Volume XXXVII, No.5

PDA Letter

May 2001

A Monthly Communication for the Members of PDA—
An International Association for Pharmaceutical Science and Technology

FDA Reported on Biological Product Deviations in Manufacturing at PDA Spring Conference, page 13

Process Validation for Manufacturing of Biologics and Biotechnology Products

Berlin, Germany, September 6–7, 2001

PDA and the International Association for Biologicals (IABs) will present a conference on **Process Validation for Biologics and Biotechnology Products: A State-of-the-Art Perspective** at the Berlin Hilton Hotel, Berlin, Germany, September 6–7, 2001.

The purpose of the conference is to address the complex issues associated with the science and technology involved with manufacturing process validation and the regulatory expectations of FDA and European regulatory agencies. The conference will provide a public forum to discuss appropriate practices with various regulatory agencies and international representatives from the pharmaceutical and biotechnology industries. In 2000, a PDA/FDA co-sponsored conference on Validation of Manufacturing Processes for Biologics exposed an authentic need by FDA and the industry for a practical framework to address process validation in biologics manufacturing. The Berlin conference will facilitate dialogue on these issues between industry and regulators.

Discussions will focus on appropriate practices and will serve as a good basis on which to connect issues of comparability and process validation. PDA and IABs will work in conjunction with regulatory agencies to develop scientifically and technically sound approaches to reuse and cleaning.

The program for this meeting is currently in development. IABs is planning to provide proceedings for the conference to attendees as part of meeting registration. For up-to-date information, visit PDA's Web site at www.pda.org.

Program Committee Co-Chairs:

Vincent Anicetti, Ph.D., Genentech, Inc.

Brendan P. Hughes, GlaxoSmithKline, UK ■

—Leslie Zeck

PDA Attends FDA Trade Association Meeting

PDA representatives attended the FDA Office of Pharmaceutical Sciences (OPS) meeting for trade associations on April 6th.

The following points summarize the information presented by FDA.

Common Technical Document

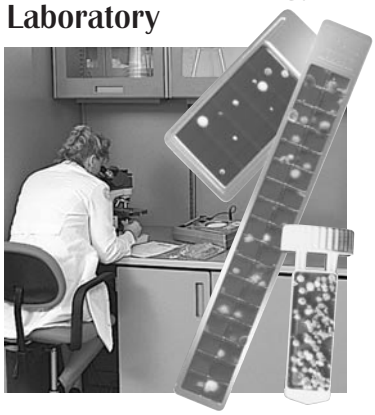
- The FDA is still working on implementing the Common Technical Document (CTD) as the "blueprint" for New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs).
- The CTD was produced by the International Council on Harmonization (ICH) in order to have a common structure for drug applications in the US, Europe and Japan. July 2001 is FDA's target date for voluntary use of the CTD by industry. The FDA is considering issuing a waiver of current submission guidances that are superceded when the CTD is used.
- A general considerations guidance will be issued describing what the FDA expects in future submissions.
- In Europe and Japan, use of the CTD format is mandatory in July 2002.

continued on page 18

Biotest

Surface Sampling
Particle Counting
Laboratory Services
Air Sampling
Rapid Hygiene

Contract Microbiology Laboratory



Biotest Diagnostics Corporation has a certified microbiology laboratory available providing quantitative and qualitative analysis of your environmental samples.

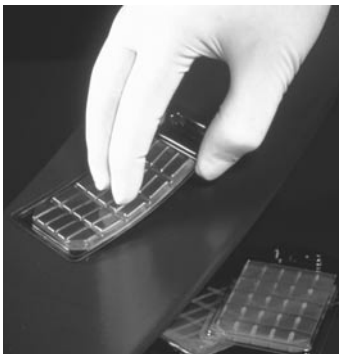
- Microbial identifications of bacteria, yeast and mold to genus/species
- 10 day turnaround time
- "Perfect Score" participant in the EMPAT Program
- Confidential reports for total plate/strip counts and cfu/volume of air
- Consultation with expert Microbiologists on staff
- Free shipping when using Biotest test slides and strips

APC Plus

Airborne Particle Counter

Convenient, economical and entirely portable particle counter detects the presence of airborne contaminants. Accurately and simultaneously measures four particle size ranges: 0.3, 0.5, 1.0 and 5.0 µm. Can be used to monitor controlled environments where particulate contamination is of concern.

- User friendly control panel
- Programmable count and hold times
- Meets JIS for counting efficiency
- Two concentration modes– particles/ft^3 and particles/liter
- Temperature and RH sensors built-in
- Easy to use software included
- Remote and facility monitoring software available



HYCON® Contact Slides

Monitoring liquids and ambient air is not sufficient for most products and processes. Surface monitoring is a must and is recommended in HACCP, ISO and USP guidelines. HYCON® Contact Slides detect surface viable contamination that may adversely affect your product or process.

- Flexible self-contained culture-medium-coated slides ensure surface contact
- Excellent for irregular surfaces
- Provides a 25 cm^2 contact surface
- Various agar media available

Biotest HYCON® RCS High Flow Microbial Air Sampler

The RCS High Flow Microbial Air Sampler allows you to monitor contaminants in any area where reproducible results are necessary. The RCS High Flow monitors air quality—

Faster—the RCS High Flow has an air flow rate of 100 liters per minute, reducing sampling time to 10 minutes for 1 m^3.

Easier—the upgraded infrared remote control with a newly designed keyboard panel and integrated display transmits and receives data from the instrument up to a distance of 10 m.

Better—the rotor, protection cap, and air direction ring are all detachable, easy to clean and autoclavable, allowing less margin for contamination when sampling in any environment.

The instrument is portable and precise and with the use of Biotest HYCON® agar media strips, results are always reproducible. Whether you are monitoring the microbiological quality of ambient air, testing your air handling equipment, or verifying the results of decontamination efforts, you'll find the RCS High Flow to be an effective, reliable sampling device.

Call us at 800.522.0090 for more information.

CE

Biotest DIN EN ISO 9001 HYCON

Biotest

BIOTEST DIAGNOSTICS CORPORATION
66 Ford Road, Suite 131, Denville, New Jersey 07834
Phone: 973.625.1300 • 800.522.0090 • Fax: 973.625.9454
www.BiotestUSA.com

PDA
7500 Old Georgetown Road, Suite 620
Bethesda, MD 20814 USA
Tel: (301) 986-0293 Fax: (301) 986-0296
E-mail: *info@pda.org*
www.pda.org

PDA Training & Research Institute
c/o UMBC Technology Center
1450 S. Rolling Road
Baltimore, MD 21227 USA
Tel: (410) 455-5800 Fax: (410) 455-5802

PDA Europe Office
Postfach 620
CH-4144 Arlesheim, Switzerland
Tel: +41 61 703 1688 Fax: +41 61 703 1689
E-mail: *lyda@pda.org*

The ***PDA Letter*** is published monthly by PDA, exclusively for PDA members. Subscriptions are not available.

PDA President
Edmund M. Fry

Director, Communications & Marketing
Linda M. Williams

Editor/Web Editor
Joseph G. Bury

Manager, Publications & Production
Janet Raysick

PDA Letter

Important Dates...

Call for Papers Deadlines

- **June 15th – PDA/FDA Viral Clearance Forum**
- **June 15th – 2001 PDA Annual Meeting – Compliance: Challenges and Pragmatic Solutions**
- **June 29th – 2002 PDA International Congress (Basel) – Adding Value to the Pharmaceutical Industry**

IN THIS ISSUE...

USP UPDATE

by Roger Dabbah, Ph.D., USP

Dr. Eric Sheinin joined USP as Vice President, Information and Standards Development. Sheinin spent 30 years with FDA, most recently as Deputy Director for the Office of Pharmaceutical Science (CDER) and has served as an elected member of the USP Committee of Revision for a 15-year period.

Starting in 2002, USP plans to publish USP-NF annually, with one Supplement published halfway in the year. A list of proposed omissions from USP 25-NF 20 is published in the May–June 2001 Pharmacopeial Forum and readers are asked to check the list and let USP know if a specific monograph needs to be retained for a valid reason. Notification can be made via e-mail at gla@usp.org, or by Fax at (301) 816-8373 to the attention of Gerry Anderson.

The May–June 2001 PF has the Tenth Interim Revision Announcement to USP 24 and to NF 19. This IRA, unless otherwise indicated, is Official June 1, 2001. It includes changes to the following monographs: Cyclobenzaprine Hydrochloride Tablets; Cyclosporine; Cyproheptadine Hydrochloride Tablets; Fludeoxyglucose F 18 Injection; Sodium Fluoride F 18 Injection; Ammonia N 13 Injection; Water O 15 Injection; and Valine. Under Limit Tests, IRA for <281> Residue on Ignition is included. Also included is Chapter <823> Radiopharmaceutical For Positron Emission Tomography-Compounding. In the Nutritional Supplements section, the IRA includes changes to Calcium with Vitamin D Tablets, and Calcium and Vitamin D with Minerals Tablets.

In the In-Process section of the same PF, a number of monographs are listed for addition under Packaging and Storage of the statement "…and stored at controlled room temperature". Other monographs indicated that storage temperature will be at that recommended by the manufacturers or indicated on the label. New monographs proposed in this section are Bupropion Hydrochloride; Bupropion Hydrochloride Tablets; Clomipramine Hydrochloride; Clomipramine Hydrochloride Capsules; Dinoprost Tromethamine; Dinoprostone; Ferumoxides Injection; Iodixanol; Iodixanol Injection; Paclitaxel Injection; Verteporfin; Verteporfin for Injection; Technetium TC 99 mL Depreotide Injection. New NF monographs in that section includes Myristyl Alcohol; Magnesium Aluminometasilicate; and Magnesium Aluminosilicate.

The Harmonization section of PF (a new feature) includes the Official Inquiry Stage 4 for <905> Uniformity of Dosage Units. It also includes a Proposal Stage 3 for <231> Heavy Metals. The Pharmacopeial Previews section in the same PF includes a new USP monograph, Fluoxetine Tablets, and 2 NF monographs, Modified Starch and Pregelatinized Modified Starch. ■

International Calendar

2001

September 6–7, 2001
PDA/IABs Conference on Process Validation for Biologics and Biological Products
Hilton Berlin
Berlin, Germany

September 17–18, 2001
PDA Canada Chapter/A3P International Conference and Exhibition
Holiday Inn Montreal Midtown
Montreal, Quebec, Canada

2002

February 11–15, 2002
PDA International Congress, Courses and Exhibition
Basel Congress Center
Basel, Switzerland

Contact PDA or go to www.pda.org for additional details on PDA events

Are you challenged by the possibilities of changing the world with great care? Inspired by the opportunities of this challenge? Desire to be part of an innovative premier healthcare company that celebrates your successes as well as our own? Then, you have found it at Bayer. Right now, we have the following exceptional opportunities at our Biological Manufacturing Facilities in Clayton, North Carolina and in Berkeley, California. We are responsible for the discovery, production, and preclinical development of novel biopharmaceuticals that address highly unmet medical needs. These agents are developed together with the worldwide Bayer organization, offering you the opportunity to join a global team whose values are linked directly to our patients and to the lives of future generations.

