FDA/PQRI Workshop on A Drug Quality System in the 21st Century

April 22-24, 2003

Renaissance Washington DC Hotel

Washington, DC

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Workshop Information

Goals and Objectives

This workshop is designed to:

- Provide an overview of FDA activities and current thinking
- Provide an opportunity for in-depth discussion on four topic areas, namely:
  Risk-Based cGMPs: Defining Risk and Quality
  Integrated CMC Review and Inspection
  Changes Without Prior Approval
  Manufacturing Science
- Develop a workshop report summarizing stakeholder perspectives and suggestions on the FDA initiative and current thinking

Planning Committee

FDA and PQRI would like to recognize and thank the planning committee members listed below for their time, effort and dedication to the planning and execution of the FDA/PQRI Workshop on A Drug Quality System in the 21st Century.

Ajaz S. Hussain, Ph.D., Food and Drug Administration, **Co-Chair**
Tobias Massa, Ph.D., Eli Lilly and Company, **Co-Chair**
Ed Allera, Animal Drug Alliance
William Bargo, Food and Drug Administration
Robert Baum, Ph.D., Pfizer Global Research and Development
Steve Bende, Ph.D., Generic Pharmaceutical Association
Bruce Bird, Pfizer, Inc.
Don G. Burstyn, Ph.D., Alkermes, Inc.
Dennis Casey, Ph.D., Pfizer, Inc.
Anthony A. Charity, Food and Drug Administration
Jon Clark, Food and Drug Administration
Robert Coleman, Food and Drug Administration
Raafat Fahmy, Ph.D., Food and Drug Administration
Sylvia Gantt, Product Quality Research Institute
C. Greg Guyer, Ph.D., Merck and Company, Inc.
Todd Harrison, Animal Drug Alliance
Charles P. Hoiberg, Ph.D., Food and Drug Administration
Frank O. Holcombe, Jr., Ph.D., Food and Drug Administration
Christopher C. Joneckis, Ph.D., Food and Drug Administration
Kathleen Jordan, Food and Drug Administration
Edward Kaminski, Ph.D.,Wyeth Pharmaceuticals
See-Yan Lam, Pharm.D., Ph.D., Food and Drug Administration
Ken Lavin, TEVA Pharmaceuticals USA
Clark Lennon, Pfizer, Inc.
Gerry Migliaccio, Pfizer, Inc.
David J. Miner, Ph.D., Eli Lilly and Company
Christine Mundkur, Barr Laboratories
Elise Murphy, Food and Drug Administration
Nicholas Pelliccione, Ph.D., Schering-Plough Research Institute
Donna Peterson, Amgen, Inc.
Sandy Phelan, Animal Health Institute

Workshop Information continued

Janet Showalter, Food and Drug Administration
Rick Smith, Aventis Pasteur, Inc.
Wendy Taylor, Biotechnology Industry Organization
Alice Till, Ph.D., Pharmaceutical Research and Manufacturers of America
Henrietta Ukwu, M.D., F.A.C.P., Merck Research Laboratories
D. Christopher Watts, Ph.D., Food and Drug Administration

Handouts

Speaker handouts not distributed at this meeting may be available from *AAPS Pharmaceutica* after April 29, 2003 at **http://pqri.org/gmpworkshop/**

Workshop Agenda

Monday, April 21

5:00 pm - 7:00 pm *Grand Ballroom South Foyer*
Registration

Tuesday, April 22

7:00 am - 5:45 pm *Grand Ballroom South Foyer*
Registration

8:00 am - 5:45 pm *Grand Ballroom South*
General Session

8:00 am
Introduction and Welcome
John M. Taylor, Esq.
Food and Drug Administration

8:30 am
Keynote Address: Overview and Current Status of the Initiative
Janet Woodcock, M.D.
Food and Drug Administration

9:15 am
Industry Perspective on the Initiative
C. Greg Guyer, Ph.D.
Merck and Company, Inc.

