Pharmaceutical Education Associates
a division of Financial Research Associates, LLC

Conference Mission Statement:

To develop an understanding of the benefits XML technology offers the Pharmaceutical Industry by effectively gathering and communicating critical information within organizations and to regulatory authorities.

Dear Colleague:

As drug companies invest enormous resources in R&D to replenish depleting pipelines, there is a clear need for the most efficient technology to compile and transfer information within organizations, as well as to the regulatory bodies for faster approval. The pharmaceutical industry as a whole is faced with critical business decisions regarding the adoption of the most efficient technology to meet this need, in addition to the resources required to support the technology. As delays can cost drug companies as much as one million dollars per day, leveraging the benefits of XML (Extensible Markup Language) is vital to saving time, money and resources for both industry and the agencies that regulate it.

XML is an emerging standard for data interchange gaining widespread acceptance in the pharmaceutical industry. Currently, disparate data models make data interchange a daunting and time-consuming manual process. An XML-based DTD (Document Type Definition) standard that is supported by the entire industry will allow pharmaceutical companies to gather and exchange data for collaborations and analysis with minimal manual intervention. This progress can save individual companies millions.

With the changing global regulatory landscape, document management has become a number one priority for the pharmaceutical industry. Future FDA standards for delivery of submission components may well specify XML as the format of choice. ***Are the key members of your organization up to speed on the benefits of XML that can get your product to market sooner?***

Pharmaceutical Education Associates, *a division of FRA, LLC,* is proud to present the ***Leveraging XML for Pharmaceutical R&D Information Exchange*** *conference.* In this topical and interactive conference, our experts address issues including:

- Case studies focusing on the exchange of financial data related directly to the provision of global Phase IV clinical trials using XML within a major international pharmaceutical company
- How the development of XML-based standards and software that implement them will converge the authoring and publishing of numeric content and text content and streamline regulatory submission creation and review
- Important considerations regarding large-scale conversion projects, including issues such as cost (dollars and manpower), scalability, schedule and quality

Plus!

Hear a special presentation from **Norman Stockbridge, MD, PhD, Medical Team Leader, Division of Cardio-Renal Drug Products, CDER, FDA on** FDA XML format requirements for cardiographic waveform data.

Don't miss the pre-conference workshop, ***Understanding the Relationship between XML Technology and Business Processes Across the Pharmaceutical Enterprise,*** expert-led by **Jean Kaplansky** of **Pfizer Global R&D.** This must-attend primer provides participants with a non-technical background of XML technology and explains its importance in document management process business decisions maximizing your organization's valuable resources.

Don't wait — register early and reserve your spot! Call us at **800-280-8440** or register online at **www.pharmedassociates.com**. To fax your registration, complete the form on the back panel of this brochure and fax it to **831-420-2678**. Join us **November 18TH, 2002** in **McLean, VA** for this exciting event!

Sincerely,

Lesly Atlas

Lesly Atlas, Conference Director
Pharmaceutical Education Associates
a division of Financial Research Associates, LLC

Thanks to Our Media Partners:

PharmCast.com Pharmaceutical Internet

www.PharmCast.com is a pharmaceutical community based website which is visited by over 10,000 pharmaceutical professionals each week. It features the latest information on pharmaceutical patents, FDA, news, jobs and Buyer's Guide — information that enhances one's career. www.PharmCast.com has fast become the premier Internet content provider for pharmaceutical professionals.

R&D Directions

R&D Directions offers original editorial covering issues, trends, and strategies affecting the R&D of prescription drugs by providing substantial coverage of products in the pipeline and presenting a broad perspective on business activities surrounding clinical research as well as news about major suppliers such as contract research organizations.

LabCompliance

Labcompliance, global resource for validation and compliance in laboratories, with more than 100 free pages.

Pharmaceutical Technology NORTH AMERICA

Celebrating 25 years serving the pharmaceutical/biopharmaceutical industry, 1977-2002. Pharmaceutical Technology provides authoritative and timely information covering all aspects of pharmaceutical/biopharmaceutical manufacturing including: drug delivery, applied research and development, solid dosage, manufacturing machinery and equipment, information technologies, contract services, biotechnology trends and regulatory issues. Published monthly, Pharmaceutical Technology has a BPA audited circulation of over 33,000.

zapthink

Founded in October 2000, ZapThink, LLC (*www.zapthink.com*) is an industry research and analysis firm that provides quality, high-value, focused research, analysis, and insight on emerging technologies that will have a high impact on the way business will be run in the future. ZapThink focuses on XML and Web Services technologies that provide open, standards-based, loosely-coupled systems and represent an evolutionary advancement in computing that requires a new way of thinking about computing resources, capabilities, development methodology, and architecture. ZapThink is headquartered in Waltham, Massachusetts. Its customers include Global 1000 firms as well as many emerging businesses.