Project Manager II (Clayton)

Manage the portfolio project management system compatible to internal and external partners to guarantee the expected disposition of specific protein intermediate projects. Requires a PhD or equivalent with 5+ years' relevant biological/pharmaceutical experience, including plasma/fractionation processes and various manufacturing processes.
Job Code PDAC0803

QA Product Line Manager (Raleigh)

Champion QA/QC for facilities upkeep and improvements with emphasis on environmental conditions. Establish microbiological standards for specifications and process validation requirements. **Job Code PDAC0882**

QA Principal/Senior Discrepancy Investigators (Clayton)

Administer the discrepancy management program to investigate discrepancies affecting the safety and integrity of biological products.
Job Code PDAC0921 for Principal position and PDAC0922 for Senior position

Senior QA Development Stability Scientist (Clayton)

Develop/implement stability programs and projects to ensure compliance with regulatory authorities, GMPs, ICH Stability Guidelines, and internal standards. **Job Code PDAC0994**

Director of Quality Control (Berkeley)

Direct QC administration at multi-site operations, including analytical testing and release, biological and chemical control, analytical investigations, and viral validation risk assessment for plasma-derived products. Requires an advanced degree in Chemistry and/or Microbiology and 8+ years' managerial experience in a biological/parenteral setting, including immunology, virology, physical inspection techniques, worldwide government regulations and GMPs.
Job Code PDAB1542

Directors of Quality Assurance (Berkeley and Clayton)

Direct QA administration/control for Berkeley plasma products, ensuring that QA units adhere to federal GMP and other worldwide regulatory requirements and that R&D clinical lots are manufactured according to GMP. Advanced knowledge in chemistry and/or microbiology, immunology, virology, and physical inspection techniques needed. **Job Code PDAB1338 for Berkeley position, PDAC1336 for Clayton position**

Vice President of Quality (Berkeley)

Manage all QA/QC functions at the Berkeley site in accordance with Pharmaceutical Division policies. Requires a PhD with 15+ years' managerial experience in a biological/parenteral setting. Advanced knowledge in chemistry and/or microbiology, immunology, virology, physical inspection techniques needed.
Job Code PDAB0000

Process Engineer — Filling & Packaging (Clayton)

Support the Filling (aseptic filling & freeze drying) and Packaging operations for the site, modifying these operations to optimize process efficiencies.
Job Code PDAC0914

Control Systems Engineer (Clayton)

Provide instrumentation, electrical and control system support for projects at the Clayton and Raleigh area sites; and coordinate standard development for instrumentation, documentation and revision control.
Job Code PDAC0888

Computer Validation (Clayton)

Write validation protocols, analyze data, prepare validation reports, and coordinate/maintain documentation for validation activities. Also support the validation of computerized systems site-wide. **Job Code PDAC0670**

Validation Specialist/Senior Validation Specialist (Clayton)

Develop and write validation protocols for equipment and utility systems, analyze data, prepare validation reports, and coordinate and maintain documentation for validation activities.
Job Code PDAC0783

For more information on these or other exciting opportunities within Bayer, please visit our website at www.founditatbayer.com

Please forward your resume or CV, referencing Job Code, to:
Bayer Corporation, Pharmaceutical Division
P.O. Box 3238
Scranton, PA 18505-0238

Fax: 1-888-805-7474
E-mail: bayerpharma@alexus.com

For direct consideration:
E-mail to kathleen.fleming.b@bayer.com

No agencies or phone calls please. For more information, please feel free to visit our web site at http://www.founditatbayer.com. Bayer offers a competitive salary plus comprehensive benefits package which take effect day one of employment. We also pay 100% of tuition reimbursement. We are part of the Bayer Corporation, a $32 billion international diversified organization & one of the most broadly based healthcare companies in the US and a leading manufacturer of plasma derived therapies in the world. We are an equal opportunity employer committed to diversity in the workplace.

Join us in changing the world with great care.

Bayer

Pharmaceutical Division

TR-32 UPDATE

by Harvey Greenawalt, Audit Repository Center

Industry participation in the PDA Process for Auditing of Suppliers Providing Computer Products and Services for the Regulated Pharmaceutical Operations, defined in PDA Technical Report 32, continues to increase.

Since the issue of TR-32 in January of 2000, the inventory of available audits in PDA's licensed audit repository administered by Audit Repository Center (ARC) has grown at an average rate of one audit per month.

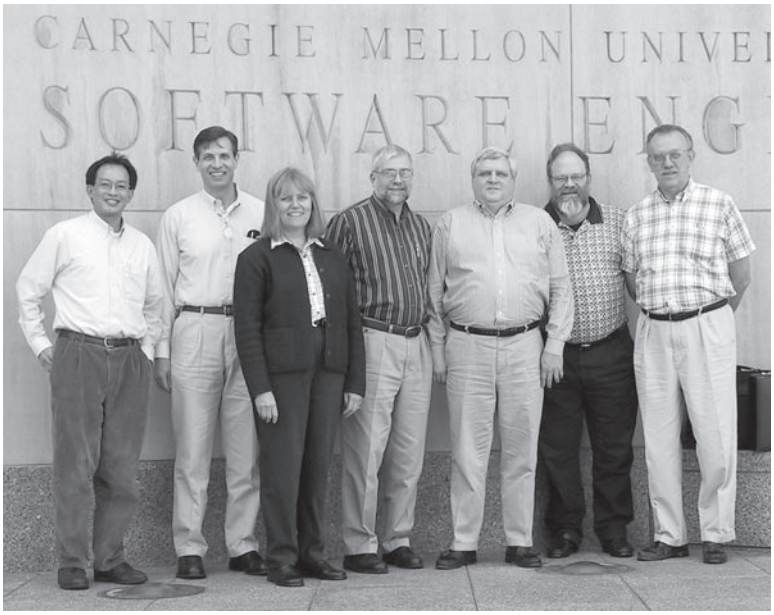
PDA and Software Engineering Institute Begin Collaboration

PDA and Carnegie Mellon, Software Engineering Institute, began their collaborative work arrangements on April 10–12 with two activities.

On April 10th Tricia Obendorf, SEI Technical Staff, Harvey Greenawalt, ARC President, and George Grigonis, Merck & Co., Inc., met to launch an SEI case study and technical report on PDA TR-32 as method for organizational appraisals in COTS Evaluation Activities and as a model for sharing objective information about supplier practices. The work effort here is planned as an SEI Technical Report, which the Institute will publish and make available to Department of Defense (DoD) sponsors and the software community. Also planned is a paper to be delivered at the International Conference on COTS-Based Software System, February 2002.

On April 11–12, industry representatives, ARC, and PDA-TRI participated in the first of three planned alpha reviews, with external affiliates, of a new two-day SEI tutorial on COTS Software Products Evaluation for Practitioners. The tutorial was the result of collaborative research and development agreement between the SEI and the National Research Council of Canada. The alpha review gave the SEI some practical insights into how our FDA regulated industry executes projects relying on COTS software products as well as some useful information regarding selection and technical integration issues associated with implementation of COTS assemblies. The information exchange on course content and exercises will help the SEI tune the tutorial before deployment to software industry.

Rick Rogers, PDA-TRI, connected with SEI in an effort to determine a way to make selected SEI COTS courseware available to the Pharmaceutical Industry through PDA-TRI. Talks are presently underway to evaluate the training possibilities that would support TR-32 implementation and COTS-Based System development and validation.



Industry representatives participating in work with SEI. Left to right. Rory Budihandojo, GlaxoSmithKline; Craig McGill, Abbott Laboratories; Chris Laiacona, BASF; George Grigonis, Merck & Co., Inc.; Harvey Greenawalt, Audit Repository Center; Warren Campbell, Private Consultant; and Ed Crosson, Aventis.

Membership

Four-major Pharmaceutical/Chemical, one Biotechnology Company and three Suppliers of computer products to the industry have become members of the Audit Repository since June of 2000.

In February of 2001 ARC entered into subscription agreements with three major suppliers of computer products and services to voluntarily place their audit data in the repository for distribution to the pharmaceutical industry.

Availability of Audits

Currently 39 audits are either available for distribution, in process or planned to be implemented within the next six months.

For more information about the audit repository visit ARC's Web site at www.auditcenter.com or www.pda.org.

Auditor Resources

Ninety-one auditors have been trained and qualified by PDA to date. Forty-eight percent of these auditors are from pharmaceutical industry companies, with seven percent coming from the European Union. Nine independent consulting firms have placed agreements in effect to provide qualified auditors to the industry.

Table 1.0 provides a summary of the audits that are currently available for distribution from the repository. ■

Table 1.0 Audits Currently Available in ARC

Supplier	Product
Accraply, Inc.	Label Applicators, Automatic Labeling Systems, & Custom Designed and Self Adhesive Material Application Systems
ActionPoint	Input Accel Document Imaging LIMS
Applied Biosystems	SQL*LIMS - Laboratory Information Management System including the QA Stability & Schedule Modules
Decision Management International, Inc. (DMI)	Regulus™ Document Authoring (DA) a member of the Regulus™ off-the-shelf solution set
Etrails.com, Inc.	Electronic Data Capture - EDC Electronic Patient Diaries - EPD Electronic Trail Management- ETM
Fanuc Robotics North America	Robotic Controllers & Communications
First Consulting Group, Inc.	Custom information based strategy software, operations improvements management and integration services
Infinity QS International (Lyle-Kearsley, Inc.)	Infinity QS Statistical Process Control Software
Merant, Inc.	PVCS Dimensions & PVCS Replicator Configuration Management Systems
Precision Solutions	Custom Development, SLE-Capture of check weight data Custom Software Programming
Qumas, Ltd. (Participating Supplier)	Qumas-Doc: Electronic Records Document Management Systems

Regulatory Briefs

From the *Federal Register* (FR), March 20, 2001 (Volume 66, Number 54): The Food and Drug Administration (FDA) is issuing this final guidance for the reduction of civil money penalties (CMPs) for small entities (penalty reduction guidance) as mandated by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Public Law 104-121) and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995).

Each agency regulating the activities of small entities shall establish a policy to provide for the reduction (and under appropriate circumstances for the waiver) of civil penalties for violations of a statutory or regulatory requirement by a small entity. Under appropriate circumstances, an agency may consider ability to pay in determining penalty assessments on small businesses.

Conditions and Exclusions—Subject to the requirements or limitations of other statutes, policies or programs established under this section shall contain conditions or exclusions that may include, but not be limited to:

1) Requiring the small entity to correct the violation within a reasonable correction period;
2) Limiting the applicability to violations discovered through participation by the small entity in a compliance assistance or audit program operated or supported by the agency or a State;
3) Excluding small entities that have been subject to multiple enforcement actions by the agency;
4) Excluding violations involving willful or criminal conduct;
5) Excluding violations that pose serious health, safety or environmental threats; and
6) Requiring a good faith effort to comply with the law.

The final guidance became effective on April 19, 2001 and can be found at the Office of Regulatory Affairs (ORA) home page at www.fda.gov/ora.

Address for written comment to FDA unless otherwise indicated:
Dockets Management Branch (HFA-305)
FDA
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

On March 29, 2001, the FDA Investigations Operations Manual (IOM) (the primary source of guidance regarding Agency policy and procedures for field investigators and inspectors) was updated. The IOM applies to all individuals who perform field investigational activities in support of the Agency's public mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations. Although the IOM is the primary source of policy, the specific information in this manual is supplemented, not superseded, by other manuals and field guidance documents. Recognizing that this manual may not cover all situations or variables arising from field operations, any significant departures from IOM established procedures must have the concurrence of district management with appropriate documentation as needed.

There are many changes and additions to the Year 2001 IOM. The FDA has modified the implementation of the medical device expansion pilot to make optional the notification of inspections outside the medical device area or as directed by a specific program. The agency has included new guidance on the preparation of inspection reports. This additional information is compatible with TURBO EIR, being piloted in multiple Districts.

Since December 1996, the IOM has been posted to ORA's Internet Home Page, http://www.fda.gov/ora. The entire IOM is available there, with all graphics included. Future updates to the IOM will be done periodically during the year to this online version. Hard copy publication will be printed yearly. In its role of protecting the public health, ORA developed a vision, a mission statement and specific core values. These are presented in the pages immediately following the "Foreword" to the IOM.

On March 27, 2001, the FDA Office of Regulatory Affairs Directory was updated. It contains the telephone numbers of personnel and the mailing addresses of the ORA Headquarters, the Field Directory, Field Monitors, Regional Offices and District Offices. The directory can be found at www.fda.gov/ora.

On February 9, 2001, the Center for Devices and Radiological Health (CDRH) issued the "CDRH Manual for the Good Guidance Practices (GGP) Regulations; Final Guidance for FDA Staff." The FDA GGP regulations went into effect on October 19, 2000 and describe the practices established by the FDA to assure the appropriate level of public participation in the development of FDA guidance documents. 21 CFR 10.115(1)(1) requires that all FDA employees involved in the development, issuance or application of guidance documents receive training on the FDA GGP regulations. The GGP regulations will be in 21 CFR 10.115 when the 2001 issue of the Code of Federal Regulations (CFR) is published. Until then, the GGP regulations are available in the *Federal Register* published on September 19, 2000 (65 FR 56468).

FDA's "Mad Cow" page has been updated with several new information sources. Go to http://www.fda.gov/oc/opacom/hottopics/bse.html.

