Boston Area Chapter

# Boston Area Chapter Newsletter

June 2003 Volume XIII, Number 4

## President's Message

How do you like the new look of our newsletter? Dave Novak and the rest of the Communications Committee have been working very hard to improve the Boston Area Chapter's newsletter. They have beefed up the technical articles, increased the frequency, and added the color cover. Hopefully, you agree that all of these changes are for the better. For those of you who are always on the go, we also are considering an electronic distribution. As always we appreciate your input into how we can improve our service. Speaking of changes, please check out the new look to our Web site: http://www.ispe.org/boston/.

I hope everyone is enjoying his or her summer vacation. This summer is a busy one for our Chapter. On Tuesday August 12, we will hold the Chapter's first ever golf tournament. The Social Committee has put in a lot of effort selecting the location and organizing the event. I expect it to be a big success, and become an annual event. This year's tournament will be held at the Cyprian Keyes Golf Club in Boylston, MA. Here in the Boston area, the summers come and go all too quickly. Stay tuned for an end of summer social sometime in September.

September marks the start of a new program year. The program committee is building on last year's success, and launching a new exciting season. Our first program will be on September 25 at the Sheraton Needham Hotel. The topic will be disposable technology. The Program Committee also is looking into new ways to better serve our members. One way is to reach members who find it difficult to travel to the Boston area. To address this concern, we are planning commuter programs. These programs would be offered at a remote location.Two areas under consideration are New Hampshire and Cape Code. Another way to reach members who cannot travel to our meetings is to use Web technology to offer members an opportunity to watch the presentations remotely. Stay tuned for the details.

In closing, this is a good time to start reflecting on my year as President of the Boston Area Chapter. I feel that the Board of Directors has done an excellent job running the Chapter. I'm especially grateful to all the members who volunteered their time this past year. By getting more volunteers involved, we have been able to share the workload and come up with new and innovative services. For all those volunteers who served the Chapter this year, thank you for your efforts. For all of those volunteers who offered their services, but were not given the opportunity to help, thank for your patience. You are still on our list and we will contact you.

*Joe Musiak*

## ISPE Plant Tour of Wyeth BioPharma

On May 1, 2003, Wyeth BioPharma in Andover hosted the monthly ISPE Boston Area Chapter meeting, which featured presentations given by Scott Harrison, Greg Spotts, and Pat Perfetto.

Scott Harrison, Director of Development Production Operations, reported the status of the Andover Development Facility (ADF). He communicated that the expansion will lead to increased flexibility with process development and scale-up of clinical drug substances. The ADF project will result in the optimization of process design/operations.

Greg Spotts, Manager of Systems Engineering, presented an automation overview in regards to ADF as well as the new commercialization suites, Suites E/F. He provided a historical account of the technological advances associated with the automation systems onsite. He also highlighted the challenges and accomplishments of using high-reliability infrastructure, redundancy, and back up systems to increase the quality of the product.

Pat Perfetto, Manager of Quality Assurance Technical Support, summarized the validation approach used throughout the ADF and E/F projects. He stressed Wyeth's efforts to comply with FDA and EU requirements for clinical pharmaceutical drug products.

*continued on page 7.*

*Tour group eagerly awaiting to see the utilities.*

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# The Life Cycle of a Consent Decree

*Mark A. Lynch, Senior Compliance Consultant, KMI*

## Introduction

Consent Decrees of Permanent Injunction are used by the FDA for companies with continuing GMP problems. The process that a company goes through to remove or prevent a Decree has become relatively standard.

## Recognition

An important step in the life cycle is recognizing that your company may be on the FDA's radar screen for a Consent Decree. If top management recognizes this risk early, then there is a greater chance that actions taken can prevent it. For example, a company may decide to cease manufacturing the problematic product or product line. In order to be able to recognize the symptoms, a company must have a comprehensive corporate compliance measurement mechanism operated by an effective Quality Organization. In addition to monitoring FDA Form 483s, company response correspondence, and FDA Warning Letters, the mechanism should capture informal communications with Agency officials at the District and Center levels about scheduling preapproval inspections, government contracts, applications and supplements, and other relevant intelligence. Also, you should understand that silence (the reluctance to meet to discuss an issue) from Agency officials also is a signal.

## Initiation

Discussion with an experienced Food and Drug law firm is essential because a consent decree will require a multi-year effort and the Decree will be in effect for the duration. If there are statutory or procedural errors that you believe the Agency made, it is worth considering litigation. However, companies must consider the effect that litigation might have on their business, partners, customers, and stockholders.