Charles F. Goldfarb's XML TIMES.com

The "father of markup" and an expert staff bring you breaking XML-specific news in real time from dozens of sources. Plus the knowledge you need to interpret it, in the form of friendly but accurate tutorials on aspects of XML and related technologies that affect your business and its information resources.

Pharmaceutical Education Associates Proudly Presents:

Leveraging XML for Pharmaceutical R&D Information Exchange

Hear directly from the FDA!

Innovative Solutions for Accelerated Data Interchange and Integration

November 18th-19th, 2002 • The Ritz-Carlton, Tysons Corner • Mclean, VA

This exclusive event addresses timely issues including:

- Why XML is the frontrunner of tools to acquire in implementing the most efficient document management method
- How XML can provide a single solution for submission authoring, publishing and review
- Utilizing XML as a means of expediting clinical development and regulatory submissions processes and enhancing capabilities for safety surveillance
- Interacting successfully with the FDA e-review team and making the cost-benefit assessment of an FDA e-submission
- How XML fits into your organization's eCTD strategy
- An overview of the CDISC Operational Data Model
- Establishing standards for multi-system interoperability which allows data exchange between systems at the transaction level
- Making the go/no go decision to migrate existing data to XML and planning the scope of the project
- *...and much more!*

Don't Miss our Pre-Conference Workshop:
Understanding the Relationship between XML Technology and Business Processes Across the Pharmaceutical Enterprise facilitated by Jean Kaplansky, *Systems Analyst, Global Document Solutions,* PFIZER GLOBAL R&D

Featuring Case Studies and Presentations From:

- FDA
- Regeneron Pharmaceuticals
- Arbortext
- Data Conversion Laboratory
- Purdue Pharma LP
- Intrasphere Technologies
- Zurich Biostatistics
- Novartis Pharmaceuticals
- PHT Corporation
- Pfizer Global R&D

Hear a Special Presentation from Norman Stockbridge, MD, PhD, Medical Team Leader, CDER, FDA on *FDA XML Standard for Exchange of Annotated ECGs*

Pharmaceutical Education Associates
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Media Partners:

Register Today! Call 800-280-8440 or Visit Us at www.pharmedassociates.com

Leveraging XML for Pharmaceutical R&D Information Exchange

To Register:

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c/o FRA LLC
16311 NE 91st St.
Vancouver, WA 98682
Online: www.pharmedassociates.com

Make check payable to Financial Research Associates, LLC

- ❑ Yes! Register me for the conference and the Pre-Conference Workshop
- ❑ Yes, register me for the conference
- ❑ I qualify for the FDA/federal government employee rate
- ❑ Please contact me: I'm interested in a group discount rate for my team
- ❑ Please contact me: I'm interested in marketing opportunities at this event
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Register Today! Call 800-280-8440 or Visit Us at www.pharmedassociates.com

DAY ONE: Monday, November 18, 2002

PRE-CONFERENCE WORKSHOP

Understanding the Relationship between XML Technology and Business Processes Across the Pharmaceutical Enterprise

7:45 Pre-Conference Workshop Registration & Continental Breakfast

8:30 Workshop Opens

XML technology is marketed as the ideal tool to help industries streamline business processes in terms of data management, electronic communications and content management. This workshop provides a non-technical explanation of XML technology and related business processes for individuals responsible for making document management business process decisions and working with regulatory submission content.

This tutorial aims to explain what XML is, where it came from, how it is used and how it can help regulatory affairs professionals streamline the document management and submission assembly process.

