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-
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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
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No cost if coming for the speaker only.

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

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(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.

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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:
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