In addition, Congressional Testimony by the FDA on Bovine Spongiform Encephalopathy (BSE) took place on April 4, 2001. Stephen Sundlof, DVM, Ph.D., Director, Center for Veterinary Medicine testified before the Committee on Commerce, Science and Transportation on measures by the Federal government to prevent bovine spongiform encephalopathy (BSE) or "Mad Cow Disease" from occurring in the United States. In his testimony, Sundlof outlined protective measures being enforced by the FDA and its sister public health service agencies. Working in conjunction with the Center for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the US De-

partment of Agriculture (USDA), the Customs Service and other Federal and State agencies, many protective measures have been introduced. The FDA currently has no evidence of BSE in the United States. Protective measures such as cattle feed restrictions, inspections, education and import controls are in place to prevent the introduction of BSE into the US. FDA also has taken steps to protect medical products (such as drugs, blood, vaccines, and medical devices) for human use. Since 1993, FDA has sent a number of letters to manufacturers of FDA-regulated products providing guidance on the use of bovine materials from countries affected by BSE and taken other actions.

The full text of Sundlof's testimony can be found at www.fda.gov/ola/2001/bse0401.html.

International Briefs

Health Canada's Therapeutic Products Programme (TPP) issued five final process validation guidance documents on March 1, 2001. The effective date for these guidances was May 1, 2001.

- Moist Heat Sterilization for Pharmaceuticals.
- Irradiation Sterilization for Pharmaceuticals.
- Gaseous Sterilization for Pharmaceuticals.
- Form-Fill-Seal for Drugs.
- Aseptic Processes for Pharmaceuticals.

These guidance documents can be found at the TPP Web site, http://www.hc-sc.ca.gc/hpb-dgps/therapeut.

In early March, the EMEA (The European Agency for the Evaluation of Medical Products) started the first evaluation visit of the FDA as part of the Mutual Recognition Agreement (MRA) process. The equivalence assessment will include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the agency's capabilities. The EMEA team will spend time with each FDA center and visit FDA field offices. The goal of the EMEA is to determine if there is "equivalence" of the regulatory systems of the United States and the European Community (EC). In the Sectoral Annex approved by the US and EC, the term "equivalence" means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. "Equivalence" does not require that the respective regulatory systems have identical procedures. The products covered in the initial phase of the MRA will be drugs for human or animal use, biological products for human use and active pharmaceutical ingredients. Human blood, human plasma, human tissues and organs, and veterinary immunologicals are excluded from the scope of the MRA . Human plasma derivatives (such as immunoglobulins and albumin), investigational new drugs, human radiopharmaceuticals and medical gases are also excluded from this phase of the MRA process. Their situation will be reconsidered at the end of the transition period. Products regulated by the Center for Biologics Evaluation and Research as devices are not covered under Sectoral Annex.

In the EC, the "qualified person" will be relieved of the responsibility for carrying out the controls required by the EC GMPs provided that these controls have been carried out in the US and that each batch or lot is accompanied by a batch certificate issued by the manufacturer. The batch certificate must be in accordance with the World Health Organization (WHO) certification scheme on the quality of medical products and must certify that the product complies with the requirements of the marketing authorization and is signed by the person responsible for releasing the batch.

Current projections indicate that the FDA will not complete their assessments of all the EU member states by the end of the assessment period (November 30, 2001).

For more information go to the EMEA Web site, www.emea.eu.int.

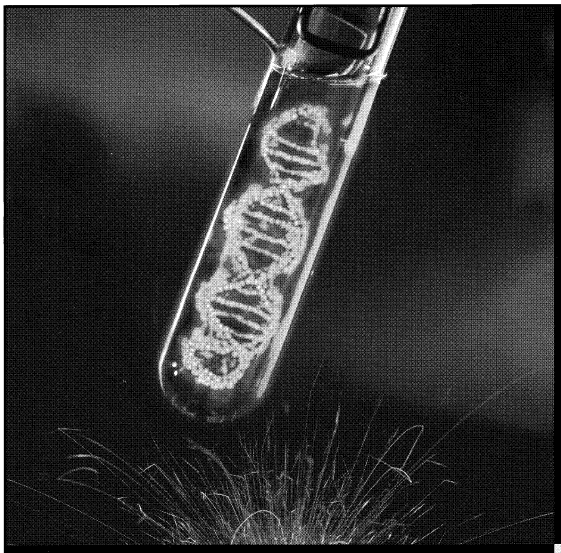
The Committee for Proprietary Medicinal Products (CPMP) adopted a Note For Guidance on In Use Stability Testing of Human Medicinal Products (Final) in February 2001.

The purpose of in use stability testing is to establish, where appropriate, the period of time where a multidose product can be used while retaining its quality within the accepted specifications once the container has been opened. Multidose containers which due to repeated opening and closing may pose a risk to the contents with regard to microbiological contamination, proliferation and/or chemical degradation once the closure system has been breached. The guidance offers examples of test storage conditions, test parameters, and a discussion of test design, data evaluation and labeling requirements.

This document was adopted by the CPMP in February 2001 and comes into effect in September 2001. The document number is CPMP/QWP/2934/99 and can be found on the EMEA (European Agency for the Evaluation of Medicinal Products) Web site, www.emea.eu.int.

The Committee for Proprietary Medicinal Products (CPMP) has adopted a Note for Guidance on Parametric Release (Final).

A medical product must comply with the requirements stated in the authorized specifications for release and shelf life. This does not mean that all tests in the specifications have to be carried out on the finished product before release. The manufacturer may obtain assurance that the product is of stipulated quality, i.e., meets its specifications, through a system called parametric release. This system is based on evidence of successful validation of the manufacturing process and review of the documentation from process monitoring carried out during the manufacturing process to provide the desired assurance of the quality of the product.



INITIATIVE SPARKS INITIATIVE.

Innovation works at Biogen. The creativity and ambition of our workplace sparks our teams to take responsibility, move on intelligent risks, and drive innovative decisions that are changing not only the science of medicine, but the lives of people with serious diseases. If you're ignited by taking initiative, you'll meet your match at Biogen.

www.biogen.com

BIOGEN®

DELIVERING ON THE PROMISE OF BIOTECHNOLOGY.

CONTRACT MANAGER, CLINICAL MANUFACTURING

You will directly manage contract manufacturing sites and projects and be responsible for developing/maintaining business relationships with contractors, leading projects to transfer new technologies/products, and leading cross-functional teams to troubleshoot/implement processes. In addition, you will be responsible for on-site observation of all production and for communicating project status to manufacturing management and to cross-functional line management. You must ensure cGMP compliance of the contract facility and be the primary contact for both business and technical issues for the contractor. Requires a BS in Biology, Biochemistry, Biological Sciences, Biotechnology, Chemical Engineering or Applied Science with the ability to manage and lead technical projects, learn rapidly, and handle an extremely time-constrained environment. Lotus Notes, MS Excel, MS PowerPoint, MS Word, and MS Project experience also required. Experience with cGMP manufacturing and FDA drug product regulation environment, project management, biotech/pharmaceutical processes/concepts, and small molecule manufacturing desired. Source Code: JL-B147-PDA

MANAGER, MANUFACTURING SCIENCES

You will be responsible for leading the tech transfer and scale-up of secondary manufacturing processes (final formulation, aseptic fill, lyophilization) from the Process Sciences group into clinical and commercial manufacturing (in-house and contract). Additionally, you will participate in process troubleshooting efforts (bulk and secondary), evaluate/recommend new equipment (bulk and secondary), and critically assess and resolve formulation and packaging issues. Requires a minimum of a BS in Chemical Engineering, Biochemistry, or Chemistry with 3-5 years experience in a secondary manufacturing GMP environment. MS or PhD in Chemical Engineering with 0-2 years experience in a secondary manufacturing environment preferred. Good troubleshooting and process analysis skills also required. Familiarity with process historian trend analysis is a plus. You must have excellent verbal and written communication skills, and be a team player capable of functioning well in a multi-disciplinary environment. Source Code: JL-A311-PDA

Foster your initiative and creativity at Biogen. We have one of the strongest financial profiles in the industry and our compensation and benefits package, including equity participation, is unmatched. For consideration, please forward your resume to: Biogen, Inc., Attn: Human Resources, Source Code: ____, 14 Cambridge Center, Cambridge, MA 02142; Email: resumes@biogen.com (Source Code ONLY must appear in the subject line). Biogen is an Equal Opportunity Employer. No phone calls, please.

The Note for Guidance on Parametric Release is intended to outline the requirements for applications that propose parametric release for finished products. The guideline highlights the different requirements that have to be fulfilled in the application and during regulatory inspections.

With regard to the sterility test, the statistical limitations of that test in predicting sterility assurance are well known. The European Pharmacopeia states "When a fully validated terminal sterilization method by steam, dry heat or ionizing radiation is used, parametric release, (that is the release of a batch of sterilized items based on process data rather then on the basis of submitting a sample of the items to sterility testing) may be carried out, subject to the approval of the competent authority." Parametric release can only be applied to products terminally sterilized in their final container and all relevant sterilization parameters, e.g., temperature, pressure and time must be accurately controlled, measured and reviewed.

This document was adopted by the CPMP in February 2001 and comes into effect in September 2001. The document number is CPMP/QWP/3015/99 and can be found on the EMEA (European Agency for the Evaluation of Medicinal Products) Web site, www.emea.eu.int.

The Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products (CVMP) have adopted a Note for Guidance on Process Validation (Final).

Process validation is the means of ensuring and providing documentary evidence that processes are capable of consistently producing a finished product of the required quality. This note for guidance is intended to demonstrate and standardize the data that should be routinely included in the marketing authorization dossier describing the validation of the manufacturing process.

It is recognized that at the time of submission of a marketing authorization dossier, manufacturers may not have completed formal validation studies on production scale batches. If validation of three production scale batches is not available, the firm should submit a validation plan as part of the application for marketing authorization. The plan should outline the formal studies for the production scale batches (normally three) before the product is placed on the market.

This Note for Guidance addresses the relationships between product development studies and process validation data, the relationship between the method of manufacturer and process validation data, and the relationship between process validation and the specifications of the finished product. The document also discusses the correlation of laboratory scale batches, pilot batches, production scale batches, data requirements, scale-up and change control.

Annex I of the guidance gives a list of the minimum validation elements required to be submitted with the application.

This document was adopted by the CPMP/CVMP in February 2001 and comes into effect in September 2001. The document number is CPMP/QWP/848/96 and can be found on the EMEA (European Agency for the Evaluation of Medicinal Products) Web site, www.emea.eu.int.

The Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products (CVMP) have adopted a Note for Guidance on Quality of Water for Pharmaceutical Use (Draft).

The European Pharmacopoeia (Ph Eur) contains standards for grades of water for pharmaceutical use, including Water For Injection (WFI) and Purified Water. In 1999, in response to requests from national delegations to permit reverse osmosis (RO) for WFI production, a major international symposium was organized to discuss the issue. The meeting concluded that there was insufficient evidence at the present time to support the use of RO to produce WFI and in view of the safety concerns, WFI should be prepared only by distillation as described in the Ph Eur. Furthermore, as a result of these activities, a new Ph Eur monograph entitled "Highly Purified Water" has been adopted and will be implemented in the Ph Eur on January 1, 2002.

Potable Water complies with the regulation on water intended for human consumption as specified by the competent authority. It is the prescribed source feed water for the production of Pharmacopeial grade waters.

Purified Water is water for the preparation of medicinal products other than those that are required to be both sterile and non-pyrogenic.

Highly Purified Water is intended for use in the preparation of medicinal products where high biological quality is needed except where Water for Injection is required. Highly Purified Water meets the same quality standards as WFI, but the production methods are considered less reliable than distillation and thus it is considered unacceptable for use as WFI.

Water For Injection is water for the preparation of medicines for parenteral administration when water is used as a vehicle for dissolving or diluting preparations for parenteral administration. WFI complies with the tests for Purified Water with the addition of the test for bacterial endotoxins (nmt 0.25 IU of endotoxin per ml).

The document has five tables providing guidance on the use of different grades of pharmaceutical water in manufacture of different classes of products and different production operations.