Highlights of this workshop include:

- A brief history of XML
- A discussion of business processes across the enterprise that have led to the adoption of XML-based technologies
- An overview of basic XML tools for document authoring, assembly, and management
- A discussion of how XML fits into the ICH eCTD strategy

10:00 *30-Minute Networking & Refreshment Break*

12:00 *Luncheon for Workshop Attendees*

Meet Your Workshop Leader:

Jean L. Kaplansky *is currently the systems Analyst,* Global Document Solutions, Information Management at Pfizer Global R&D, Ann Arbor Laboratories. She joined Parke-Davis, a Warner-Lambert Company in January 2000. Ms. Kaplansky is currently responsible for providing consulting for and application development of XML-based document authoring/ editing/publishing solutions to a variety of clients across the PGRD organization. Prior to the Warner-Lambert merger with Pfizer, Inc., she was responsible for developing and supporting imaging systems for the Digital Imaging Services group, and providing XML project consulting for the Document Administration Services department. Prior to her employment at Pfizer Global R & D, Ms. Kaplansky was employed at Arbortext, Inc. from 1995 – 2000 as an XML consultant specializing in XML stylesheet and DTD development. Ms. Kaplansky holds a Bachelor's degree from the University of Michigan.

12:15 Main Conference Registration

1:15 Chairperson's Welcome

Barbara E. Tardiff, MD, MBA, *Vice President, Clinical Informatics*
REGENERON PHARMACEUTICALS, INC.

1:30 FDA XML Standard for Exchange of Annotated ECGs

Pharmaceutical manufacturers, ECG device manufacturers, clinical research organizations, and academic investigators have collaboratively developed an XML-based, HL7-compliant format for efficiently communicating ECG waveform data along with annotations to describe waveform features. This open data standard facilitates communication among investigator sites, central reading facilities, sponsors, and regulatory agencies. Hear directly from the FDA on how:

- the data structure is well captured by the XML format
- associated information provides clues to a data viewer
- the same data format would accommodate other multi-channel, clinical time-series data

Norman Stockbridge, MD, PhD, *Medical Team Leader, Division of Cardio-Renal Drug Products*
CDER, FDA

2:15 Leveraging XML in Clinical Development: Enabling the e-vision

The clinical development process is heavily dependent on the assimilation of data from multiple sources and choreography of multiple data transfers across time. XML based technical standards, by providing a mechanism that allows data to be transferred in a reliable and secure manner and in a way that specifies what data is being transferred, offers a means of speeding up the clinical development and regulatory submissions processes and enhancing our capabilities for safety surveillance. Highlights of this session include:

- Why and how software vendors, biopharm companies, and regulatory agencies are all embracing XML-technology to improve organization-to-organization and application-to-application data interchange and integration
- How XML will help achieve the goal of interoperability of clinical data and e-clinical vision
- Why XML is only part of the picture: The importance of developing and adopting clinical research standards that can be "enabled" in the e-environment using XML

Barbara E. Tardiff, MD, MBA, *Vice President, Clinical Informatics*
REGENERON PHARMACEUTICALS, INC.

3:00 *Mid-Afternoon Networking & Refreshment Break*

3:30 Understanding the CDISC Operational Data Model

Introduction to the CDISC Operational Data Model (ODM) CDISC (Clinical Data Interchange Standards Consortium) is an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. The mission of CDISC is to lead the development of global, vendor-neutral, platform independent standards to improve data quality and accelerate product development in our industry. Through the use of case studies, our speaker illustrates a high-level review of the CDISC ODM.

Richard Ferris, *Principal Software Engineer*
LINCOLN TECHNOLOGIES, INC.

4:15 Implementing Open Standards Using XML to Meet the Challenges of Shared Information and Interoperability

Despite the proliferation of standards and integration, sponsors still cannot easily get a single view of all the data streams in their clinical trials. The CDISC Operational Data Model is a critical step, but it's just the beginning. To realize the dream of integrated systems, standards must be established for multi-system interoperability, allowing data exchange between systems at the transaction level. We now have the technology to make this a reality. In this session, the speaker discusses why:

- Multiple data sources allow for maximum flexibility during data collection but lead to difficult interim trial monitoring and tedious end of trial data integration
- CDISC is an answer for data interchange but still leaves us wanting more
- Open standards benefit both sponsors and vendors
- Web services builds on the XML infrastructure we are all putting in place

Gail Browder McDowell, *Executive Vice President, Products and Services*
PHT CORPORATION

5:00 *Day One Concludes*

DAY TWO: Tuesday, November 19, 2002

8:00 *Continental Breakfast*

8:45 *Chairperson's Re-Cap of Day One*
Barbara E. Tardiff, MD, MBA, *Vice President, Clinical Informatics*
REGENERON PHARMACEUTICALS, INC.