10:00 am *Grand Ballroom Foyer*
Break

10:30 am
International Regulatory Perspective and Consideration
Gordon Munro, Ph.D.
Medicines Control Agency

11:00 am
Part 11 Update
Joseph Famulare
Food and Drug Administration

11:15 am
Risk-Based cGMPs: Defining Risk and Quality
Bruce Burlington, M.D.
Wyeth Pharmaceuticals

11:45 am
Risk-Based cGMPs: Defining Risk and Quality—Academic Perspective
Nuzer Singpurwalla, Ph.D.
George Washington University

12:15 pm *Grand Ballroom Central*
Lunch
Complimentary to all registrants

1:30 pm
Integrating CMC Review and Inspection
John M. Taylor, Esq.
Food and Drug Administration

2:00 pm
Integrating CMC Review and Inspection
Christine Mundkur
Barr Laboratories

2:30 pm
Changes Without Prior FDA Approval
Dennis M. Bensley, Jr., Ph.D.
Food and Drug Administration

3:00 pm
Changes Without Prior FDA Approval
Kenneth Seamon, Ph.D.
Amgen, Inc.

3:30 pm *Grand Ballroom Foyer*
Break

4:00 pm
Manufacturing Science
G.K. Raju, Ph.D.
Massachusetts Institute of Technology

4:30 pm
Manufacturing Science - Industry Perspective
Gerry Migliaccio
Pfizer, Inc.

5:00 pm
Quality Systems and Regulatory Innovation for the 21st Century
Joyce Ramsbotham
European Federation of Pharmaceutical Industries and Associations

5:15 pm
Panel Discussion
Objectives and Logistics for Breakout Sessions

Workshop Agenda continued

6:00 pm - 7:00 pm *Renaissance Ballroom*
Reception

Wednesday, April 23

7:30 am - 5:00 pm *Grand Ballroom South Foyer*
Registration

8:30 am - 10:00 am
BREAKOUT SESSIONS

Breakout Session A *Grand Ballroom South*
Risk-Based cGMPs: Defining Risk and Quality
PhRMA Lead

Breakout Session B *Renaissance East*
Changes Without Prior Approval
GphA Lead

Breakout Session C *Renaissance West A*
Manufacturing Science
BIO Lead

Breakout Session D *Renaissance West B*
Integrating CMC Review and Inspection
ADA/AHI Lead

10:00 am *Grand Ballroom Foyer*
Break

10:30 am - 12:00 pm
BREAKOUT SESSIONS REPEATED

Breakout Session A *Renaissance West B*
Risk-Based cGMPs: Defining Risk and Quality
ADA/AHI Lead

Breakout Session B *Grand Ballroom South*
Changes Without Prior Approval
PhRMA Lead

Breakout Session C *Renaissance East*
Manufacturing Science
GPhA Lead

Breakout Session D *Renaissance West A*
Integrating CMC Review and Inspection
BIO Lead

12:00 pm *Grand Ballroom Central*
Lunch
Complimentary to all registrants

1:30 pm - 3:00 pm
BREAKOUT SESSIONS REPEATED

Breakout Session A *Renaissance West A*
Risk-Based cGMPs: Defining Risk and Quality
BIO Lead

Breakout Session B *Renaissance West B*
Changes Without Prior Approval
ADA/AHI Lead

Breakout Session C *Grand Ballroom South*
Manufacturing Science
PhRMA Lead

Breakout Session D *Renaissance East*
Integrating CMC Review and Inspection
GphA Lead

3:00 pm *Grand Ballroom Foyer*
Break

3:30 pm - 5:00 pm
Breakout Sessions Repeated

Breakout Session A *Renaissance East*
Risk-Based cGMPs: Defining Risk and Quality
GPhA Lead

Breakout Session B *Renaissance West A*
Changes Without Prior Approval
BIO Lead

Breakout Session C *Renaissance West B*
Manufacturing Science
ADA/AHI Lead

Breakout Session D *Grand Ballroom South*
Integrating CMC Review and Inspection
PhRMA Lead

Thursday, April 24

8:00 am - 12:30 pm *Grand Ballroom South Foyer*
Registration

8:30 am - 12:30 pm *Grand Ballroom South*
General Session

Workshop Agenda

8:30 am
Benchmarking Semiconductor Manufacturing and Its Applicability to Pharmaceutical Manufacturing
Jackson Nickerson, Ph.D.
John M. Olin School of Business, Washington University

Jeffrey Macher, Ph.D.
McDonough School of Business, Georgetown University

9:00 am
Breakout Session Summary: Changes Without Prior Approval
Rick Smith
Aventis Pasteur, Inc.