This document was adopted by the CPMP/CVMP in February 2001 and the deadline for comments is August 2001. The document number is CPMP/QWP/158/01 (draft) and can be found on the EMEA (European Agency for the Evaluation of Medicinal Products) Web site, www.emea.eu.int. ■

—William Stoedter

Reporting of Biological Product Deviations in Manufacturing

On Sunday, March 11 at the PDA Spring Meeting in Las Vegas, the FDA's Sharon O'Callagahan and Jerome Davis gave a four-hour briefing on the reporting of biological product deviations in manufacturing. The FDA's Center for Biologics Evaluation and Research has amended the existing regulation requiring licensed manufacturers of biological products to report deviations and unexpected events in manufacturing that may affect the safety, purity or potency of a product. The final rule requires licensed manufacturers, unlicensed registered blood establishments, and transfusion services that had control over the product when a deviation occurred to report that deviation to the FDA. This requirement amends 21 CFR 600.14 and became effective on May 7, 2001.

According to this final rule:

- The terms "error" and "accident" are eliminated and the focus is on deviations and unexpected events;
- There is a reporting time of 45 calendar days from the date that the deviation or unexpected event is discovered;
- Reporting is only required for events that may affect distributed products;
- Manufacturers are still required to perform a thorough evaluation and investigation of unexplained discrepancies and failures to meet specifications; and
- Manufacturers are still required to maintain records of complaints and investigations.

Manufacturers should have procedures in place that:

- Require investigations be performed in a timely manner;
- Call for corrective action plans (short term and long term) to prevent recurrence;
- Describe procedures to gain control of unsuitable product in a timely manner; and
- Provide for the appropriate disposition of all affected product, both in date and expired.

FDA's Sharon O'Callagahan

Per 21 CFR 600.14(b), manufacturers must report any event associated with the manufacturing of licensed biological products that:

1) Represents a deviation from CGMP regulations, standards or specifications that may affect safety, purity or potency; or
2) Represents an unexpected or unforeseeable event that may affect the safety, purity or potency; and
3) Occurs in your facility or a facility under contract to you; and
4) Involves a distributed biological product.

Reports are to be submitted on Form FDA-3486, Biological Product Deviation Report Form and should be mailed to:

Director, Office of Compliance
and Biologics Quality
1401 Rockville Pike, 200N (HFM-600)
Rockville, MD 20853-1448

Reports may also be submitted electronically through CBER's Web site www.fda.gov/cber/biodev/biodev.htm. ■

—William Stoedter

Michael J. Miller, Ph.D., Bausch and Lomb, Inc., Program Chair and Robert B. Myers, Schering-Plough, PDA Chair.

PDA Membership Application

Return your completed PDA membership application, with payment made to: **PDA, Inc., P.O. Box 79465, Baltimore, MD 21279-0465 USA** or fax it to: (301) 986-1093. *(If form is faxed, it must include necessary credit card information.)*

Member Info

Please type or print clearly

Last Name _____

Mr.❍ Ms.❍ Dr.❍ First Name _____ MI_____

Job Title _____

Company _____

Address _____

City _____ State/Province _____

Country _____ Zip+4/Postal Code _____

Business Phone# _____ Fax# _____

E-mail _____

Member Profile

Business Environment (check only one)

- ❑ Academic
- ❑ Consultant
- ❑ Engineering and Construction
- ❑ Government Regulatory Agency
- ❑ Industry Supplier
- ❑ Medical Device Manufacturing
- ❑ Pharmaceutical Manufacturing
- ❑ Pharmacy
- ❑ Recruiter
- ❑ Other

Professional Interest (check all that apply)

- ❑ Aerosols
- ❑ Analytical Chemistry
- ❑ Biologicals
- ❑ Biotechnology
- ❑ Computers
- ❑ Engineering
- ❑ Formulation Development
- ❑ GMP Compliance/Inspection Trends
- ❑ Liquids
- ❑ Maintenance
- ❑ Manufacturing/Production
- ❑ Microbiology
- ❑ Ointments
- ❑ Ophthalmics
- ❑ Packaging
- ❑ Parenterals
- ❑ Quality Assurance/Quality Control
- ❑ Regulatory Affairs
- ❑ Research
- ❑ Solid Dosage Forms
- ❑ Sterilization/Aseptic Processing
- ❑ Training
- ❑ Validation

Payment (US Dollars Only)

Please note: *Contributions or gifts to PDA are not tax-deductible as charitable contributions. However, they may be deductible as ordinary and necessary business expenses.*

Individual Membership $150. Please check the appropriate box:

❑ **Check** enclosed ***Charge:*** ❑ MC/EuroCard ❑ VISA ❑ AMEX ❑ **Wire Transfer:**

(must be net of all bank charges; include member name) Instructions: SunTrust Bank, ABA #051000020, PDA Account #209364254, Swift#UVBIUS33

Account Number _____ Exp. Date _____

Name _____
(exactly as on card)

Signature _____ Date _____

Federal Tax I.D. #52-1906152

LTR 05/01

PDA USE:
Date:_____ Check:_____ Amount:_____ Account:_____

PDA Capital Area Chapter Meeting

On Tuesday, February 20, 2001, the PDA Capital Area Chapter and the Institute of Environmental Sciences and Technology (IEST) Chesapeake Chapter held a joint meeting on the new ISO cleanroom standards. Richard Matthews of Filtration Technology Inc. presented an overview of progress made by the ISO Technical Committee 209 on cleanrooms and associated controlled environments. These ISO standards were developed to establish an international baseline, provide global consistency, assure common denominators for industry, regulatory authorities and multinational commerce, and to serve all cleanroom users, from microelectronics to pharmaceuticals.

ISO/TC209 consists of 37 countries, 8 working groups, more than 1,000 individuals, 81 classes of cleanliness, 6 particulate sizes, 3 states of occupancy and 11 documents. Room Classification is dependent on the user specifying the ISO Class, the occupancy state (as built, at rest or in operation), and the particle size(s) being counted. Particulates are counted per cubic meter (not in cubic feet as in Fed Std 209E), although the relative numbers are the same. The US FDA is monitoring the ISO process and has advised the US voting members of FDA's expectations for the final documents.

IEST maintains Fed Std 209E and will most likely let that standard expire after the ISO documents are finalized. E-mail: iest@iest.org. ■

ISO documents can be purchased from:
Institute of Environmental Sciences & Technology
940 East Northwest Hwy.
Mt. Prospect, IL 60059
Tel: (847) 255-1561
Fax: (847) 255-1699

Airborne Particulate Cleanliness Class Comparison:

ISO 14644-1	Fed Std 209E	International Units
1	N/A	N/A
2	N/A	N/A
3	1	M 1.5
4	10	M 2.5
5	100	M 3.5
6	1,000	M 4.5
7	10,000	M 5.5
8	100,000	M 6.5
9	N/A	N/A

Overview and Document Status:

Document	Title	Status
14644-1	Classification of Air Cleanliness	Issued May 1, 1999
14644-2	Specifications for Testing	Issued Sept. 15, 2000
14644-3	Metrology and Test Methods	To go out for DIS vote 2Q01
14644-4	Design and Construction	Currently out for FDIS Vote
14644-5	Cleanroom Operations	To go out for DIS vote 2Q01
14644-6	Terms, Definitions and Units	To go out for DIS vote 3Q01
14644-7	Separative Enclosures	To go out for DIS vote 2Q01
14644-8	Molecular Contamination	To go out for DIS vote 4Q01
14698-1	Biocontamination, General	To go out for FDIS vote 2Q01
14698-2	Biocontamination Evaluation of Data	To go out for FDIS vote 2Q01
14698-3	Measuring for Evaluating Cleaning Process	To be issued as a TR in 2001

Definitions:

DIS—Draft International Standard, document used for review and comment; FDIS—Final Draft International Standard, document used for review prior to approval; TR—Technical Report

Mountain States Chapter Roundtable Dinner Well Attended

by John M. Elvig, Colorado Quality Assoc., Inc.

A Mountain States Chapter Roundtable Dinner was well attended (100+) at the Raintree Inn in Longmont, Colorado on April 5, 2001. Roundtable topics included FDA Inspections, OOS systems, data handling, 21 CFR 11, cleaning validation, stability programs, chromatography validation, training and contract manufacturing. Volunteer facilitators ensured all participants were given an opportunity to share and learn from each other's valuable experiences. Dr. Jeanne Novak (Colorado Bioreg) was the keynote speaker after the networking and dinner meeting. Novak, former FDA employee within CBER and CDRH, related current expectations of FDA investigators performing PAI and biannual inspections.

Coming this fall, look for more information on the Denver Educational Course Series and a Vendor Night. For more information, visit our Web page at www.mspda.org. ■

Interest Groups Update

Many of the PDA Interest Groups met at the PDA Spring Conference in Las Vegas, Nevada, in March 2001. This article summarizes the Microbiology/Environmental Monitoring IG session. Summaries from other IG sessions will be published in future issues of the *PDA Letter*. More information about PDA Interest Groups can be found on the PDA Web site at www.pda.org.

Microbiology/Environmental Monitoring

Jeanne E. Moldenhauer, Ph.D., Vectech Pharm. Consult., Inc.

The Microbiology/Environmental Monitoring Interest Group had a very lively discussion on Environmental Monitoring for Non-Sterile Drugs and also on the Impact of the New Drug Inspection Pilot Program on the Laboratories. The group was fortunate to have several companies that had been inspected under the new policy and were willing to share their experiences. The key point for all was that the laboratory is a major focal point under this new guideline and that they are using the listed items almost as a checklist for the inspection. Also stressed were the new types of data summaries that were being requested.

For non-sterile drugs the group acknowledged an increased focus on environmental monitoring, with little to no regulatory guidance. There was also a great deal of concern with the proposed ISO documents suggesting something like Class 100,000 requirements for non-steriles. Many in the group felt that there was a lack of understanding of the actual manufacturing process to think that these limits would be appropriate. It was also noted though, that industry as a whole did not take the time to respond to the document as a draft. It is currently out for final approval.

On a business note, we are looking for volunteers to participate in a program committee for the group. This group would help select topics for the meetings and find appropriate speakers.

A second committee is being formed to generate an IG newsletter and updates for the Web site. If you are interested, please contact Jeanne Moldenhauer at jmoldenhauer@vectech.com. ■

What is an Acceptable Sterility Test False Positive Rate?

The following remarks are taken from an exchange in the Pharmaceutical Sci-Tech Discussion Group, a PDA-sponsored Online Forum held on the Internet at www.pda.org. PDA Online Forums are free of charge and open to the public. They serve as a platform for exchanging practical, and sometimes theoretical, ideas within the context of some of the most challenging issues confronting the pharmaceutical industry. If you are not currently a member of a discussion group, we encourage you to visit our Web site and join.

This month's posting…

Question

For sterility testing, what percentage rate would be considered too high for false positives (assuming one could prove the sterility test vial was indeed a "false positive")? At what percent would a regulatory agency start to take notice?

These sterility tests are performed in a class 100 hood, which itself in located in a class 10,000 room. They are not performed in an isolator.

Thanks for your comments.

Response 1

The FDA Guideline on Sterile Drug Products Produced by Aseptic Processing indicates that "in FDA's experience, it should be normal for a laboratory to find an initial positive sterility rate less than 0.5% of all sterility tests."

Response 2

NMT 0.5% is the rate specified in the FDA guidelines. USP recommends that the rate not exceed 2%.

Response 3

According to the USP 24 the "false positive" frequency should not exceed the level of 2% (page 2148). Though skilled operators working under the prescribed conditions should be able to achieve a much lower level (this will be expected by the regulatory agencies). A survey of 8 years of sterility testing of three major Dutch pharmaceutical companies showed a contamination rate of only 0.17% can be realized (*PDA Journal of Pharmaceutical Science and Technology*, 52, 159-164 (1998)).

In 1998 the Therapeutic Goods Administration of Australia published a guideline for Sterility Testing of Therapeutic Goods in which an achievable false positive rate as low as one contamination in five thousand units (0.02%) is mentioned.

Response 4

The USP gives a value of 2%. In practice a value of less than 0.2% can be achieved (*PDA Journal of Pharmaceutical Science and Technology*, 52, 159-164 (1998)).

Response 5

USP 24 page 2148 specifies 2% while FDA guideline expects it to be NMT 0.5%. Practically it should not exceed (and is achievable) 0.2% and even less.

Response 6

I agree with being able to achieve a false positive rate of 0.2% or better. We routinely hold below that in our sterility suite.

Response 7

Actually, 0.2% is quite high for a modern sterility testing operation. Isolator based sterility testing operations typically result in false % rates approaching zero.

