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 Kaplanovsky 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

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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Fax: 831-420-2678
Mail: Pharmaceutical Education Associates
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
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A division of Financial Research Associates
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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
• 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
• Establishing standards for multi-system interoperability which allow data exchange between systems at the transaction level
• Using XML for accelerated data interchange and integration

… and much more!

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

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

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

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

Pharmaceutical Education Associates Proudly Presents:
Innovative Solutions for Accelerated Data Interchange and Integration

Media Partners:
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!

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

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Media Partners:

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 PG&D 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, M.s. Kaplansky was employed at Arbortext, Inc. from 1995 to 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 REG ENERO N PHARMA CEUTICALS, IN C.

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 REG ENERO N PHARMA CEUTICALS, IN C.

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 LIN CO LIN 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:
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 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 CONVERSIONS & RATIO

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 the 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 BIO STATISTICS, 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
A RBO RTEXT

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 asking 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 inevitably add to the bottom-line cost of bringing 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 creates the formation 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 TECHNOLOGY, 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 GLO BAL R&D

Panelists:
Tom DiCorcia, Marketing Director
A RBO RTEXT

Barbara E. Tardiff, M.D., M.B.A.
Vice President, Clinical Informatics
REG ENERO N PHAR AM AC EURICALS, INC.

Peter Spiers, Integration Manager, eClinical
NO VARI TE S PHAR A M AC EURICALS

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

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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Administrative Details

Four Ways to Register:

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16311 NE 91st St.
Vancouver, WA 98682
Phone: 800-280-8440
Online: www.pharmedassociates.com

Venue Information: The Ritz-Carlton, Tysons Corner
1700 Tysons Boulevard
McLean, VA 22102
(703) 506-4300

Should you require overnight accommodations, please contact the hotel and let them know 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 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 next calendar year.

For information on sponsoring or exhibiting, please call Ian Rappaport at 212-558-6467 or email irappaport@pharmedassociates.com

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