9:30 am
Breakout Session Summary: Manufacturing Science
Gerry Migliaccio
Pfizer, Inc.

10:00 am *Grand Ballroom Foyer*
Break

10:30 am
Breakout Session Summary: Risk-Based cGMPs: Defining Risk and Quality
Edward Kaminski, Ph.D.
Wyeth Pharmaceuticals

11:00 am
Breakout Session Summary: Integrating CMC Review and Inspection
Joseph J. Anisko, Ph.D.
Alkermes, Inc.

11:30 am
Panel Discussion

12:30 pm
Adjournment

Speaker Abstracts and Biographies

Introduction and Welcome

John M. Taylor, Esq., Food and Drug Administration

John M. Taylor is currently the Associate Commissioner for Regulatory Affairs, FDA where he oversees the Office of Regulatory Affairs' headquarters and field operations. Mr. Taylor received his law degree in 1991 from the College of William and Mary. He started his career with the Food and Drug Administration in 1991. From 1991 to 1996 he worked in the Office of the Chief Counsel (OCC). In OCC, he was responsible for all phases of criminal and civil litigation, involving violations of the Federal Food, Drug and Cosmetic Act, and other federal laws. He then moved to the Office of the Commissioner and became the Senior Advisor for Regulatory Policy. In the spring of 1999, he served as a special assistant to Dennis Baker in the immediate Office of the Associate Commissioner for Regulatory Affairs. From April through July 2000, he served as the Acting Director of the Office of Compliance in the Center for Drug Evaluation and Research. From August through September 2002, Mr. Taylor served as the Director of the Office of Enforcement before accepting the position of Associate Commissioner for Regulatory Affairs.

Notes

Keynote Address: Overview and Current Status of the Initiative

No abstract available at time of print.

Janet Woodcock, M.D., Food and Drug Administration

Janet Woodcock, M.D. is the Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. The Center is responsible for regulating prescription, over the counter and generic drugs. As head of CDER, Dr. Woodcock has close interactions with diverse constituencies, including the clinical and scientific communities, members of Congress and the Administration, national media, patient and consumer advocacy groups, the International Drug Regulatory Community, the pharmaceutical industry, and representatives of Federal and State agencies. She frequently appears in, or is quoted by, the national media and has testified repeatedly before Congress. During her tenure, Dr. Woodcock has led the Center through many changes. At her selection for the director's position in 1994, the Center faced the task of meeting formidable performance goals of the Prescription Drug User Fee Act (PDUFA) of 1992. Under Dr. Woodcock's stewardship, CDER sped delivery of new drugs to Americans while preserving high standards for quality, efficacy and safety. To date, the Center has cut new and generic drug review times nearly in half. For its accomplishments related to drug review, FDA received the Innovations in American Government Award in 1997. Among the nation's most prestigious public-service prizes, the award recognizes governmental initiatives that provide creative solutions to pressing social and economic problems. Under Dr. Woodcock's leadership, CDER's regulatory decision-making has been made more open and transparent to the public. Changes have included publishing CDER's regulatory procedures and policies, developing more than 100 technical "guidances" that describe regulatory standards, providing an unprecedented degree of participation of consumer and patient representatives in CDER processes, and creating an extensive Center website which includes drug reviews and consumer information. A current initiative involves transferring all CDER information processes to electronic format. At present, adverse drug event reports and many regulatory submissions are being filed electronically. When completed, this initiative will allow the Center to make much more drug information publicly available in an organized format. Prior to joining CDER, Dr. Woodcock was director of the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER). There she oversaw approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis. Dr. Woodcock has earned numerous FDA awards including two Commissioner's Special Citations. She received a Presidential Rank Meritorious Executive Award, the Nathan Davis Award from the American Medical Association in 1999, and the Roger W. Jones Award for Executive Leadership from American University in 2000. Dr. Woodcock received her M.D. from Northwestern University Medical School in 1977. She received her undergraduate degree from Bucknell University. She has held faculty appointments at the Pennsylvania State University and the University of California at San Francisco. She lives in Maryland with her husband and is the mother of two daughters.