Response 8

It's important to remember that the FDA Guideline on Sterile Products Produced by Aseptic Processing is now 14 years old. This document does not reflect the current state of the art. There were only a handful of sterility testing isolators in use at the time that document was written. ■

—compiled by Russell Madsen

FDA Trade Association Meeting from cover

Electronic Submissions

- To date, the FDA has received more than 500 electronic NDAs (ENDAs) and they are now receiving about 100 a month.
- 75% of all NDA's have an electronic component.
- 35% of NDA's received are entirely in electronic format.
- This has resulted in a 50% reduction of paper storage at FDA.

Orange Book Patent Listing

- Gary Buehler, Acting Director, Office of Generic Drugs, discussed FDA's role in patent listings.
- According to the Hatch-Waxman amendment, brand companies must submit patents to the FDA.
- Patents are published in the *Orange Book* when the application is approved.
- If an ANDA sponsor wants to market before patent expiration, it must submit Paragraph IV certification (patent is invalid, not enforceable and/or not infringed) and notify the NDA and patent holder.
- If the ANDA sponsor is sued for patent infringement within 45 days, FDA cannot approve the ANDA for 30 months unless patent litigation is resolved sooner. 21 CFR 315.53(b) describes the conditions under which a patent must be submitted. Manufacturing process patents are not eligible.
- Because the FDA has no expertise in the field of patents, the agency has no basis for determining whether a use patent covers the use sought by the applicant. Nor does the FDA believe that Congress intended for the agency to make such decisions.

Here is the problem

- Brand companies can list questionable patents in the *Orange Book*, especially well after the NDA is approved.
- FDA does not look into patents listed in the *Orange Book*.
- Even if a patent is not a true obstacle to generic competition, ANDA applicants must file Paragraph IV certifications, leading to patent litigation and 30 month delays of ANDA approval.
- The FDA understands the problems this issue causes for ANDA sponsors but the agency must follow the laws as they are written. The way to correct this situation is through the legislative process.

Coordinating Committee Updates

- The Investigational New Drug CMC Meetings Guidance will be published in the next three months.
- Guidances on nasal sprays, liposome drug products and blend uniformity will be published in three to six months.
- Guidances on drug products, drug substances and stability will be published in six to nine months.
- The revision to 21 CFR 314.70 (supplements and other changes to approved applications) is not expected to be published before the end of 2001.
- The 1998 draft guidance on stability received 3,000 comments. The new guidance is complete and the FDA internal review process should be ready near the end of 2001. ■

—William Stoedter

NEW: Pharmaceutical Report Writer Tailored to Your Needs

Introducing The Newest In Temperature Measurement!

- Precision Temperature Measurement
- Wireless temperature and relative humidity measurement with the smallest, most flexible units on the market. Temperature range –100 to 400°C
- Real time monitoring and alarming for chambers, freezers and autoclaves
- Liquid and dry calibration baths for thermocouples and wireless loggers
- Automated calibration
- Validated software, compliant with 21 CFR, Part 11 (Electronic Signature)
- Pharmaceutical Report Writer with minimum, maximum, average at user defined intervals for parameters and F values

Only Ellab has the total solution for measuring temperature, pressure and relative humidity with wireless or real time dataloggers, automated calibration and reports that meet your specifications.

ellab
Building Confidence

ELLAB, Inc 1·888·53·ELLAB (35522)

For Information On TrackSense II, E-Val and Our New Automatic Calibration System, Mail or Fax This Form

Name _____

Company _____

Address _____ City _____ State _____ Zip _____

Phone _____ Fax _____ e-mail _____

☐ Please send me information ☐ Please have a sales representative call me

6355 Ward Road, Suite 308, Arvada, CO 80004 • Telephone 888-53-ELLAB (888-533-5522)
Fax 303-975-5630 • e-mail: hh@ellab.com • www.ellab.com

Company, Colleague & Product Announcements

US Pharmacopeia (USP), a non-government organization that establishes state-of-the-art standards to ensure the quality of medicines and other health care technologies, announced that **John R. Bergeron** has joined the organization as Director, Reference Standards Production. Bergeron will provide leadership in areas of acquisition, evaluation, packaging, storage and global distribution of USP Reference Standards. He will work collaboratively with the Directors of Reference Standards Evaluation and the Reference Standards Laboratory to maintain smooth and efficient production operations and will work to employ the latest technology, equipment and systems to satisfy USP customer needs. Bergeron comes to USP from University Pharmaceuticals of Maryland, Inc., in Baltimore, Maryland, where he was Director of Operations. He has over 23 years of experience in pharmaceutical manufacturing with responsibilities for process development, biotechnology and parenteral manufacturing, quality assurance and inventory maintenance under CGMP for multiple manufacturing sites and projects. Bergeron can be reached at (301) 816- 8289 or jxb@usp.org. See also, www.usp.org.

FeRx Inc. announced that Richard W. Keatinge, Ph.D., has joined FeRx as Vice President of Corporate Development and Kenneth A. Norton, Ph.D., has joined the company as Senior Director of Pharmaceutical Development. "We are thrilled to have Richard and Ken join FeRx," said Jacqueline Johnson, Ph.D., President and CEO of FeRx Inc. "With Richard's comprehensive business development expertise and Ken's extensive background in leading the research and development of pharmaceuticals, we have strengthened both the business and the science aspects of the company." Prior to joining FeRx, Keatinge was Vice President, Business Development at Digital Gene Technologies Inc. For eight years previously he was President of Keatinge & Associates Inc., a biotechnology consulting firm serving clients throughout the western US. Norton has over 16 years experience in leading pharmaceutical research and development teams. Most recently, he was Director of Analytical Research and Development at InfiMed Therapeutics Inc., where he authored the company's first IND and implemented its CGMP manufacturing and testing systems. Previously, Norton was Senior Director of Analytical Research and Development at Geltex Pharmaceuticals Inc. For more information, contact Jacqueline Johnson, Ph.D. at (858) 677-7788 or jjohnson@ferx.com. See also www.ferx.com.

Meridian Bioscience, Inc. announced that it has hired Larry Baldini as its Vice President of Operations. Most recently, Baldini was Director of Operations (Sensory Systems) at Instrumentation Laboratories, Ann Arbor, MI. Baldini has extensive experience in managing a wide variety of operations, including implementing quality systems (QSRs and ISO 9002), establishing metrics, controlling scrap and overtime, reducing backorders and improving manufacturing efficiencies. Jack Kraeutler, President of Meridan said, "We are delighted to welcome Larry as the newest member of Meridian's senior management team. Mr. Baldini has a broad background in *in vitro* diagnostic product manufacturing and operations management. His focus on efficient, high Quality System Regulation and other international regulatory standards, will provide Meridian with important leadership in its Operations areas." For more information, contact John A. Kraeutler at (513) 271-3700. See also www.meridianbioscience.com.

The **US Department of Commerce** announced a full calendar of export promotion activities for US companies in the medical equipment sector, as well as in the related fields of dental equipment, laboratory equipment and analytical instruments. The Department of Commerce also announced that export assistance programs would offer small and medium-sized firms a cost-effective means to have their literature displayed at major international trade shows, find distributors in key markets, and expand their foreign sales. Finally, eight trade show opportunities for 2001 were announced. Activities will be sponsored at trade shows in the Philippines, Brazil, Mexico, Panama, Ecuador, Peru, Argentina, and Taiwan. In early 2002, activities will also be sponsored at shows in the Middle East and South Korea. For more information contact Steven Harper, International Trade Specialist, US Department of Commerce / International Trade Administration at (202) 482-2991 or steven_harper@ita.doc.gov. See also www.ita.doc.gov.

Bio Science Contract Production Corp. was successfully inspected for CGMP compliance by the FDA in December 2000 and by the European regulatory authorities (EMEA) in November

2000. The agencies concluded that Bio Science operates in accordance with FDA and EU GMP regulations. Based on these inspections, Bio Science will be recommended for approval to make licensed products for both the US and European markets. Jaques Rubin, Chairman and CEO, stated "Not only is Bio Science committed to compliance to ensure consistency and quality, but also successfully integrates customer satisfaction, improved operations and customer market/timeline requirements." The company offers CGMP contract production of purified, active biopharmaceutical ingredients for companies worldwide. For more information contact Denise Rosenfeld, Business Development Coordinator, at drosenfe@bscp.com. See also www.bscp.com.

The **Dow Chemical Company** manufacturers DOWEX ion exchange resins that are typically used for applications like water purification. Ion exchange resins can also be applied to separate and purify disease fighting, therapeutic agents from impurities during the drug manufacturing process. This is important because many drugs are present in very small concentrations with other chemicals and must be separated and concentrated to be useful. Dow is one of the few companies in the world to offer a line of Fine Mesh resins that can serve as processing tools to enable drug development and production. Without this capability, many drugs would be harder to produce en masse and be far more expensive. The key to making drugs is often linked to the ability to separate useful ingredients from the rest of the "soup". Ion exchange resins offer the technology to solve the separation and concentration of these products. DOWEX ion exchange resins are the enabling technology for the discovery and production of pharmaceuticals and nutraceuticals. Drugs like vancomycin, streptomycin, and erythromycin are all partially purified using DOWEX ion exchange resins. For more information contact Harold Nicoll at (517) 636-9086 or hgnicoll@dow.com. See also www.dow.com. ■

—Joe Bury

PDA Good Electronic Records Management (GERM) Conference, Courses and Exhibition a Resounding Success!

With over 200 participants and exhibitors in attendance from around the world, PDA's GERM Conference, held April 2–5 in Tampa, Florida, proved to be a resounding success. The forum provided an opportunity for information exchange based on practical experiences and real life lessons learned from 21 CFR Part 11 compliance efforts.

Members of the PDA Good Electronic Records Management Conference program committee and FDA representative: John McKenney, SEC Associates, Inc.; Marta Haley Fields, Amgen, Inc.; Jennifer Thomas, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, and member, Part 11 Task Force; Robert Williams, Cohasset Associates, Inc.

The opening plenary session set the stage for the conference with Jeffrey Rothenberg, author of the landmark *Scientific American* article, "Ensuring the Longevity of Digital Documents," delivering a thought-provoking session on the longevity of electronic media and alternative approaches for long-term record retention. The conference's multi-track format enabled participants to choose from a variety of important topics, including concepts and practices in GERM and strategies and approaches for compliance with 21 CFR Part 11. Widely popular among conference attendees were sessions that addressed legal issues related to e-signatures and e-records. Jennifer Thomas, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, and member of the Part 11 Task Force, provided updated information on the status of FDA guidance.

PDA members may access the GERM conference slide presentations by visiting the PDA Web site at www.pda.org and clicking on "members only".

> I found PDA's GERM Conference to be quite interesting and useful. I was also impressed that there was a good mix of industry, vendor, and "other" presenters. Those "other" presenters were quite a refreshing change from what has become the norm for such technically oriented seminars and conferences.—*Michael Specht, Dupont Pharmaceuticals*

■

—Leslie Zeck

Charles M. Dollar, Ph.D., Cohasset Associates, Inc., GERM Conference presenter with conference planning committee co-chairs George Grigonis, Merck and Co., Inc. and Robert Williams, Cohasset Associates, Inc.

A filter validation promise to customers all around the world:

Dreissig Tage
Trente jours
Dertig dagen
Trenta giorni
三十天
Trienta dias
Thirty days

No Excuses. Yes, We Can!

From vaccines and cell cultures to blood products– only Sartorius lets you validate with CONFIDENCE®

In matters of validation, Sartorius makes an extra effort to ensure quality in your process. And we do it all in 30 days or less. It's all part of our FACTS® program of Fully Advanced Customer Total Support. We take the time to do it right. We test your filters with your product under your process conditions. We run "worst-case" bacteria challenge tests and worst-case extraction. Our modern analytical validation labs include FT-IR, GC/MS, RPHPLC, UV-VIS, GPC, HPCE, SFC, NVR and TOC. No other filter manufacturer performs these validation procedures with more accuracy than Sartorius.

So when it comes down to deciding who the most viable filtration partner is to properly challenge your process, in 30 days or less, call us. Yes, we can!

