Antoinette Azevedo Curriculum Vitae

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Consulting Services

- eCTD readiness assessment & gap analysis
- eCTD training targeted at company leadership, regulatory strategists, regulatory operations, information technology
- eCTD quality control & validation for all ICH regions
- eCTD publishing systems selection, implementation and validation.
- EDMS systems selection, implementation and validation.
- eCTD submission publishing services
- eCTD submission publishing staff augmentation
- MS Word templates, toolbars, and user training for eCTD document authoring

Consulting Virtual Technical Infrastructure

- Adobe Acrobat Professional 7.x, 8.x, 9.x, X.x and XI.x for PDF manipulation and preflight http://www.adobe.com/products/acrobat/index.html
- Enfocus PitStop Professional for PDF troubleshooting and preflight http://www.enfocus.com/product.php?id=855
- EXTEDO eCTD Manager for paper and electronic submission publishing http://www.extedo.us/
- GlobalSubmit eCTD Validate+Review for eCTD validation http://www.globalsubmit.com/
- Image Solutions Inc. ISIToolbox Pharma edition for PDF manipulation and preparing submission-ready documents http://www.isitoolbox.com/Default.aspx?tabid=724
- LORENZ Archiv-Systeme GmbH docuBridge for paper and electronic submission publishing http://www.docubridge.com/dbasp.cfm
- Microsoft Office Professional 2000, 2003, 2007 and 2010
- Microsoft Windows XP, 2003, and Vista 2007
- Sage Submissions MS Word templates for regulated product submissions http://www.sagesubmissions.com/
- Microsoft Office Sharepoint Server (MOSS) hosted document management.

Consulting Capabilities

- Vendor-neutral on all components of a total solution.
- Years of experience implementing submission publishing and electronic document management systems (EDMS) in the life sciences regulatory environment.
- Expert in technologies, practical techniques and processes for producing paper and electronic submissions for pharmaceutical, biotechnology, and medical device industries.

- Expert in current and emerging requirements for information technology, regulatory affairs, and regulatory operations.
- Implemented systems, processes, and standards to support paper and electronic submissions for FDA, EU, Canada, and other health authorities around the world.
- Full liability insurance coverage for general and business and professional errors and omissions.

ProBono Activities

Leader, DIA EDM Reference Model Working Group, Process Zone: Pharmacovigilence/Drug Safety/Risk Evaluation and Management System (REMS)

Core Team Member, DIA EDM Reference Model Working Group, Process Zone: Regulatory Submissions

Member, DIA EDM Reference Model Working Group, Process Zone: Prescribing Information

Member, DIA Reference Model Working Group: Trial Master File

Advisor to NIH Clinical and Translational Science Awards (CTSA) IND/IDE Task Force on Electronic Submissions http://www.ncats.nih.gov/research/cts/ctsa/ctsa.html

Employment/Professional Experience

Sage Submissions, San Diego, CA (a California corporation)
February 2007 to present. President

Responsible for day-to-day product development, sales, marketing, business development, and promotional activities of Sage Templates.

e-Submissions Solutions.com, San Diego, CA. (a California "S" corporation)
October 2000 to present. Founder, Principal, President & CEO

Independent consultancy advising life sciences companies on solutions for regulatory publishing and document management. Offering consulting services in the following areas:

- eCTD Validation Services
- eCTD Gap Analysis and Readiness Assessment
- eCTD training
- Submission publishing services – paper and electronic submissions, including eCTD and CDRH eCopy
- Training and technical support services – EDMS and submission publishing systems

- Electronic submission & EDMS strategy and corporate standards; vendor selection & implementation/validation

ESPS, Inc. (now Liquent), Horsham, PA

July 1997 to October 2000. Director, West Coast Operations

Expert in CoreDossier, kPublisher, kPortal products applied within pharmaceutical, biotechnology, and medical device companies to produce BLAs, NDAs, MAAs, PMAs, and INDs in paper and electronic formats.