Notes

Industry Perspective on the Initiative

FDA has undertaken a visionary initiative to enhance the regulation of pharmaceutical manufacturing and product quality. Industry applauds FDA's leadership in this challenging task and welcomes the opportunity to participate and support efforts to improve the process for "smarter" regulation development and application. The success of this initiative relies on the close collaboration between FDA, Industry and Academia on an on-going basis. While safety and efficacy will never be compromised, industry and FDA are seeking a more effective and efficient process for establishing useful and sound regulations, technologies, and systems to advance overall product quality assurance. Understanding and agreeing to a consistent definition of risk is key to the success of this initiative. Risk and science-based approaches should be used to establish focused and value-added expectations for GMP control. Having an issue resolution process that is based on good science and risk-based principles will aid in defining what is "current" in cGMP. Facilitating the introduction of new technologies, that are scientifically sound, can help optimize effort to achieve overall success while improving GMP control. Filing requirements and GMPs must stay focussed on what "should" be measured and controlled, rather than what "can" be analyzed. While the end point has always been the same—assurance of product safety and efficacy, the route may not have always been clear or direct. A Quality Systems oriented approach will provide a systematic means for establishing consistent expectations for GMP controls and pave the way for further harmonization of GMP expectations worldwide. It is essential that a collaborative and unified effort be made to assure GMP expectations are useful, value-added and truly contribute to overall product quality and benefit to the patient.

C . Greg Guyer, Ph.D., Merck & Co., Inc.

Dr. Guyer is Vice President, MMD Quality Assurance, Merck & Co., Inc. West Point, PA. He received his B.S. in Chemistry from the University of Georgia in 1983, a Ph.D. in Analytical Chemistry from American University in 1991 and an M.B.A. from Lehigh University in 1998. From 1984-1992, Dr. Guyer was Branch Chief and Research Chemist, Division of Chemistry, FDA, Center for Veterinary Medicine, in Rockville, MD. From 1992-1994 Dr. Guyer was Director, Division of Chemistry, Office of Generic Drugs, FDA, Center for Drug Evaluation & Research, Rockville, MD. In 1994, he joined Merck & Co., Inc., Merck Research Laboratories, West Point, PA as Associate Director in Worldwide Regulatory CMC. He increased responsibilities in that area until 1997, and then moved into positions of increasing responsibility as Senior Director, North American Quality Operations until he was appointed Vice President, Quality Assurance in 2001. Dr. Guyer is serving or has served on the following committees: PhRMA GMP Steering Committee, PhRMA Quality Technical Committee, PQRI Technical Manufacturing Sub-Committee, PhRMA Quality Bulk Pharmaceutical Working Group, Quality Executive Roundtable, Adjunct Professor, Regulatory Training, Temple University, Regulatory Affairs Professional Society, and Joint World Health Organization/FAO Expert Committee on Food Additives.

Notes

International Regulatory Perspective and Consideration

No abstract available at time of print.

Gordon Munro, Ph.D., Medicines Control Agency

Gordon has a B.Sc. in Pharmacy and a Masters and Ph.D. in Analytical Chemistry. He was employed within the pharmaceutical industry by Glaxo for over 25 years at various times in research, production and quality assurance of both drug substances and drug products. His career has incorporated a range of senior technical positions working in the United Kingdom, Singapore and the United States of America, as well as several years in Glaxo's International Quality Assurance Division. His final role in industry was as Director of Quality and Compliance for Glaxo Wellcome Operations. For the past five years he has been Director of Inspection and Enforcement Division for the United Kingdom Medicines Control Agency, where he is responsible for the GMP, GDP, GLP and GCP Inspectorate; the licensing of manufacturers and wholesale dealers, enforcement of the Medicines Act and related legislation; the United Kingdom's medicines testing scheme and provision of laboratory service to the Agency; the classification of borderline substances and the management of the British Pharmacopoeia and the policy matter relating to these operations. He has represented the Agency on the PIC/S Committee of Experts, the EMEA Ad Hoc Inspection Working Group and served recently as rapporteur for the ICH Q7A topic on Good Manufacturing Practice for Active Pharmaceutical Ingredients on behalf of the European Community Regulators. In his wider role as a member of the Management Board of the MCA, he has been involved in a range of corporate initiatives such as championing an Agency-wide Culture and Communication change program and leading on pan Agency Business Development. The latter involves, for example, acting as the UK Project Director for the "twinning" activities with the Czech Medicines Regulatory Authority. He is currently Acting Chief Executive at the Medicines Control Agency.