Focus On Validation Support

sartorius

Sartorius AG, Germany: 49 551 308 0 • Sartorius S.A., France: +33 1 69 19 21 00 • Sartorius Ltd.,UK: +44 1 372 737100
Sartorius S.p.A., Italy: +39 055 505671 • Sartorius Corp., USA: +1 800 368 7178 • Sartorius K.K., Japan: +81 3 3329 5533

continued from Back Cover

September 17-18, 2001
PDA Canada Chapter/A3P International Conference and Exhibition
Holiday Inn Montreal Midtown
Montreal, Quebec, Canada

OCTOBER

October 1-3, 2001
PDA/FDA Viral Clearance Forum
Hyatt Bethesda
Bethesda, Maryland

October 1-5, 2001
PDA-TRI Aseptic Processing Course (week 1)
Baltimore, MD

October 11-12, 2001
PDA-TRI Course: Computer Products Supplier Auditing Process Model: Auditor Training
Baltimore, MD

October 15-17, 2001
PDA Isolation Technology Conference
Hilton New Brunswick
New Brunswick, NJ

October 16-18, 2001
PDA-TRI Palm Springs Course Series
Palm Springs, CA

October 22-24, 2001
PDA-TRI Course: Cleaning Validation
Baltimore, MD

October 25-26, 2001
PDA-TRI Course: Validating a Steam Sterilizer
Baltimore, MD

NOVEMBER

November 5-9, 2001
PDA-TRI Aseptic Processing Course (week 2)
Baltimore, MD

November 15-16
PDA-TRI Course: Computer Products Supplier Auditing Process Model: Auditor Training
Baltimore, MD

November 30, 2001
PDA-TRI Course: Contamination Control Basics
Baltimore, MD

DECEMBER

December 3-7, 2001
PDA ANNUAL MEETING, COURSES AND EXHIBITION
Marriott Wardman Park
Washington, DC

2002
FEBRUARY

February 11-15, 2002
PDA International Congress, Courses and Exhibition
Basel Congress Center
Basel, Switzerland

Be sure to watch **www.pda.org** for conference and course updates!

Trainers! New Forum Announced!

Every specialized group in the pharmaceutical environment has questions related to their job specifics. Nowhere is this truer than in the arena of CGMP and Regulatory Training. Have you ever had questions yourself? What training resources are available? Where can I get a decent training video? How much training should my people be completing? When is the next training conference?

Now there is a platform where CGMP and regulatory trainers can meet and exchange information. PDA's Training Interest Group, in conjunction with the Training and Research Institute in Baltimore, has initiated a Trainers' Discussion Forum in the Online Forums section of PDA's Web site. On-the-site trainers can pose and answer questions, list resources they've found useful, make announcements about upcoming events, and just generally swap whatever non-commercial information they want.

How does it work?

It's easy. Do this:

1) Navigate to www.pda.org.
2) At the top of the left navigation bar click "Online Forums."
3) On the next screen click the red link: "Go Directly to the Forums."
4) You will then be asked to sign in to the forums. (You do not have to be a PDA member to join.) For your first visit click either "New Users" to create a profile for yourself, or, if you just want to check things out, "Guest." If you already have a profile just sign in.
5) After you have completed your profile, or after you have signed in, click the "+" next to "CGMP Training Discussion Group".
6) Enjoy.

The discussion group is moderated, which means that a discussion group leader reviews all comments and questions before they are posted.

Take advantage of this new feature. And let us know what else you would like to see on the site. Send a note to the discussion group leader, Rick Rogers, at rogers@pda.org. ■

—Rick Rogers

What training resources are available?

Where can I get a decent training video?

How much training should my people be completing?

When is the next training conference?

Upcoming PDA-TRI Education Courses

Contamination Control Basics (PDA #213), *Three dates remaining*: June 29, 2001; September 7, 2001; November 30, 2001—*taught by Sandra A. Lowery, President of Quality Systems Consulting*; $750 PDA members/$900 nonmembers.

Validating a Steam Sterilizer (PDA #322), *one date remaining:* October 25–26, 2001—*taught by Ronald Kraus, Associate Director of KMI Systems and Christopher Mansur, Sr. Computer Validation Compliance Specialist, Genetics Institute*; $1,500 members/ $1,650 nonmembers.

Computer Products Supplier Auditing Process Model: Auditor Training, October 11–12 and November 15–16, 2001 in Baltimore, Maryland; June 6–7, 2001 in East Brunswick, New Jersey; $950 PDA members/ $1,100 nonmembers. *For more information, vist our Web site,* www.pda.org. ■

Additional Course Offerings appear on page 27 and in the Calendar.

These courses will be held at PDA-TRI in Baltimore, Maryland unless otherwise noted.

For course content information, call PDA-TRI directly at (410) 455-5800.

To register, call PDA headquarters in Bethesda, Maryland at (301) 986-0293. PDA-TRI Location/Hotel Information follows.

PDA-TRI Thanks the Following...

Sponsors

Abbott Laboratories
Allegiance Healthcare Corporation
Alma, Inc.
Becton Dickinson Microbiology Systems
Berkshire Corporation
Biolog, Inc.
bioMerieux Vitek, Inc.
Biotest Diagnostics Corporation
Chemunex, Inc.
Cole-Parmer
Comar, Inc.
Contec, Inc.
Corning, Inc.
Dow Corning, Inc.
DuPont Pharmaceutical Co.
Dycem Ltd.
Eagle Picher
Eisai U.S.A., Inc.
Electrol Specialties Company
Endosafe
Environmental Monitoring Technologies
Genesis Machinery Products, Inc.
GlaxoSmithKline
Helvoet Pharma
IDEXX Laboratories, Inc.
Interpharm
Kimberly Clark, Corp.
KMI/Systems
La Calhene, Inc.
Larson Mardon Wheaton
Micro Diagnostics
MIDI Laboratories, Inc.
Millipore Corporation
Nalge Co.
Pacific Scientific Instruments
Pall Corporation
PML Microbiologicals
Raven Biologicals, Inc.
Research Equipment Services
Rhone-Poulenc Rorer
Sartorius AG
Siemens Building Technologies, Inc.
SGM Biotech, Inc.
STERIS Corporation
Veltek Associates, Inc.
VWR Scientific Products
West Pharmaceutical Services
Wilco AG
Wyeth-Ayerst Laboratories

Contributors

Amgen, Inc.
Automated Liquid Packaging, Inc.
Berkshire Corporation
Chesapeake Biological Laboratories, Inc.
Cotter Corp.
Eli Lilly and Co.
Fedegari
Kaye Instruments, Inc.
Kimberly Clark, Corp.
National Instrument Co., Inc.
Neslo, Inc.
Perfex Corporation
Pharmacia
Sievers Instruments, Inc.
Technovation

PDA-TRI Location/Lodging Information

Unless otherwise noted, PDA Institute courses are held at: PDA Training and Research Institute, 1450 South Rolling Road, Baltimore, MD 21227, Tel: (410) 455-5800; Fax: (410) 455-5802. PDA has not secured any specific room blocks for participants attending courses at the Training and Research Institute. There are several hotels in the Inner Harbor (downtown Baltimore) and BWI airport areas. These include, but are not limited to:

- **Baltimore Hilton & Towers Inner Harbor**—Tel: (410) 539-8400; Fax: (410) 625-1060
- **Baltimore Marriott Inner Harbor**—Tel: (410) 962-0202; Fax: (410) 625-7892
- **Embassy Suites-BWI**—Tel: (410) 850-0747; Fax: (410) 859-0816
- **Holiday Inn-BWI**—Tel: (410) 859-8400; Fax: (410) 684-6778
- **Holiday Inn Inner Harbor** —Tel: (410) 685-3500; Fax: (410) 727-6169
- **Homewood Suites BWI****—Tel: (410) 684-6100; Fax: (410) 684-6810
- **Hyatt Regency Baltimore Inner Harbor**—Tel: (410) 528-1234; Fax: (410) 685-3362
- **Sheraton Inner Harbor Hotel**—Tel: (410) 962-8300; Fax: (410) 962-8211.
- **Marriott Residence Inn-BWI****—Tel: (410) 691-0255; Fax: (410) 691-0254.

***no on-site restaurant*

For additional hotel information, please visit www.baltconvstr.com, the Baltimore Convention and Visitors Bureau's Web site. **Transportation to PDA-TRI:** All listed hotels are no more than a 15–20 minute taxi ride to the Training and Research Institute. All hotels can assist you with taxi arrangements. Registrants may prefer to rent a car for easier access to and from the Institute. ■

PDA-TRI New Jersey Course Series

June 5-7, 2001

Hilton – East Brunswick
East Brunswick, NJ

June 5, 2001
- **Using INFOSEC Technology and Procedures for 21 CFR Solutions**
- **PDA Audit Process Model Management Overview Training**

June 5–6, 2001
- **Basic Concepts in Cleaning and Cleaning Validation**

June 5–7, 2001
- **GMP Training Manager Workshop**
- **Active Pharmaceutical Ingredients: Manufacture Validation**
- **Pharmaceutical Water Systems Design and Validation**

June 6, 2001
- **Designing Regulatory Training that Works**

June 6–7, 2001
- **PDA Computer Products Supplier Auditor Training**

June 7, 2001
- **Writing and Auditing CGMP Documentation**
- **A Practical Guide to Change Control** ■

For Registration Information, contact PDA at (301) 986-0293 or visit www.pda.org.

For Course Content Information, contact PDA-TRI directly at (410) 455-5800.

Upcoming New Orleans Courses

August 6–8, 2001

Hyatt Regency New Orleans
New Orleans, LA

August 6, 2001
- **Understanding the Regulatory Compliance Requirements of the US Pharmacopoeia**

August 6-7, 2001
- **A Practical Approach to Aseptic Processing and Contamination Control**
- **A System-Based Approach to an FDA Inspection**

August 6-8, 2001
- **Tablet Formulation**

August 7, 2001
- **Good Documentation Practices in the Pharmaceutical Industry**

August 8, 2001
- **Everyday Compliance: Introduction to the CGMPs & Drug Regulation**
- **Conducting Compliant Deviation Investigations for the Pharmaceutical Industry**
- **Identification of Microorganisms Using Comparative DNA Sequencing** ■

For Registration Information, contact PDA at (301) 986-0293 or visit www.pda.org.

For Course Content Information, contact PDA-TRI directly at (410) 455-5800.

Make your reservations directly with the hotel by July 16, 2001, and mention PDA to secure the group rate of $109.00 - single occupancy. After July 16, reservations—if available—will be at the hotel's prevailing rate.

Aseptic Processing 2001

July 23–27 & August 20–24
October 1–5 & November 5–9

Baltimore, Maryland

A Comprehensive Program in Manufacturing Sterile Products

For Course Content Information, contact PDA-TRI directly at (410) 455-5800.

For Registration Information, contact PDA at (301) 986-0293 or visit www.pda.org.

PDA-TRI Education Courses Registration Form

1. Please type or print your name, address and affiliation.

❑ Mr. ❑ Ms. ❑ Dr. First Name Middle Initial Last Name

Membership Number

Job Title Company

Business Address

City State/Province ZIP/Postal Code

Tel Fax E-mail

❑ Substituting for (Check only if you are substituting for a previously enrolled colleague; nonmember substituting for member must pay the additional fee.)

2. Indicate the course(s) you'd like to attend (please print). Individuals registering at the nonmember rate receive one full year of PDA membership. Nonmembers registering for multiple events need only pay the nonmember fee once. (If you do **NOT** want to become a PDA member, please check here ❑).

COURSE TITLE	COURSE #	DATE	LOCATION	PRICE (member or nonmember)
			TOTAL :	$

3. Please check the appropriate box:

❑ **Check** enclosed ❑ Wire Transfer ***Charge:*** ❑ MC/EuroCard ❑ VISA ❑ AMEX

Account Number_____ Exp. Date _____

Name _____
(exactly as on card)

Signature_____ Date _____

Payments must be made to PDA in US dollars by check drawn on a US bank, by electronic money transfer **(SunTrust Bank ABA #051000020, PDA Account #209364254, Swift#UVBIUS33), net of all bank charges**; by American Express, MasterCard, or VISA.

4. Return completed form with payment made to:

PDA, Inc.
P.O. Box 79465
Baltimore, MD 21279-0465 USA
USA Fax: (301) 986-1093 (credit cards only)

Payment must be included to be considered registered.