Once you have decided entry into the Consent Decree is inevitable, there is still an opportunity to have your experienced legal counsel negotiate language that is favorable to the company. For example, the Agency may agree to exclude orphan drugs, or medically necessary drugs in short supply from some of the terms. Also, the decree language may identify only a few specific GMP systems and sites that need to be repaired. An experienced counsel will negotiate the most favorable terms possible.

## Commitment to Organizational Culture Change

Top corporate management support is essential. The FDA expects to see involvement and communication from a key corporate executive. Also, regular communication by a corporate executive to impacted personnel is essential to convince them it is necessary to change the organizational culture and to assure them that progress is being made.

## Plan

A management structure will need to be formed and key personnel made responsible for forming plans, directing daily activities, solving problems, and reporting progress to management and to the FDA. Frequently, this is a multi-layered structure with a Task Group reporting to an Executive Committee or Steering Committee. The Executive Committee frequently includes a representative from the outside counsel, and a third party GMP regulatory consultant company as well as necessary corporate officials. Personnel may need to be reassigned. Plan to perform the activities required by the Decree with an ultimate objective of vacating it in the shortest possible time.

A Comprehensive Corrective Action Plan must be developed, updated, and provided to the FDA at requested intervals. Management should consider information systems availability to house this information and the efficiency of any necessary interface with other company systems (deviations, change control). Planning should include FDA communication and reporting activities with the goals of demonstrating top executive involvement and building a rapport and level of confidence between the local FDA district and company personnel.

Plan to address large and difficult issues first. Plan to address any personnel issues that may be detrimental to the effort. Decide on and publish the process that will be used to track and document corrections.

## Complying with the Decree Provisions

The FDA communications and the Consent Decree will identify systems to address. These communications also will suggest the deficiencies may not be all-inclusive. Therefore, it is important to assure that all the important deficiencies, including information from internal audits and customer audits, are collected in the beginning of the effort. This usually involves comprehensive reassessment of GMP systems, areas, and issues identified in FDA inspections and specifically mentioned in the Consent Decree by an expert GMP consultant. You should consider if the same expert consultant company or personnel should perform initial assessments and help with corrective activities as those who will perform the surrogate FDA assessment under the terms of the Consent Decree. All of the collected issues should be identified in the Comprehensive Corrective Action Plan.

One of the dilemmas will be how to keep doing business and have key personnel involved in effective change at the same time. Also, if expert GMP consultants are helping with corrections, the efficiency of information exchange is extremely important. It is important to address inefficient processes and large physical changes early. Some issues that require special consideration are: start-up protocols for classified areas; new equipment purchase, delivery, and installation; revalidation/ requalification; regulatory filings required for A/NDA product changes; and training.

Some companies elect to use a third party GMP consultant to verify changes are effective in solving the identified problems. They do this because they recognize there may be institutional confusion about what was done when compared to what the original problem was.

## Communication

It is essential to plan, assign personnel, rehearse, and document all communications, particularly those reporting plans and progress to the FDA District(s) and Center(s). A key corporate official and task group representatives should deliver the initial Corrective Action Plan. You should plan to include legal counsel and key consultants who can answer questions about qualifications, methods, and plans for performing Consent Decree audits, as well as personnel assigned to take notes and observe behaviors. Status reports should be delivered by the method agreed upon with the FDA District Office, but meetings should be conducted to assure activities are explained and feedback is received. It will be necessary to continue to communicate and coordinate the timing of needed FDA inspection to measure progress under the Consent Decree or conduct other inspections. It is important for the company to get FDA agreement on the method to be used to convey auditors' recommendations or concurrence with the company's corrective action plan if this is not clear in the Consent Decree.

*continued on page 5.*

# The Life Cycle of a Consent Decree

*continued from page 3.*

It is equally important to report progress during a Consent Decree to company personnel, parent corporations, board of directors, key customers and partners, stockholders, and the public.