Notes

Part 11 Update

Joseph Famulare, Food and Drug Administration

No abstract available at time of print.

Joseph Famulare is the Director, Division of Manufacturing and Product Quality, Office of Compliance in the Center for Drug Evaluation and Research. The Division reviews and follows up on all cGMP cases submitted by FDA field offices. He is also responsible for the issuance of cGMP guidance to FDA field offices and to industry. The Division is responsible for the issuance of guidance documents and for regulations that issue in the cGMP area. The Division also handles the Preapproval Inspection Program for foreign and domestic firms and is the home of the Foreign Inspection Team, which reviews all foreign pharmaceutical inspections. Mr. Famulare began his career as an Investigator in Newark District in 1977. He subsequently worked as a Resident In Charge Investigator in the Buffalo District and a Supervisory Investigator in the New York District. Much of his fieldwork has been in the drug cGMP area.

Notes

Risk-Based cGMPs Defining Risk and Quality

- Scope
- Goals
- Definition
- Introduction
- Background information
- Guiding principles to achieve these goals
- Controls to achieve goals
- Conclusion
- Addendum
- Examples of using risk-based management principles
- Existing requirements

Bruce Burlington, M.D., Wyeth Pharmaceuticals

Bruce Burlington is Executive Vice President for Quality, Regulatory, and Safety at Wyeth Pharmaceuticals located in Radnor, Pennsylvania. In this position, he has responsibility for the Regulatory Affairs, Safety Surveillance, Health Outcomes, Quality Operations, Compliance Operations and Audit Departments all on a worldwide basis. These responsibilities span the company's human prescription products (pharmaceuticals, bio-pharmaceuticals, medical devices and vaccines) and (for the Quality, Compliance and Audit Departments) all human pharmaceuticals, bio-pharmaceuticals, vaccines, medical devices, infant formula and OTC drugs. As a member of the corporate Law and Regulatory Committee, as well as both the Wyeth Research and Wyeth Pharmaceutical Management Committees, he is broadly involved in Wyeth's general management. Graduated with a M.D. from Louisiana State University School of Medicine at New Orleans in 1976, Bruce undertook clinical training at the University of Colorado earning board certification in Internal Medicine and Infectious Diseases. He served on the University's faculty from August 1979 through October 1981. Bruce moved to Wyeth in March 1999 after 17 years at the United States Food and Drug Administration. While at FDA, he was a research fellow in the Center for Biologics (the Viral Vaccine program) and then headed the Investigational New Drug Division during the development of many key biotechnology products (Tissue Plasminogen Activator, Alfa Interferon, Erythropoietin, GCSF, recombinant vaccines, etc.). He moved to the New Drug Evaluation program from 1988 through 1993. Subsequent to the generic drug scandals, he spent one year (as a collateral assignment) heading and reestablishing the credibility of the Generic Drugs program and then became Deputy Center Director for Medical Affairs. From 1993 to 1999 he managed FDA's Center for Medical Devices and Radiological Health, overseeing the U.S. government's regulatory programs for medical devices, *in vitro* diagnostic products, radiological health and mammography quality. During his career at FDA, Bruce received numerous awards for creative management and exceptional performance. He also continued a part-time medical practice and was a teaching preceptor in Emergency Medicine.

Notes

Risk-Based cGMPs: Defining Risk and Quality—Academic Perspective

Nozer Singpurwalla, Ph.D., George Washington University

No abstract or biography available at time of print.

Notes

Integrating CMC Review and Inspection

No abstract available at time of print.