Federal Tax I.D. #52-1906152

Deadline*: Enrollment is limited for the benefit of all attendees; this necessitates early registration. Paid registrations must be received one week prior to the event.*
Confirmation*: Written confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event.*
Substitutions*: If a registrant is unable to attend, substitutions are welcome and can be made at any time, even on-site. If you are pre-registering as a substitute attendee, indicate this on the registration form.*
Refunds*: Refund requests must be in writing. If received one month prior to start of an event (course series, conference, etc.), a full refund, minus a $35.00 handling fee, will be made. If received two weeks prior to the event, one-half of the registration fee will be refunded. After that time, no refunds will be made.*
Event Cancellation*: PDA reserves the right to modify the material or instructors without notice or to cancel an event. If the event must be canceled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PDA will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.*

LTR 05/01

PDA USE:
Date:_____ Check:_____ Amount:_____ Account:_____

Fujisawa Healthcare, Inc., a subsidiary of Fujisawa Pharmaceutical Co, Ltd., pursues the healing power of science with great hope. Many of our discoveries are therapeutic innovations that, over time, have become new standards of care.

Fujisawa Healthcare, Inc. currently employs approximately 700 employees in the US and Canada with offices in Deerfield, IL as our corporate headquarters. Fujisawa offers competitive wages, both short and long term performance incentives, and an excellent benefits package. Fujisawa is currently seeking experienced professionals in the following areas to help us make our vision a reality:

Manager, Regulatory Affairs

As a Manager, Regulatory Affairs your primary responsibilities will include oversight of regulatory submissions and significant interactions outside the Regulatory Affairs Department on complex issues to ensure the compilation and submission of IND/NDA/ANDA's are within defined time schedules; provides highly skilled expertise to the direction of projects including international regulatory support, advertising/labeling, and liaisonhsip with the FDA; defines and communicates FHI's regulatory strategy for assigned projects.

Qualifications for the Manager, Regulatory Affairs include a minimum of a BS/MS/PhD in the Life Sciences, 10 years pharmaceutical industry experience with at least 3-5 years Regulatory Affairs experience dealing directly with the FDA in the filing of IND/NDA/ANDA's.

Manager, Technical Services

As a Manager, Technical Services you will be responsible for managing FHI R&D Clinical Supplies system in support of all studies conducted for IND applications. Your primary role will be to liaison between R&D, Fujisawa-Japan, and Fujisawa-Ireland, outside vendors, contract manufacturers, CRO's, Compliance, Regulatory Affairs, etc in regards to to matters regarding ordering clinical supplies, manufacturing, labeling, packaging, forecasting, inventory, expiration and stability information, and shipments.

Qualifications for the Manager, Technical Services include a minimum of a BS/BA in Chemistry or Life Sciences and 3-5yrs pharmaceutical industry experience in clinical research, product/process develpment, manufacturing, and at least two years clinical supplies management.

Interested candidates should send a resume to: Attn CP/HR, Three Parkway North, Deerfield, IL 60015. Fax: 847-317-1245 or by email to carrie_passavnt@fujisawa.com. We encourage you to visit our website at www.fujisawa.com for additional information about our company and employment opportunities. As you discover more about us, we will continue searching the world around us to help the world inside us. EOE/M/F/D/V.

Fujisawa Healthcare, Inc.

Biotechnology
Frank Matarrese
Chiron Corporation
4560 Horton Street
Emeryville, CA 94608
Tel: (510) 923-3128
Fax: (510) 923-3375
E-mail—
frank_matarrese@cc.chiron.com

Computer Systems
Michael L. Wyrick
KMI/Parexel
2080 St. Andrew's Court
Franklin, IN 46131
Tel: (317) 736-0853
Fax: (317) 736-9249
E-mail—
mwyrick@belmont.kminc.com

Contract Manufacturing
Michael R. Porter
Eli Lilly & Company
DC 3814
Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: (317) 277-2595
Fax: (317) 277-9693
E-mail—
porter_michael_r@lilly.com

Drug/Device Delivery Systems
Michael A. Gross, Ph.D.
Aventis Behring
1020 First Avenue
P.O. Box 61501
King of Prussia, PA 19406-0901
Tel: (610) 878-4490
Fax: (610) 878-4461
E-mail—
michael.gross@aventis.com

Filtration
James D. Wilson
115 Newell Village Circle
Seymour, TN 37865
Tel: (865) 609-1694
Fax: (865) 609-1690
E-mail—
wilsojdel@chartertn.net

GMP Purchasing
Nancy M. Kochevar
Amgen, Inc.
MS 9-1-E
One Amgen Center
Thousand Oaks, CA 91320-1799
Tel: (805) 447-4813
Fax: (805) 447-1904
E-mail—
nancyk@amgen.com

Inspection Trends/ Regulatory Affairs
Robert L. Dana
Elkhorn Associates Inc.
4828 Patrick Place
Liverpool, NY 13088
Tel: (315) 457-3242
Fax: (315) 451-7363
E-mail—
rld1242@aol.com

Isolation Technology
Dimitri P. Wirchansky
Jacobs Engineering Group, Inc.
Three Tower Bridge
Two Ash Street, Ste. 3000
Conshohocken, PA 19428
Tel: (610) 567-4452
Fax: (610) 238-1100
E-mail—
dimitri.wirchansky@jacobs.com

Lyophilization
Edward H. Trappler
Lyophilization Techology
30 Indian Drive
Ivyland, PA 18974
Tel: (215) 396-8373
Fax: (215) 396-8375
E-mail—
etrappler@lyo-t.com

Microbiology/Environmental Monitoring
Jeanne E. Moldenhauer, Ph.D.
16100 W. Port Clinton Rd.
Lincolnshire, IL 60069
Tel: (847) 478-1745
E-mail—
jeannemoldenhauer@yahoo.com

Ophthalmics
Richard M. Johnson
Abbott Laboratories Inc.
Dept. 03-QA Bldg. AP6C
100 Abbott Park Road
Abbott Park, IL 60064-6091
Tel: (847) 938-1750
Fax: (847) 938-3106
E-mail—
richard.m.johnson@abbott.com

Packaging Science
Edward J. Smith, Ph.D.
Packaging Science Resources
237 Chapel Lane
King of Prussia, PA 19406
Tel: (610) 265-9029
Fax: (610) 265-2307
E-mail—
esmithpkg@aol.com

Production and Engineering
David W. Maynard
Maynard & Associates, LLC
226 Renfrew Ave.
Trenton, NJ 08618
Tel: (609) 392-6462
Fax: (609) 392-8623
E-mail—
davmaynard@aol.com

Quality Assurance/ Quality Control
Don E. Elinski
120 Peregrine Circle
Broomfield, CO 80020
E-mail—
elinski@aol.com

Solid Dosage Forms
Pedro J. Jimenez, Ph.D.
Eli Lilly & Co.
Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: (317) 277-3618
Fax: (317) 276-4669
E-mail—
jimenez_pedro_j@lilly.com

Stability
Rafik H. Bishara, Ph.D
Eli Lilly & Co.
DC 2623 Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: (317) 276-4116
Fax: (317) 276-1838
E-mail—
rhb@lilly.com

Sterilization/Aseptic Processing
James P. Agalloco
Agalloco & Associates
2162 US Highway 206
Belle Mead, NJ 08502
Tel: (908) 874-7558
Fax: (908) 874-8161
E-mail—
jagalloco@aol.com

Training
Thomas W. Wilkin, Ed.D.
Schering-Plough
Building K-1-2 F41
2000 Galloping Hill Road
Kenilworth, NJ 07033
Tel: (908) 298-5213
Fax: (908) 298-2720
E-mail—
thomas.wilkin@spcorp.com

Vaccines
Frank S. Kohn, Ph.D.
Wyeth-Lederle Vaccines & Pediatrics
4300 Oak Park
Sanford, NC 27330
Tel: (919) 775-7100 ext. 4304
Fax: (919) 774-1142
E-mail—
kohnf@labs.wyeth.com

Validation
Bohdan M. Ferenc
1 Brandywine Ct.
Succasunna, NJ 07876
Tel: (973) 927-9152
E-mail—
biferenc@aol.com

Visual Inspection of Parenterals
John G. Shabushnig, Ph.D.
Pharmacia Corporation
7171 Portage Road
M/S 2130-41-108
Kalamazoo, MI 49001-0199
Tel: (616) 833-8906
Fax: (616) 833-5195
E-mail—
john.g.shabushnig@pharmacia.com

FDA Documents Available

For a full listing of documents available, please contact PDA or visit our Web site, www.pda.org.

Guide to Inspections of Pharmaceutical Quality Control Laboratories; July 1993; Office of Regulatory Affairs; 15 pp; $15 members/$30 nonmembers. **FDA 28**

Guide to Inspections of Validation of Cleaning Processes; July 1993; Office of Regulatory Affairs; 9 pp; $15 members/$30 nonmembers. **FDA 29**

Guide to Inspections of High Purity Water Systems; July 1993; Office of Regulatory Affairs; 13 pp; $15 members/$30 nonmembers. **FDA 31**

Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories; July 1993; Office of Regulatory Affairs; 8 pp; $15 members/$30 nonmembers. **FDA 32**

Guideline on Sterile Drug Products Produced by Aseptic Processing; June 1987; CDER, CBER, Office of Regulatory Affairs; 43 pp; $15 members/$30 nonmembers. **FDA 33**

Guideline on Validation of Analytical Methods: Definitions & Terminology (Q2A); March 1, 1994; CDER; 4 pp; ICH Step 5 Final Guideline. $15 members/$30 nonmembers. **FDA 53**

Review Guidance, Validation of Chromatographic Methods; November 1994; CDER; 33 pp; $25 members/$40 nonmembers **FDA 108**

Validation Documentation Inspection Guide; 1993; ORA; 27 pp; ***Not available on the Internet.*** $25 members/$40 nonmembers. **FDA 110**

Guideline on the Validation of Analytical Procedures: Methodology; May 19, 1997; ICH; 5 pp; ICH Step 5 Final Guideline. $15 members/$30 nonmembers. **FDA 125 (revised)**

Draft Guidance for Industry: Manufacturing, Processing or Holding of Active Pharmaceutical Ingredients; April 17, 1998; CDER/CBER/CVM; 57 pp; Revised draft of FDA GMP guidance for APIs originally released in September 1996. $35 members/$50 nonmembers. **FDA 158**

General Principles of Software Validation Guidance for Industry; June 1, 1997; CDRH; 20 pp; $25 members/$40 nonmembers. **FDA 187**

Stability Testing of Drug Substances and Drug Products; June 1998; CDER/CBER; 114 pp; FDA's revised draft guidance for industry on stability testing. $35 members/$50 nonmembers. **FDA 220**

Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production; Draft Guidance; September 1998; CDER; 11 pp; $15 members/$30 nonmembers. **FDA 229**

PDA Books Available

Cleaning & Cleaning Validation: A Biotechnology Perspective; *R. Brunkow* et al.; 1995; 190 pp; $125 members/$145 nonmembers. **Item No. 13002**

PDA Technical Reports Available

Evaluation, Validation and Implementation of New Microbiological Testing Methods; This report is intended to provide a general approach to the introduction of new microbiology methods in a government-regulated environment. It is also intended to provide guidance for the successful evaluation, validation and implementation of new microbiological methods needed by the pharmaceutical, biotechnology and medical device industries to assure product quality. These new methodologies offer significant improvements in terms of the speed, accuracy, precision and specificity with which testing can be performed. 2000; 37 pp; $75 members/$125 nonmembers. **TR 33**

Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations; Developed in response to an FDA challenge to develop a standard way to assess the structural integrity of acquired software, TR 32 was written by the PDA Supplier Auditing and Qualification Task Group (SA&Q), which included pharmaceutical companies, suppliers, auditors and FDA members who used their experiences with supplier audits and performed research to draft a common practice to satisfy industry needs. The scope of the project included audits of computer products and services and describes how the SA&Q Task Group, led by George J. Grigonis, Jr., Merck and Co., Inc., developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. December 1999; $90 members/$140 nonmembers (paper copy)**; TR 32**. $50 members/$75 nonmembers (CD-ROM format) **TR 32 CD**

Validation and Qualification of Computerized Laboratory Data Acquisition Systems; Prepared by the PhRMA CSVWG and the PDA Computer Related Systems-Laboratory Systems Task Group, TR 31 provides guidance to lab scientists, technicians and managers responsible for the implementation, testing, control and usage of Laboratory Data Acquisition Systems (LDAS) used within a GMP-, GLP- or GCP-regulated environment. Addresses computerized LDAS within a regulated environment; also applicable to systems critical to the operation of a company, department or function, regardless of the system's regulatory impact. 1999; 12 pp; $50 members/$75 nonmembers. **TR 31**

Points to Consider for Cleaning Validation; This document provides guidance relative to the validation of cleaning for a broad range of processing systems and product types within the pharmaceutical industry. The report includes perspectives on the application of cleaning validation guidance in the areas of finished pharmaceuticals, bulk pharmaceutical chemicals, biopharmaceuticals and clinical products. It is the pharmaceutical companion to "Cleaning and Cleaning Validation: A Biotechnology Perspective" published by PDA in 1996. 1998; 23 pp; $75 members/$125 nonmembers. **TR 29**

Ordering Documents and Publications from PDA

Use this form to order any of the documents mentioned in the *PDA Letter*. If ordering by mail, include a check payable to PDA to the address below. Be sure to include shipping and handling charges in the total. If ordering by fax, please include all credit card information. All orders must include payment.