## Expert Assessment

It is essential to invest in sufficient planning. Ideally, this should include a face-to-face meeting with a prepared agenda for company representatives, audit team and management, company liaison, and legal counsel. Any unique methodologies required by the Consent Decree or other limitations should be discussed to assure understanding. The ground rules, arrangements, and contacts for the auditors while onsite should be discussed in detail. The host company's expectations for copies of audit plans, preview of documents, auditor safety, security, and discussion of issues at conclusion should be addressed. Planning for audit activities should assure minimal disruption of normal operations. The audit should be managed similar to an FDA inspection except that the host company should assure auditors completely understand important issues. The company should be able to identify all records requested and reviewed during the audits, all discussions with personnel, and all areas visited. Observations should be discussed and a process that is agreed upon before the audit begins should resolve any disputes. Discussion of observations should take place before auditors leave the premises. The method for the auditors to obtain clarification after leaving the site should be identified. The entire audit preparation, conduct, report drafting, editing, and delivery with corrective action plan should be mapped to assure it meets the Consent Decree or District timeframe. The Consent Decree usually requires for the expert consultant to make some statement about the state of compliance of the firm as determined by the audit. The company, expert consultant, and the FDA should agree on a mechanism to begin formulation of corrective actions in response to the audit findings as soon as possible. It may even be possible to begin this during the audit if the audit process is lengthy.

Deliver the audit report and corrective action plan to the FDA on time or ahead of schedule. Either at the time of delivery or afterwards meet with the District and Center personnel face-to-face in order to clarify issues and ask for honest feedback. It is essential to have the correct team present, rehearse any presentations, decide who will respond, and document all discussions and decisions.

It is a good idea to debrief with the GMP expert consultant in order to learn what worked and what needs improvement before the next annual audit.

## Continue Corrections

The items identified by the audit should be incorporated into the comprehensive corrective action plan and assure that the commitments made to the FDA are either met or the reason they were not met is communicated to the Agency.

Some companies retain GMP consultants to perform a correction verification function. This is to assure that what was done completely addresses the issue(s) initially identified. If this is undertaken, then there must be an efficient exchange of information between the consultant group and the company's subject matter experts. Also, the standard that the consultant is assuring compliance with must be carefully defined. It is essential that this process be carefully designed to assure the intended result or deliverable.

## Plan Next Cycle

Based on the results of the first year's audit, comments by the FDA, debriefing of the audit and liaison team plans can be made for year two.

## Petition to Vacate

Based on a history of consistent compliance, the company will direct their counsel to move for vacation of the Consent Decree. The company should petition the District Office with evidence of their compliance record. The FDA's Regulatory Procedures Manual (RPM) states "*FDA has a general rule that it will not even consider dismissal until the firm has operated in compliance continuously for at least three years."* The RPM also advises that "*...FDA does not usually initiate dismissal of an injunction. If dismissal has been requested by the defendants, the district should prepare a recommendation for action on the dismissal. A long violative history or lack of cooperation by the defendant will justify a further extension of the Decree."* In the current environment, any evidence of recidivism (being in and out of compliance) would be used by the FDA as a reason to deny the company's petition and keep the consent decree in place.



## FDA Commissioner to Speak at 2003 ISPE Annual Meeting

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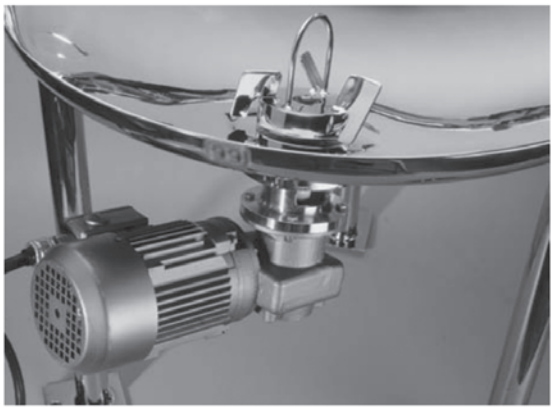

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## ISPE Plant Tour of Wyeth BioPharma

*continued from page 1.*

*Tour attendees viewing process equipment.*

Upon completion of the presentations, two tours were conducted by enthusiastic and knowledgable Wyeth employees. The "hardhat" tour explored the utilities throughout ADF. The "bootie and bouffant" tour provided an overview of the ADF processing infrastructure.

In addition to the valuable information communicated at this meeting, the event also was an excellent networking opportunity. It recognized the engineering marvels that have occurred at the Wyeth BioPharma site in Andover.