John M. Taylor, Esq., Food and Drug Administration

John M. Taylor is currently the Associate Commissioner for Regulatory Affairs, FDA where he oversees the Office of Regulatory Affairs headquarters and field operations. Mr. Taylor received his law degree in 1991 from the College of William and Mary. He started his career with the Food and Drug Administration in 1991. From 1991 to 1996 he worked in the Office of the Chief Counsel (OCC). In OCC, he was responsible for all phases of criminal and civil litigation, involving violations of the Federal Food, Drug, and Cosmetic Act, and other federal laws. He then moved to the Office of the Commissioner and became the Senior Advisor for Regulatory Policy. In the spring of 1999, he served as a special assistant to Dennis Baker in the immediate Office of the Associate Commissioner for Regulatory Affairs. From April 2000 through July 2000, he served as the Acting Director of the Office of Compliance in the Center for Drug Evaluation and Research. From August 2000 through September 2002, Mr. Taylor served as the Director of the Office of Enforcement before accepting the position of Associate Commissioner for Regulatory Affairs.

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Integrating CMC Review and Inspection

Christine Mundkur, Barr Laboratories

No abstract or biography available at time of print.

Notes

Changes Without Prior FDA Approval

The short presentation will summarize FDA's current thinking and activities regarding the supplemental change approval process. Focusing on the current supplemental approval process will discuss potential solutions to lessen prior-approval reporting requirements, including the use of comparability protocols, the use of risk analysis in the change approval process, and FDA's strategic goals. The presentation is designed to stimulate discussion and constructive feedback from stakeholders during the breakout sessions regarding the current and desired future state of the change approval process.

Dennis M. Bensley, Jr., Ph.D., Food and Drug Administration

Dennis M. Bensley, Jr., Ph.D., is a Team Leader and Master Reviewer in the Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, Center for Veterinary Medicine (CVM), FDA. CVM's Division of Manufacturing Technologies is responsible for the pre-market review and approval of the chemistry, manufacturing and controls (CMC) information for both generic and innovator animal drug products; and is also responsible for the management of CVM's Pre-Approval Inspection (PAI) compliance program. Dr. Bensley received a B.A. in Chemistry from Towson State University, M.D. in 1983, and a Ph.D. in Organic Chemistry from West Virginia University in 1988. From 1988-1990, he worked in a postdoctoral position in the Chemistry Department of Georgetown University, District of Columbia, synthesizing novel cisplatin anti-tumor derivatives. He joined CVM in 1990 as a pre-market CMC reviewer and continues to enjoy employment as a Team Leader within the same pre-market review division. Dr. Bensley is currently CVM's representative in a number of FDA working groups and committees including the Changes Without Prior Review working group and the Process Analytical Technologies (PAT) Steering Committee. Dr. Bensley is involved in the preparation of a number of topic related FDA guidance documents, including the draft Chemistry, Manufacturing and Controls Changes to an Approved NADA or ANADA; BACPAC I; and the current draft Comparability Protocol "Small Molecules" guidance.

Notes

Changes Without Prior FDA Approval

Kenneth Seamon, Ph.D., Amgen, Inc.

No abstract or biography available at time of print.

Notes

Manufacturing Science

No abstract available at time of print.

G. K. Raju, Ph.D., Massachusetts Institute of Technology

G. K. is Executive Director of the Pharmaceutical Manufacturing Initiative (PHARMI) within the Program on the Pharmaceutical Industry (POPI) at MIT. He is Chairman and CEO of Light Pharma Incorporated—a consulting and technology company that is focused on pharmaceutical manufacturing. He is also Adjunct Professor of Industrial Pharmacy at Purdue University. In addition, G. K. is the Executive Director of the Consortium for the Advancement of Manufacturing of Pharmaceuticals (CAMP). He is also a Special Government Employee (SGE) of the U.S. Food and Drug Administration. G. K. was a member of the Process Analytical Technology (PAT) Subcommittee and is a member of the Manufacturing Subcommittee for the FDA Pharmaceutical Science Advisory Committee. G. K. obtained his M.S. in Chemical Engineering from MIT in 1989, his MBA from the MIT Sloan School of Management in 1994 and Ph.D. in Chemical Engineering from MIT in 1998. G. K. has worked with most of the top pharmaceutical and biotechnology companies. His expertise is in defining the strategic role of pharmaceutical development and manufacturing and enabling its performance with the pharmaceutical and biotechnology industry. He has benchmarked the pharmaceutical and biotechnology industry's manufacturing practices for a large number of years and has been involved in multiple organizational transformation efforts. His work focuses on pharmaceutical process innovation and addresses issues of regulatory compliance, six sigma, Pharma Informatics™, systems dynamics, organizational learning, process analytical technology, on-line sensors, economic modeling, data analysis, pattern recognition and knowledge based systems. G. K.'s work makes extensive use of simulation. He is the author of several publications and book chapters.