- Prepared customer pre-eBLA and pre-eNDA demonstrations and attended meetings with FDA.
- Developed solutions using Liquent products integrated with the customer's electronic document management systems (EDMS) – including Documentum, FileNet, OpenText, PC DOCS, and Lotus Notes/Domino.
- Partnered with systems integrators to build total solutions.
- Initiated partnerships with printing services bureaus for paper submission production.

CSC Consulting & System Integration, Berwyn, PA

October 1994 to July 1997. Senior Consultant, Life Sciences Unit,

Implemented document management and publishing systems for pharmaceutical and biotechnology companies in North American and Western Europe.

- Technical architect for the integration of publishing and electronic document management system (EDMS).
- Developed Documentum virtual document architectures to support publishing requirements.
- Deployed Xerox XDA and Documentum worldwide for leading pharmaceutical company.
- Led a customer team in the evaluation of publishing solutions that resulted in the first commercial installation of CoreDossier 2.0.
- Produced first MAA published with XDA for leading European pharmaceutical company.
- Produced NDAs with Xerox XDA and CoreDossier for North American and European pharmaceutical companies.

Azevedo & Associates, San Francisco, CA

January 1993 to October 1994. Principal

- Market analyst - SGML Applications for Interconsult, Inc., Cambridge, MA. Researched and wrote industry report on SGML solutions and market sizing.
- Independent consultant on document management and publishing systems for aerospace, defense, pharmaceutical, and other industries.

- Independent consultant advising computer systems vendors on strategic alliances & technical feasibility of advanced technologies for document management and publishing, including SGML, PDF, and dataglyphs.

Sun Microsystems, Inc., Palo Alto, CA

March 1992 to January 1993. Corporate Marketing Manager for Document Management, Imaging, Executive Information Systems & Decision Support Systems

- Responsible for managing corporate partnerships with SAS Institute, Documentum, Verity, Fulcrum, Information Resources (now part of Oracle), Cognos, Business Objects, Pilot, and others.
- Trade show organization & execution in support of marketing partner announcements and launches.
- Integration of partners with Sun announcements, corporate marketing, corporate demonstration center.
- Liaison between partners and Sun companies for technical support and advanced development.

Xerox Corporation, Palo Alto, CA, and San Diego, CA

December 1986 – March 1992. Marketing Manager for Publishing Systems.

Marketing manager for SGML and structured document publishing systems.

- Integrated publishing solutions into Xerox Docutech worldwide launch program.
- Trained sales force worldwide in features and functions, sales process, customer prospecting for newly-developed publishing systems.
- Managed team which provided presales technical support and which performed post-sales implementation worldwide.

Azevedo & Associates, Oakland, CA, and Mountain View, CA

July 1984 to December 1986. Independent Consultant

Technical/marketing consultant responsible for requirements definition, competitive analysis, product positioning for publishing systems. Clients included largest offices systems vendors in the world.

Atex Systems, South San Francisco, CA

June 1983 to July 1984. Systems Engineer

Responsible for implementation of complex systems for newspaper publishing – news, classified ads, and accounting.

Mergenthaler Linotype, Hayward, CA

June 1981 to June 1983. Systems Consultant

Responsible for implementation of computer typesetting systems for newspaper, magazine, and industry applications in advertising, aerospace, pharmaceutical, defense, computer software and hardware, and telecommunications.

Various companies, San Francisco, CA Bay Area

1975 to June 1981. Typographer and book designer

Designed and developed book, magazine, corporate communication, and technical publishing projects, resulting in the production of camera-ready output for printing and distribution.

Business Skills Summary

- Operate independently.
- Deep experience in integration of complex systems using vendor supplied GUIs and configuration tools, with wide ranges of software maturity and stability.
- Long track record in managing successful implementations ranging from requirements definition, vendor identification and evaluation, component selection, prototyping, piloting, validation, deployment, and vendor management.
- Creatively define solutions within customer budget and timelines.