*By Christine Lindberg and Monique Sprueill, Wyeth BioPharma*

# ISPE Boston Area Chapter Programs Committee

The Programs Committee has been working diligently to offer seminars of interest to the general membership. Below is a tentative schedule of main programs for our upcoming program season. A tentative schedule for the new "Commuter Series" will follow. The "Commuter Series" will offer a few programs at satellite locations North, South, and West of Boston.

| | |
|---|---|
| **September 25, 2003** | **Disposable Technology** |
| **October 28, 2003** | **Part 11 - What's New?** |
| **January 8, 2004** | **Filtration Chromatography, Viral or Mycoplasma Removal** |
| **February 18, 2004** | **Regulations and Drug Development** |
| **March 18, 2004** | **Process Analytic Technology (PAT)/Risk Analysis** |
| **May 18, 2004** | **Plant, Network Security, or Intellectual Property** |

Please be advised that the schedule or topic is subject to change.

# ISPE Members Spotlight

## Hank Moes

***What influenced your interest in pursuing a career in biotech/ pharmaceutical industry?***
I received a job offer from E.R. Squibb & Sons (now Bristol-Myers Squibb) and stayed there for 30 years.

***How long have you been a member of ISPE?***
16 years

***What do you like most about ISPE?***
Interaction with people at the local and national level. It is a great networking opportunity.

***What advice do you have for new members?***
Be as active as possible. Go to a national meeting. Support and get involved with the local chapter.

***What firm do you represent?***
I consult for Arion Water, Inc. We are high purity water consultants for the pharmaceutical and other industries.

***What do you see for our industry in the next five years?***
I believe that the there will be continued consolidation in the biopharmaceutical sector. Large companies will buy out the more successful smaller entities. Emphasis on small molecules and contract manufacturing will continue to expand. Growth in the industry will pick up from the present lull.

***Favorite Pharmaceutical Term or Process?***
We didn't get any 483's.

***Least Favorite Pharmaceutical Term or Process?***
The FDA will be in tomorrow.

***If you could have three Scientists (living or deceased) visit for dinner, who would they be?***
Albert Einstein, Alexander Fleming, Bob Langer (M.I.T.)

***What is your most memorable moment of ISPE?***
Our first Boston Area steering committee meeting in Charlestown in 1990. It got us started.

***Anything else you would like to add?***
Being involved with ISPE is fun and the most fun is the Annual Meeting. In second place is our local Product Show.

# NEWSBRIEFS IN BIOTECHNOLOGY

### Genentech's Avastin Extends Life

Avastin has been found to extend the lives of colon cancer patients by slowing the growth of tumors.
(source: **Reuters,** May 19, 2003)

### Viragen Files Patent Application For Drug To Target SARS

This involves the use of the "natural human leukocyte-derived alpha interferon" to treat and prevent the spread of SARS.
(source: **Viragen, Inc.,** May 20, 2003)

### NOMOS Corporation: Image Sync (TM) Real Time Imaging/ Positioning Technology

This technology can be used to detect the location of cancer cells in real time prior to radiation therapy treatments. This will help increase the accuracy of targeting these cells during treatment.
(source: **NOMOS Corp.,** May 20, 2003)

### Infectech's Mycobacterial Identification Technique Found to be Faster Than Traditional Methods in German Trial

Identification of atypical Mycobacteria can be achieved up to 42% faster by using the Infectech method.
(source: **Infectech, Inc.,** May 21, 2003)

### Cambridge Scientific Patents Increase Bone Repair Product Line

This company has acquired new patents for products, which help prevent problems associated with spine fusion devices.
(source: **Cambridge Scientific, Inc.,** May 21, 2003)

*Monique Sprueill*

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# Regulatory Highlights

## FDA and Lincoln Technologies, Inc. to Collaborate on Developing Tools for Safety Data Mining

The FDA has established a Cooperative Research and Development Agreement (CRADA) with Lincoln Technologies, Inc. The purpose of this partnership is to use data mining to enhance the FDA's ability to monitor the safety of drugs, biologics, and vaccines after they have been approved for use.
(*Source: FDA Web site, May 1, 2003*).

## FDA Issues Final Two Proposed Food Safety Regulations

The FDA has published the final two food safety proposed regulations required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which gave the FDA new authority to protect the nation's food supply. These two proposals deal with establishing and maintaining records among food firms, and the administrative detention of foods that may pose a risk to public health.
(*Source: FDA Web site, May 6, 2003*).

## FDA to inform public regarding status of postmarketing studies

The FDA plans to inform the public about the status of manufacturers' commitments to carry out further clinical studies following the FDA's approval of certain drugs and biological products. The publication of FDA's first annual *Federal Register (FR)* report on these postmarketing studies covers commitments that are required by the FDA as well as those voluntarily accepted by the manufacturers. In addition to the *FR* report, the FDA is posting a searchable database with most of the same information on its Web site.
(*Source: FDA Web site, May 22, 2003*).