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Manufacturing Science—Industry Perspective

Gerry Migliaccio, Pfizer, Inc.

No abstract or biography available at time of print.

Notes

Quality Systems and Regulatory Innovation for the 21st Century

No abstract available at time of print.

Joyce Ramsbotham, European Federation of Pharmaceutical Industries and Associations

Joyce Ramsbotham is Global Vice President for Quality Assurance at Solvay Pharmaceuticals. She is also Chairperson of the EFPIA Manufacturing-GMP working group and member of the EFPIA Quality working group. She was also the EFPIA topic leader for ICH Q7A. She joined Solvay Pharmaceuticals in 1973. She has had a varied and interesting career starting in pharmaceutical development working on the development of new dosage forms. This was followed by a position as Director of International Regulatory Affairs. From this position she was appointed as Director of European Production for the Veterinary Division and was responsible for the production of vaccines and other sterile products in 3 factories in Europe. During this time she was also responsible for the building of a new factory for the production of vaccines. In her current position she is responsible for coordinating all quality issues within the company. She graduated with a first class honours degree from Nottingham University in the UK, but has lived in The Netherlands for the past 33 years.

Notes

Benchmarking Semiconductor Manufacturing and Its Applicability to Pharmaceutical Manufacturing

Our project seeks to study the sources of superior manufacturing performance in the pharmaceutical industry. While manufacturing technology is an obvious starting point, our operating assumption is that the interaction of incentives, organizational concerns, and regulatory oversight are central. Shop floor workers, production plant managers and new product development teams operate at a complicated nexus of incentives structured by the regulatory regime, corporate policy, business strategy, product strategy, and technological opportunities. Our goal is to develop an interdisciplinary perspective of how this complex nexus of incentives affects the adoption of new technology, manufacturing quality and performance, and regulatory performance. Our project necessarily will cross the disciplinary boundaries of economics, regulation, organization theory, manufacturing, and technology management. We will use insights gained to develop recommendations for the FDA on how to improve cGMPs for the 21st Century and for manufacturers on how to improve manufacturing performance and regulatory outcomes. Our presentation not only introduces our pharmaceutical manufacturing research project, but also summarizes the impact on the semiconductor industry of a similar study in which we were involved.

Jackson Nickerson, Ph.D., John M. Olin School of Business, Washington University

Professor Nickerson graduated from the University of California, Berkeley's Haas School of Business with a Ph.D. in Business and Public Policy. He also received an M.B.A. and a Master's degree in Mechanical Engineering from the University of California, Berkeley and a B.S.M.E. from Worcester Polytechnic Institute. His research focuses on organizational economics as it applies to business strategy and has published numerous articles on organization, strategy and manufacturing in industries ranging from pharmaceuticals, chemicals and semiconductor manufacturing to trucking and garment production. In addition to teaching undergraduate and Ph.D. courses in strategy, he teaches courses in Strategic Management in Health Organizations and Strategic Management in the Life Sciences. Prior to entering his Ph.D. Program, Jackson worked as a control systems engineer for NASA. He can be reached at (314) 935-6374 and nickerson@olin.wustl.edu.

Jeffrey Macher, Ph.D., McDonough School of Business, Georgetown University

Professor Macher received his undergraduate degree in computer engineering from the College of Engineering at the University of Michigan; his M.B.A. from the Amos Tuck School of Business Administration at Dartmouth College; and his Ph.D. from the Walter A. Haas School of Business at the University of California, Berkeley. Professor Macher has conducted research on the semiconductor industry for a number of years, mainly through the University of California, Berkeley Competitive Semiconductor Manufacturing Research Program, and previously worked for Motorola Incorporated. His research also includes an examination of the market entry, entry mode and technology choice decisions of multinational semiconductor firms. He teaches undergraduate, full-time M.B.A., and executive M.B.A. courses in microeconomics, strategy and the management of technology and innovation. He can be reached at (202) 687-4793 and jtm4@georgetown.edu.

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