9:00 The Challenge of Integration and the Need for Industry Interchange Standards

For many years individual pharmaceutical companies have built or acquired applications with little regard for interconnectivity or the ease of information collection and transfer amongst associates and partners. With the increasing complexity and distribution of data collection mechanisms and sources of information, this approach cannot continue and industry-wide standardization of interchange protocols is urgently required. Highlights of this presentation include:

- How inefficient and inflexible IT interfaces (spaghetti connections) adversely affect business operations industry-wide
- Establishing industry interconnectivity standards which allow software from multiple vendors to interact effectively while maintaining appropriate levels of flexibility and control for individual pharma companies
- CDISC (XML) provides a good foundation for this interchange but needs to be extended both in terms of its scope (i.e what data is exchanged) and applicability (i.e. is it only data that we exchange?)

Peter Spiers, *Integration Manager, eClinical*
NOVARTIS PHARMACEUTICALS

9:45 Managing the Migration of Data to XML

When putting together a business plan for implementing XML, one of the factors that must be considered is the impact of migrating your data to XML. This presentation looks at the issues involved with large-scale conversion projects, including issues such as cost (dollars and manpower), scalability, schedule, and quality. In addition, our speaker considers both the legacy and ongoing requirements that are typical. Highlights of this presentation include:

- Making the go/no go decision based on time, cost and quality
- Planning the scope of the project
- The analysis, design and engineering process
- Converting existing data into XML
- Production and validation

Don Bridges, *Account Manager, Commercial Technical Documents*
DATA CONVERSION LABORATORY

10:30 *Mid-Morning Networking & Refreshment Break; Hotel Check-Out*

11:00 Faster, Cheaper, Better: Understanding how XML and Consortium-Developed Standards Lower the Barriers between Numeric Content and Text Content to Improve Submission Creation and Review

Can XML help to converge the world of numeric data and analysis with the world of text content, document authoring, and publishing? Pharmaceutical companies and regulatory agencies, including the FDA, have recognized their mutual interest in this convergence and are focusing on standards groups such as CDISC and HL7 to develop infrastructure for it. Traditional pharmaceutical industry vendors and vendors whose traditional market is outside of pharma but who are experienced in this technology hope to leverage their expertise into this new area. The result will be faster submissions, shorter time to market for new drugs and quicker access to improved therapies for the public. Highlights include discussion on how:

- Industry, regulators, and vendors have to agree on standards for XML-based submission content and to develop XML-based software tools
- The development of XML-based standards and software that implement them will converge the authoring and publishing of numeric content and text content and streamline regulatory submission creation and review
- XML promises to streamline submission creation, publishing, and review because it supports both numeric content and text content

Michael Palmer, *President*
ZURICH BIOSTATISTICS, INC.

11:45 Electronic Submissions: Inside and Out

In this session, our speaker challenges the audience to make a number of decisions relating to the electronic publishing and submission of a new drug application (NDA) to the Center for Drug Evaluation and Research (CDER). In preparation, hear first-hand experiences from an FDA user of e-submissions to CDER and CBER and the current status of electronic regulatory submissions and XML at all 5 FDA centers (CDER, CBER, CDRH, CVM, CFSAN). You will also hear the trials & triumphs of developing and using an electronic NDA from the perspective of the clinical leader. The participant learns how to:

- Compare & contrast the e-submission needs across FDA Centers
- Determine how to best interact with the agency e-review team
- Make the cost-benefit assessment of an FDA e-submission

Daniel A. Spyker, *Senior Medical Director*
PURDUE PHARMA LP
Former FDA Medical Officer

12:30 *Luncheon for Delegates and Speakers*

1:45 XML in New Drug Submissions: Going Beyond the Backbone

Harmonization of new drug submissions promises significant time savings and efficiency improvements for global product launches. Use of XML for the eCTD backbone is a big step forward but — outside of the statistical tables — the submission content will be in unstructured PDF. This approach provides the most flexibility for submitting sponsors and an easy slope of adoption for regulatory reviewers, but XML could provide even greater benefits if properly employed upstream of the final submission.

This session addresses how XML can be used to prepare eCTD submissions, providing more efficient authoring, better reuse of material, increased control over content, accelerated

content reviews and more flexible publishing than is practical with traditional authoring and publishing techniques.