## FDA Approvals

- Iressa (gefitinib) tablets, a single agent treatment for patients with advanced non-small cell lung cancer (NSCLC). Its manufacturer, AstraZeneca LP, will market Iressa.
  (*Source: FDA Web site, May 5, 2003*)

- Velcade (bortezomib) injection, a new treatment for multiple myeloma, a cancer of the bone marrow. Velcade is distributed and marketed by Millennium Pharmaceuticals, Inc.
  (*Source: FDA Web site, May 13, 2003*)

- Gleevec (imatinib mesylate) tablets, a treatment for pediatric patients with Philadelphia chromosome positive(Ph+)chronic myeloid leukemia (CML) in chronic phase. Novartis Pharma AG manufactures Gleevec for Novartis Pharmaceuticals Corporation.
  (*Source: FDA Web site, May 20, 2003*)

*Christine Lindberg,*

# New Members

Jiwan Adhikari, Software Engineer, Millipore Corporation
Raymond L. Boudreau, Controls Engineer, Lonza Biologics
John T. Bratz, Associate Director, Wyeth Biopharma
Janice M. Brousseau, Lonza Biologics
Alfredo Canhoto, Validation Engineer IV, Wyeth BioPharma
Gregg A. Conboy, Project Manager, Erland Construction Inc.
Alberto Correia, VP, VelQuest Corporation
Richard C. Crispin, Mgr, QA & Training, Fresenius Medical Care
Ronald J. Duft
Robert J. Edgerly, Process Engineer, Tuchenhagen
Aiqi Fang, Fermentation Dev Assoc, Acambis
Adam S. Goldstein, RSO Manager Engineering, Amgen Inc.
Richard G. Gonthier, Application Engineer, Baumann Inc.
Richard M. Harty, Quality Assurance Engineer, Cytyc Corp
Yasunori Hashimura, Graduate Researcher, Massachusetts Institute of Technology
Philip M. Henry, Chemical Engineer, New England Controls Inc.
Leon M. Heredia, Manager, Stelex-TVG
Christopher M. Hogan, Controls Engineer, Lonza Biologics
Lindsey S. Humphrey, Director of Sales, Bematek Systems, Inc.
William J. Kessler, Principal Research Scientist, Physical
Jonathan K. Lyna, Process Engineer, Integrated Process Technologies
Laurie Masiello, President, Masy Systems Inc
Stephen Masiello, Project Manager, Masy Systems Inc.
Kevin W. McDonald, Process Development, Millennium Pharmaceuticals
Sean M. McGrath, Viral Fermentation Assoc., Acambis
Andrew L. McKenzie, Process Engineer, Abbott Bioresearch Center
Eduardas V. Meilus, Technical Director, Industrial Analytical Services, Inc.
Deborah Meshulam, Head, Process Development, ImmunoGen Inc.
Richard Monroe, President, Pak Tech Inc.
David J. Page, Project Executive, Turner Construction Co.
Heather M. Poirier, QA Product Disposition Specialist, Biogen Inc.
Steven G. Richter, Microtest Laboratories
John J. Romano, Mgr, Ind Plastics Div., F W Webb Co.
Jose E. Rosales, Manufacturing Associate, Acambis Inc.
Bradford Ross, Project Manager, Invensys Validation Technologies
Robert Ryland, Manager of Mftg, Altus Biologics Inc.
Barbara N. Saltz, QA Documentation Specialist, EMD Pharmaceuticals Inc.
Andrew J. Santo, Project Manager, Millipore
Richard Sbordone, Project Manager, Bovis Lend Lease
William E. Smith, Business Process Engineer, Wyeth BioPharma
Joe Sousa, District Manager, Rockwell Automation
Fred A. Sowa, FASPAK Machinery Corp.
Dean Takahata, Project Manager, Invensys
John Vandenberg, Automation Engineer, Amgen Inc.
Marc A. Vandenbulcke, Regional Manager, Document Control Systems
Keith W. Whited, PE, Senior Engineer, Process Facilities Inc.
Sasha A. Zbitnoff, Compliance Manager, Wyeth BioPharma
Mark Zemler, Assoc Director, QA, EMD Pharmaceuticals

**Student Members**
Matthew J. Nelson Student University of Massachusetts at Lowell
Daryl P. St. Laurent, Grad Student, M.I.T.

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