INFORMATION TECHNOLOGY INITIATIVES IN DRUG REGISTRATION SUBMISSIONS

JANUARY 12-14, 1998

J. W. Marriott Hotel
Washington, DC, USA

In Cooperation With:

The U.S. Food and Drug Administration and PhRMA

Program Chairpersons:

Krishan K. Arora, PhD, International Director, Electronic Submissions, Drug Regulatory Affairs Novartis Pharmaceuticals Corporation

David C. Isom, Acting Director, Office of Information Technology, U.S. Food and Drug Administration

Additional Committee Members:

Carol J. Crowley, Worldwide Director, Regulatory Affairs, Rhône-Poulenc Rorer

Ken Edmunds, U.S. Food and Drug Administration

Robert E. Hizer, MS, Senior Scientific Systems Consultant, Eli Lilly & Company

Irwin G. Martin, PhD, Vice President, FDA Liaison, Worldwide Regulatory Affairs Parke-Davis Pharmaceutical Research Division

Overview

The U.S. Food and Drug Administration has undertaken many Information Technology Initiatives to facilitate handling of regulatory submissions that are made to the agency. These initiatives include functionality such as receiving, tracking, reviewing, developing assessment reports, issuing decisions, and archiving, etc. Some initiatives are at center level, CDER and CBER, while others are at agency level; some are solely by and within the agency while others are in cooperation with industry groups such as PhRMA.

This conference is designed to provide public awareness of the near-term and long-term objectives of all relevant initiatives and to provide a forum for candid discussion of the impact of these initiatives on drug regulatory submissions.

Senior management of FDA will make keynote addresses presenting their vision of IT and its impact on the drug regulatory submission and review process for Drugs and Biologics. Key topics will include: the ***FDA IT Infrastructure***, the ***Electronic Records***, the ***Electronic Signature Rule***, ***Guidance for Submitting Electronic Information***, the ***Electronic Document Room***, the ***Electronic Regulatory Submission and Review Strategy***, ***Electronic Package Inserts***, ***Electronic Periodic Adverse Event Reports***, systems such as ***AERS***, ***EES***, ***EDMS***, etc., and ***practical experiences of FDA reviewers and the corresponding sponsors*** with most recent electronic submissions.

ACPE

This program is offered in cooperation with ABcomm, Inc. ABcomm, Inc. is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. ACPE Program I.D. No. 811-999-98-608-L04. Participants who attend this program and complete the program evaluation form may earn up to 17.0 contact hours (1.70 CEUs) of continuing education credit. This credit is acceptable by all boards of pharmacy that recognize ACPE-approved providers.

This course has been designated by the California Board of Pharmacy as meeting its C.E. requirements for 17.0 hours of credit. Pharmacists attending this program may earn up to 17.0 hours of C.E. credit.

Learning Objectives:

- To learn about recent advances in the development of electronic submissions;
- To understand FDA requirements to aid review of electronic submissions;
- To acquire knowledge of archiving needs of various electronic submissions to FDA;
- To learn the regulatory and technical aspects of adverse event reporting.

Dates and Times

Sunday, January 11, 1998

4:00-6:00 PM **REGISTRATION**

Monday, January 12, 1998

7:30-8:30 AM **Registration**

8:30-8:40 AM **Welcome and Introduction**
Krishan K. Arora, PhD, International Director, Electronic Submissions Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

Session I:

8:40-10:30 **IMPACT OF IT – AGENCY AND INDUSTRY PERSPECTIVE**

Outlook on Information Technology in Drug Regulatory Review
Janet Woodcock, MD, Director, CDER U.S. Food and Drug Administration

Outlook and Role of PhRMA
Larry R. Versteegh, PhD, Vice President Regulatory and Clinical Development Procter & Gamble Pharmaceuticals

Agency Information Systems Architecture Standards and the Gateway
William M. Bristow, II, MBA, Chief Information Officer, U.S. Food and Drug Administration

Key IT Initiatives in CDER
David C. Isom, Acting Director, Office of Information Technology, CDER U.S. Food and Drug Administration

10:30-11:00 **REFRESHMENT BREAK**

Session II:

11:00-12:30 **ELECTRONIC ADVERSE EVENTS REPORTING (AERS)**

Overview of the AERS System
Robert C. Nelson, PhD, Associate Director, Office of Epidemiology, CDER U.S. Food and Drug Administration

Use of MEDDRA in AERS
Toni Piazza-Hepp, PharmD, Group Leader, Division of Pharmacovigilance and Epidemiology U.S. Food and Drug Administration

Secure Electronic Transmission and E-Mail with Industry
Greg V. Brolund, Associate Director, Office of Information Technology, CDER U.S. Food and Drug Administration

12:30-1:30 **LUNCHEON**

Session III:

1:30-3:00 PM **ELECTRONIC RECORDS; ELECTRONIC SIGNATURES; FINAL RULE**

Overview
David A. Lepay, MD, PhD, Director, Division of Scientific Investigations, CDER, U.S. Food and Drug Administration

Highlights and Interpretation of the Regulation
Paul Motise, Consumer Safety Officer, Division of Manufacturing and Product Quality, CDER, U.S. Food and Drug Administration

Guidance for the Use of Electronic Records in Clinical Trials
Stan W. Woollen, Deputy Director, Division of Scientific Investigations, CDER, U.S. Food and Drug Administration

Implications: The Industry Perspective
Stephen J. Kopko, MS, Director, Clinical Programming, Wyeth-Ayerst Research

3:00-3:30 **REFRESHMENT BREAK**

Session IV:

3:30-5:00 **INFORMATION TECHNOLOGY INITIATIVES**

Electronic Establishment Evaluation System (EES)
Ralph Lillie,PhH, MPH Acting Director, Division of Pharmacovigilance and Epidemiology, CDER U.S. Food and Drug Administration

Electronic Document Management System (EDMS)
Greg V. Brolund, Associate Director, Office of Information Technology, CDER U.S. Food and Drug Administration

Electronic FOI System
Carolann Hooton
Director, FOI Staff, CDER U.S. Food and Drug Administration

Paul Stauffer
Medical Library, CDER U.S. Food and Drug Administration

5:00-6:00 PM **RECEPTION**

Tuesday, January 13, 1998

7:30-8:30 AM **Registration**

8:30-8:40 AM **OPENING REMARKS**

David C. Isom, Acting Director
Office of Information Technology, CDER
U.S. Food and Drug Administration

Session V:

8:40-10:30 **CASE STUDIES, NDAs AND BLAs**

Moderators:

Stephen E. Wilson, PhD, Team Leader, Division of Biometrics II, CDER, U.S. Food and Drug Administration

Mary A. Buesing, MD, Medical Review Officer, CBER, U.S. Food and Drug Administration

Case Studies: Functionality, Time and Cost of Recent Electronic Submissions – Industry and Agency Perspective

Panelists

Barbara Flashoff, CDER, U.S. Food and Drug Adminstration
Mike Sevka, CDER, U.S. Food and Drug Adminsitration
Holli Hamilton, CDER, U.S. Food and Drug Adminsitration
Greg Brolund, CDER, U.S. Food and Drug Administration
Cynthia L. Kirk, PhD, Hoechst Marion Roussel
Alice M. Wei, IDEC Pharmaceuticals
David Shen, PhD, IDEC Pharmaceuticals
Bill A. Rosen, Parke-Davis Pharmaceuticals
Krishan K. Arora, PhD, Novartis Pharmaceutical
Pamela Fruch, R.W. Johnson, PRI
Steven P. Gingras, R.W. Johnson, PRI

10:30-11:00 **REFRESHMENT BREAK**

Session VI:

11:00-12:30 **ELECTRONIC SUBMISSIONS – FORMAT AND PROCESS**

Electronic Document Room

Gregory J. Warzala, Director, Division of Data Management and Services, CDER, U.S. Food and Drug Administration

Guidance for Preparing Electronic NDAs

Randy Levin, MD, Medical Officer, Office of Review Management, CDER
U.S. Food and Drug Administration

Electronic Package Inserts

Robert E. Hizer, MS, Senior Scientific Systems Consultant, Eli Lilly & Company
Irwin G. Martin, PhD, Vice President FDA Liaison, Worldwide Regulatory Affairs, Parke-Davis Pharmaceutical Research Division