Tom DiCorcia, *Marketing Director*
ARBORTEXT

2:30 The Emergence of the Collaborative Framework for Information Exchange

This session presents a framework for handling Complex Application Interactions (CAI) using emerging eXtensible Markup Language (XML) standards. Our session leader illustrates the issues, challenges, and potential benefits by aking on a collaborative information exchange approach. The case study used throughout the presentation focuses on the actual exchange of financial data related directly to the provision of global Phase IV clinical trials using XML within a major international pharmaceutical company. The speaker addresses how:

- Manual handling and duplicated entry of data inevitability add to the bottom-line cost of bringing and keeping a drug to market
- Many large enterprise level systems in the pharmaceutical industry are required to be certified against regulations such as 21 CFR Part 11, which often causes the creation of monolithic systems that are neither efficient nor agile enough to cope with mergers & acquisitions or changes in the industry and a company's own business practices
- An alternative to wide-scale system consolidation is to focus the key enterprise systems on their areas of expertise and deploy best-of-breed systems, in order to create and maintain a competitive advantage, then integrate these systems using a 'Collaborative Exchange' of data based on XML standards

Paul Hodge, *Practice Manager, Pharmaceuticals Practice*
INTRASPHERE TECHNOLOGIES, INC.

3:15 Mid-Afternoon Networking & Refreshment Break

3:45 Panel: Understanding the Impact of XML on the Pharmaceutical Industry

Moderator:
Jean Kaplansky, *Systems Analyst, Global Document Solutions*
PFIZER GLOBAL R&D

Panelists:
Tom DiCorcia, *Marketing Director*
ARBORTEXT

Barbara E. Tardiff, *MD, MBA*
Vice President, Clinical Informatics
REGENERON PHARMACEUTICALS, INC.

Peter Spiers, *Integration Manager, eClinical*
NOVARTIS PHARMACEUTICALS

If you would like to participate in this panel discussion, please contact Ian Rappaport at 212-558-6467 or irappaport@pharmedassociates.com.

4:30 *Conference Concludes*

We would like to thank our exhibitors (to date):

Arbortext — Content that means business

Data Conversion Laboratory

Who Should Attend

This conference is designed for Vice Presidents, Directors and Senior Managers in the Pharmaceutical, Biotechnology and Medical Device industries with responsibilities in the areas of:

- R&D
- Regulatory Affairs
- Document Management
- Electronic Publishing
- Document Publishing
- Information Technology
- Systems Analyst
- Quality Compliance
- Clinical Operations
- QA/QC
- Document Technology
- Electronic Submissions
- Document Control
- Information Services
- Project Management
- Software/Systems Validation

This conference is also of interest to:
CROs, Central Labs, Vendors of XML-related technologies

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Maximize your firm's exposure at this event by sponsoring a cocktail reception or custom-designed networking event. We can design custom sponsorship packages tailored to your marketing needs. Or, if product display space is key to your marketing efforts, ask about our exhibitor opportunities. To learn more about exhibit and sponsorship opportunities at Pharmaceutical Education Associates' seminars and conferences, please contact **Ian Rappaport** at **212-558-6467**.

Administrative Details

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Online: www.pharmedassociates.com

Venue Information: The Ritz-Carlton, Tysons Corner
1700 Tysons Boulevard
McLean, VA 22102
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Should you require overnight accommodations, please contact the hotel and let them now you are attending the PEA/FRA conference on **Leveraging XML for Pharmaceutical R&D Information Exchange** to obtain the conference discount rate for rooms.

Fees and Payments: The fee for attendance at the **Leveraging XML for Pharmaceutical R&D Information Exchange** conference is:
Conference Only $1695
Best Value: Conference and Workshop $1995

The FDA/federal government employee rate is $595.
(Valid Federal ID must be presented at conference registration.)

Group Discounts are available. Please call Teri Lewis at 360-944-7880 for more information. Make checks payable to **Pharmaceutical Education Associates** and write code **P103** on your check. You may also use Visa, MasterCard or American Express. Payments must be received by November 11, 2002.

Cancellations: If you cancel four weeks or more in advance of the conference you can expect a full refund or voucher to another PEA event within the next calendar year. Cancellations occurring two to four weeks prior to the conference date receive a $200 refund or full voucher to another event. If you cancel less than two weeks prior to the conference date, you can expect a full credit voucher to be used at another PEA event within the calendar year.