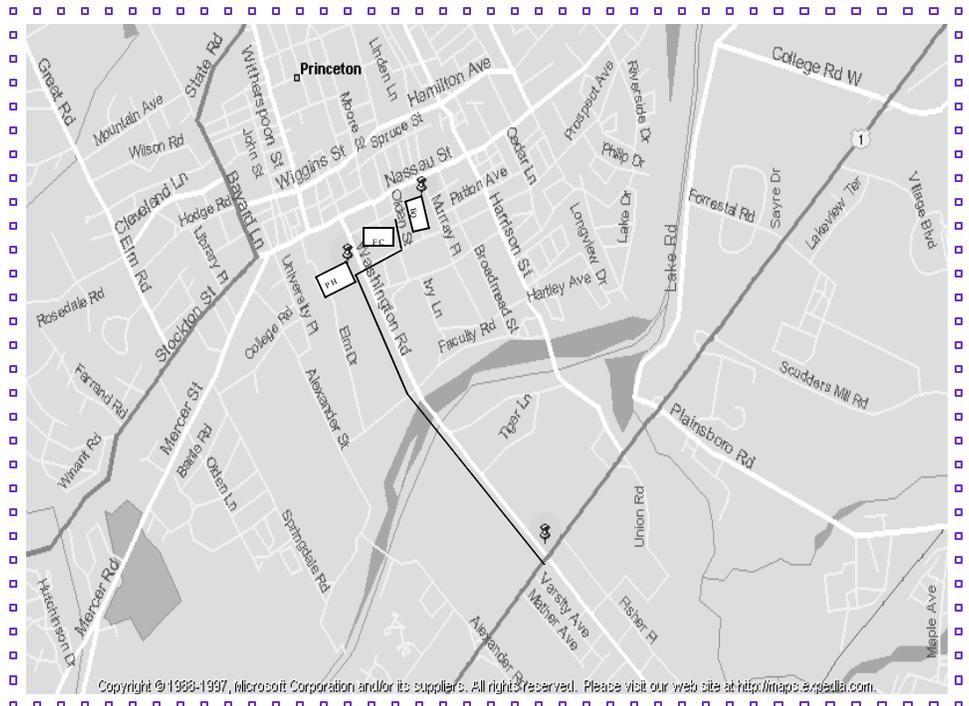
DIRECTIONS to PRINCETON UNIVERSITY

Directions to Engineering Quadrangle/Friend Center:

Take Washington Street (Rt 571) West into Princeton from Rt 1 South or Rt 1 North. At the second light make right turn onto Prospect Street. Continue to the first street on left and turn onto Olden Street. The Engineering Quadrangle will be on your right and the Friend Center on your left behind the building that fronts onto Olden. Parking available on the street along Prospect Street, William Street, Olden Street, and at night in the University Parking lots in back of the Engineering Quadrangle or on William Street. If you cannot make it to dinner and wish to join us afterwards, remember to ask a student for the building if you cannot find it easily.

To get to Prospect House:

There is NO parking available in front of Prospect House which is in the center of campus. Park near the E-Quad and walk to Prospect House. Walk east on Olden Street (away from Rt 27) and walk south on Prospect Street to the light at Washington Road (Rt 571). Cross Washington Road and proceed through the arch into the main part of campus. After going through the arch you will be facing the Music Building and Architecture Buildings. Prospect House is directly in back of the Music Building (on left). Continue straight on the walk between the two buildings and you will get to the front entrance of Prospect House just beyond the pavement circle & grass center.



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*AICHE Newsletter Editor
David Marabello*

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