12:30-1:30 **LUNCHEON**

Session VII:

1:30-3:00 PM **ELECTRONIC SUBMISSIONS – CONTENT STANDARDS**

Overview of ORM's Electronic Data Submission and Review Projects

- Good Review Practices
- Content Standards
- Review Discipline Data Submission Projects

Kaye H. Fendt, MSPH, Regulatory Health Information Specialist, ODE3/ ORM, CDER, U.S. Food and Drug Administration

John R. Senior, MD, Medical Officer, Division of Gastrointestinal and Coagulation Drug Products, CDER, U.S. Food and Drug Administration

G. Alexander Fleming, MD, Medical Group Leader, Division of Metabolism and Endocrine Drug Products, CDER, U.S. Food and Drug Administration

Overview of Office of Pharmaceutical Science Electronic Data Submission and Review Projects

- Data Concept
- Review Discipline Data Submission Projects
- Development and Implementation Issues

Jonathan D. Cook, Supervisory Operations Research Analyst, Head, Operations Staff, CDER
U.S. Food and Drug Administration

Roger L. Williams, MD, Director, Office of Pharmaceutical Science, U.S. Food and Drug Administration

John Lazor, PharmD, Director, Division of Pharmaceutical Evaluation III, U.S. Food and Drug Administration

Steven Koepke, PhD, Deputy Director, Division of New Drug Chemistry II, U.S. Food and Drug Administration

Session VIII:

3:30-5:30 **ELECTRONIC SUBMISSIONS INITIATIVES IN CBER**

CBER's Electronic Submissions Efforts

Kathryn C. Zoon, PhD, Director, CBER
U.S. Food and Drug Administration

Guidance for Electronic BLA

Mary A. Buesing, MD, Medical Review Officer, CBER, U.S. Food and Drug Administration

Edward McSweegan, PhD
Health Administrator, CBER,
U.S. Food and Drug Administration

Submitting Electronic Data to CBER: Experience with SAS and JMP Files

Peter A. Lachenbruch, PhD
Chief, Biostatistics Branch, CBER
U.S. Food and Drug Administration

Ghanshyam Gupta, PhD, Math Statistician, Biostatistics Branch, CBER, U.S. Food and Drug Administration

Guidance for Electronic IND, Pilot Phase 2

Fred W. Miller, MD, PhD, Medical Officer, Senior Investigator - Division of Monoclonal Antibodies, CBER
U.S. Food and Drug Administration

Guidance for Electronic Lot Release Protocol Product Information

Deborah Parshall, MS,
Director, Product Release Branch, CBER, U.S. Food and Drug Administration

Joseph Quander, Consumer Safety Officer, CBER,U.S. Food and Drug Administration

Wednesday, January 14, 1998

8:30-8:40 AM **OPENING REMARKS**

Krishan K. Arora, PhD, International Director, Electronic Submissions
Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

Session IX:

8:40-12:30 **AERS OPEN HOUSE**

Overview of the AERS System and Its Pharmacovigilance Strategy

Robert C. Nelson, PhD, Associate Director, Office of Epidemiology, CDER
U.S. Food and Drug Administration

FDA ESTRI Gateway

Rod K. Bond, Director, Planning, Resources, and Information Systems Management Staff
U.S. Food and Drug Administration

CDER will provide a detailed overview of the AERS system and its re-engineered pharmacovigilance strategy, and will then kick off an AERS technology open house that will cover the following key areas of the AERS system:

Facilitators:

James Hunter, U.S. Food and Drug Administration

Ralph Lillie, PhH, MPH, U.S. Food and Drug Administration

Robert C. Nelson, PhD, U.S. Food and Drug Adminsitration

- *Electronic Submission Handling*
- *Database Model*
- *Autocoder/Browser (Using MEDDRA)*
- *Use of MEDDRA in AERS*
- *AERS Pharmacovigilance Capability*
- *Graphical Signalling in AERS*
- *Technical Specifications for ICH Compatible ADR Transmissions*
- *Registration for Participants as an AERS Pilot*

12:30 PM **MEETING ADJOURNED**