Name _____ Member No. _____

Company _____

Address _____

City _____ State _____ Country _____ Zip/Postal Code _____

Tel: _____ Fax: _____ E-mail: _____

Payment type: ☐ Check drawn on a US bank ☐ MC ☐ VISA ☐ AMEX

☐ Wire Transfer

Credit Card # _____ Exp. _____

Mail to: PDA, P.O. Box 79465
Baltimore, MD 21279-0465 USA
Fax: (301) 986-1093

Name as it appears on credit card (please print clearly) _____

Questions? (301) 986-0293 x133 or *info@pda.org* Signature _____

Document No.	Title	Qty.	Price	Total

Shipping
Domestic US orders are shipped via UPS Ground. Second-day and Next-day Air service is available. Call or e-mail for prices.

Domestic US Shipping & Handling Rates

If your order totals:	*Add:*
$ 15.00 and under	$ 5.95
$ 15.01–$ 75.00	$ 7.95
$ 75.01–$150.00	$ 9.95
$150.01–$250.00	$11.95
$250.01 or more	$13.95

International orders (including Puerto Rico & Canada): Please add 20%, minimum $18.00, maximum $150.00. Items are sent priority air, but 2-day service is available for some countries; please call for details.

Payment
Payments must be made in US dollars by check drawn on a US bank, **by electronic money transfer (SunTrust Bank ABA #051000020, PDA Account #209364254, Swift #UVBIUS33), net of all bank charges**; or credit card.

Federal Tax I.D. #52-1906152

Please allow 4-6 weeks for delivery on some items.

Subtotal	
Shipping & Handling	
5% Tax *(MD Residents Only)*	
TOTAL	

LTR 05/01

PDA USE:
Date: _____ **Check:** _____ **Amount:** _____ **Acct:** _____

New member contact information is forwarded to chapters on an ongoing basis. For immediate notification of chapter events, please contact your local representative below and ask to be placed on the chapter mailing list.

Australia Chapter
Contact: **Mary Sontrop**
ZLB Bioplasma AG
Tel: +41-31-344-4305
Fax: +41-31-344-5555
E-mail: *mary.sontrop@zib.com*

Canadian Chapter
Contact: **Grace Chin**
Pellemon, Inc.
Tel: (416) 422-4056 x230
Fax: (416) 422-4638
E-mail: *ching2@snc-lavalincom*
Web site: ***www.pdacanada.org***

Capital Area Chapter
Areas Served: Maryland, District of Columbia, Virginia, West Virginia
Contact: **Allen Burgenson**
DynPort Vaccine Company, LLC
Tel: (301) 607-5046
Fax: (301) 607-5099
E-mail: *BurgensA@dynport.com*
Web site: ***www.pdacapitalchapter.org***

Delaware Valley Chapter
Areas Served: Delaware, New Jersey, Pennsylvania
Contact: **Mark Kaiser**
Lancaster Laboratories
Tel: (717) 656-2300 x1263
Fax: (717) 656-2681
E-mail: *Mwkaiser@lancasterlabs.com*
Web site: ***www.pdadv.org***

European Chapter
Contact: **James Lyda**
PDA Europe Office
Switzerland
Tel: +41-61-703-1688
Fax: +41-61-703-1689
E-mail: *lyda@pda.org*

Israel Chapter
Contact: **Karen S. Ginsbury**
PCI–Pharmaceutical Consulting Israel Ltd.
Tel: +972-3-9214261
Fax: +972-3-9215127
E-mail: *kstaylor@netvision.net.il*

Italy Chapter
Contact: **Vincenzo Baselli**
Pall Italia
Tel: +39-02-477-961
Fax: +39-02-4122-985
E-mail: *vincenzo_baselli@pall.com*

Japan Chapter
Contact: **Hiroshi Harada**
Tel: +81-3-3815-1681
Fax: +81-3-3815-1691
E-mail: *van@bcasj.or.jp*

Korea Chapter
Contact: **Jong Hwa A. Park**
Tel: +82-2-538-9712
Fax: +82-2-569-9092
E-mail: *Jong_Hwa_Park@pall.com*

Metro Chapter
Areas Served: New Jersey, New York
Contact: **Felicia Manganiello**
Tel: (732) 521-8274
Fax: (732) 521-5933
E-mail: *fmanganiello@aol.com*

Midwest Chapter
Areas Served: Illinois, Indiana, Ohio, Wisconsin, Iowa, Minnesota
Contact: **Robert S. Murphy**
Searle
Tel: (847) 581-6118
Fax: (847) 581-6553
E-mail: *robert.s.murphy@monsanto.com*

Mountain States Chapter
Areas Served: Colorado, Wyoming, Utah, Idaho, Nebraska, Kansas, Oklahoma, Montana
Contact: **John M. Elvig**
Colorado Quality Assoc., Inc.
Tel: (303) 666-0319
Fax: (303) 926-9006
E-mail: *carl10@prodigy.net*

New England Chapter
Areas Served: Massachusetts, Connecticut, Rhode Island, New Hampshire, Vermont, Maine
Contact: **Robert A. Pazzano, P.D.**
Validation and Training Services
Tel: (508) 870-0007 x140
Fax: (508) 870-0224
E-mail: *robert_pazzano@vtsinc.net*

Southeast Chapter
Areas Served: North Carolina, South Carolina, Tennessee, Virginia, Florida, Georgia
Contact: **Mary Carver**
Eisai, Inc.
Tel: (919) 474-2149
Fax: (919) 941-6934
E-mail: *carver@eisai.com*
Web site: ***www.pdase.org***

Southern California Chapter
Areas Served: Southern California
Contact: **Maria Wagner**
International Medication Systems Limited
Tel: (626) 459-5279
Fax: (626) 459-5592
E-mail: *mariaw@ims-limited.com*

Taiwan Chapter
Contact: **Tuan-Tuan Su**
Tel: +8862-2550-9301
Fax: +8862-2555-4707
E-mail: *pdatc@ms17.hinet.net*

United Kingdom and Ireland Chapter
Contact: **Colin Booth**
GlaxoSmithKline
Tel: +44-1-920-883-637
Fax: +44-1-920-882-295
E-mail: *cb3883@glaxowellcome.co.uk*

West Coast Chapter
Areas Served: Northern California
Contact: **Michele Livesey**
Genentech, Inc.
Tel: (650) 225-3536
Fax: (650) 225-5402
E-mail: *Livesey@gene.com*

PDA
An International Association For Pharmaceutical Science And Technology

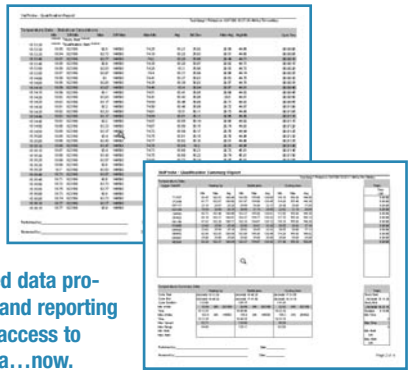
Introducing

ValProbe™

Another innovation from the leader in process validation.

Process monitoring has never been easier.

Wireless design. Advanced data processing. Wide operational ranges. FDA compliant. Customized reporting. It all adds up to a revolutionary wireless process monitoring and validation system with unprecedented ease-of-use benefits.



Advanced data processing and reporting provide access to your data…now.

Accuracy and flexibility you can count on…because it's from Kaye.

The ValProbe system employs a wireless probe design which eliminates the need for hard-wired sensors, simplifying access to hostile, remote, and hard-to-reach environments. Operating from –60° C to 360° C and 0–75 psi, it's suitable for a wide range of applications including steam and Et0 sterilization, tunnels, ovens, incubators, rotating machinery, and conveyors.

Innovation from the leader.

ValProbe's ability to rapidly process data from up to 50 sensors saves time and provides quick access to critical temperature, humidity, and pressure data. Of course, the ValProbe system complies with FDA Regulation 21 CFR Part 11, ensuring that the most stringent requirements for electronic signatures and records are met.

To request more information or a demonstration of this breakthrough process validation system, call us at

1-800-964-5293

or visit us at www.kayeinstruments.com

- **ACCURACY**
- **COMPLIANCE**
- **EASE OF USE**
- **SERVICE**

KAYE®

Calendar of Events

PDA
An International Association For Pharmaceutical Science And Technology

JUNE

June 5-7, 2001
PDA-TRI New Jersey Course Series
Hilton - East Brunswick
East Brunswick, NJ

June 5, 2001
- **Using INFOSEC Technology and Procedures for 21 CFR Solutions**
- **PDA Audit Process Model Management Overview Training**

June 5-6, 2001
- **Basic Concepts in Cleaning and Cleaning Validation**

June 5-7, 2001
- **GMP Training Manager Workshop**
- **Active Pharmaceutical Ingredients: Manufacture Validation**
- **Pharmaceutical Water Systems Design and Validation**

June 6, 2001
- **Designing Regulatory Training that Works**

June 6-7, 2001
- **PDA Computer Products Supplier Auditor Training**

June 7, 2001
- **Writing and Auditing CGMP Documentation**
- **A Practical Guide to Change Control**

June 18-22, 2001
PDA-TRI Aseptic Processing Course (week 2)
Baltimore, MD

June 29, 2001
PDA-TRI Course: Contamination Control Basics
Baltimore, MD

JULY

July 18-19, 2001
PDA Southeast Chapter Meeting & PDA-TRI Courses
Sheraton Chapel Hill
Chapel Hill, NC

July 18, 2001
- **Using INFOSEC Technology and Procedures for 21 CFR 11 Solutions**

July 18-19, 2001
- **Parenteral Packaging: Rubber, Glass, Plastic, and Metal Seals**

July 19, 2001
- **Writing and Auditing CGMP Documentation**

July 23-27, 2001
PDA-TRI Aseptic Processing Course (week 1)
Baltimore, MD

AUGUST

August 6-8, 2001
PDA-TRI New Orleans Course Series
New Orleans, LA

August 6, 2001
- **Understanding the Regulatory Compliance Requirements of the US Pharmacopoeia**

August 6-7, 2001
- **A System-Based Approach to an FDA Inspection**
- **A Practical Approach to Aseptic Processing and Contamination Control**

August 6-8, 2001
- **Tablet Formulation**

August 7, 2001
- **Good Documentation Practices in the Pharmaceutical Industry**

August 8, 2001
- **Conducting Compliant Deviation Investigations for the Pharmaceutical Industry**
- **Everyday Compliance: Introduction to the CGMPs & Drug Regulation**
- **Identification of Microorganisms Using Comparative DNA Sequencing**

August 20-24, 2001
PDA-TRI Aseptic Processing Course (week 2)
Baltimore, MD

SEPTEMBER

September 6-7, 2001
PDA/IABs Conference on Process Validation of Biologics and Biotechnology Products: A State-of-the-Art Perspective
Berlin Hilton Hotel
Berlin, Germany

September 7, 2001
PDA-TRI Course: Contamination Control Basics
Baltimore, MD

September 10-14, 2001
PDA/FDA Joint Conference, Courses and Tabletop Exhibit
Hyatt Regency Washington, DC on Capitol Hill
Washington, DC

September 17-18, 2001
PDA-TRI Course: Fundamentals of D, F & z Values
Baltimore, MD

Be sure to watch
www.pda.org
for conference and course updates!

continued on page 24