Technical Skills Summary

- Electronic Document Management Systems (DMS): Microsoft Office Sharepoint Server (MOSS), Documentum, QUMAS, OpenText, Hummingbird/PC DOCS, FileNET, Lotus Notes/Domino, Lorenz DocuBridge, MasterControl.
- eCTD Publishing: Lorenz DocuBridge. Image Solutions, Inc. eCTDXpress, EXTEDO eCTD Manager, Liquent Insight Publisher.
- eCTD Validation: GlobalSubmit Validate+View.
- Submission Publishing: Liquent CoreDossier, kPublisher, kPortal and EZsubs. Xerox XDA/XDP.
- Adobe Acrobat family of products: Professional, Distiller, Catalog, and Reader.
- Adobe Acrobat plug-ins and toolkits: Image Solutions, Inc. ISI Toolbox Deluxe Pharma Edition, Enfocus PitStop Professional.
- Productivity Applications: MS Office and numerous vendors' applications.

Partners

Submission Publishing

- EXTEDO, Inc., http://www.extedo.us/

- GlobalSubmit, http://www.globalsubmit.org/
- LORENZ Archiv-Systeme GmbH, http://www.lorenz.cc/

EDMS

- Computer Sciences Corporation, http://www.csc.com/newsandevents/news/12129.shtml
- EMC, Documentum Division, http://software.emc.com/products/product_family/documentum_family.htm
- MasterControl, http://www.mastercontrol.com/
- Montrium, Inc., http://www www.montrium.com/
- NextDocs Corporation, http://www.nextdocs.com/
- OpenText, http://www.opentext.com/
- QUMAS http://www.qumas.com/

Medical Writing, Data Management, Datasets Conversion

- Agility Clinical, www.Agility-Clinical.com
- Audubon PM Associates Inc., http://www.linkedin.com/company/audubon-pm-associates-inc/
- Bowman Regulatory Consulting Group, LLC, http://www.eregulatoryconsulting.com/index.html
- MMS Holdings, Inc., http://www.mmsholdings.com/

PDF Remediation Services

- Bowman Regulatory Consulting Group, LLC, http://www.eregulatoryconsulting.com/index.html
- MMS Holdings, Inc., http://www.mmsholdings.com/
- Reed Technology and Information Services Inc., http://www.reedtech.com/

Prescribing Information Conversion Services (SPL, PIM)

Reed Technology and Information Services Inc., http://www.reedtech.com/

Publication Search & Retrieval

Reprints Desk, http://www2.reprintsdesk.com/

Regulatory Consulting

- Agility Clinical, Inc., http://www.agility-clinical.com/
- Bowman Regulatory Consulting Group, LLC, http://www.eregulatoryconsulting.com/index.html
- MMS Holdings, Inc., http://www.mmsholdings.com/

Memberships

- American Medical Writers Association, http://www.amwa.org/default.asp?id=1
- Association for Imaging and Information Management (AIIM). http://www.aiim.org/
- BIOCOM/San Diego. http://www.biocom.org/
- Drug Information Association (DIA). http://www.diahome.org/ Member of Special Area Interest Committees (SAIC) on Pharmacovigilence, Biotechnology, Document and Records Management, and Electronic Regulatory Submissions Publishing. Core member of EDM Reference Model for Regulatory Submissions.
- Implementation of Regulatory Information Submissions Standards (IRISS). http://www.iriss-forum.org/
- International Pharmaceutical Excipients Council of the Americas. http://ipecamericas.org/
- Regulatory Affairs Professional Society (RAPS). http://www.raps.org/
- San Diego Regulatory Affairs Network (SDRAN) http://www.sdran.org/
- Founding board member and treasurer, Northern California SGML Users Group.

Education

1974-75 Sociology/Psychology, University of San Francisco.

1976 + --Graduate level studies in marketing, finance, strategic planning.

1984 + --Professional development on publishing, document management, image management decision support/executive information systems, knowledge management, TQM, customer satisfaction, teambuilding, interpersonal communication, ISO 900x.

1997 + -- Professional development on requirements of government agencies worldwide for marketing applications for human drug/biologic/device/cosmetic/food products; animal products; plant products.

Publications

- 2007 eCTD Vendor Survey.
- 2007 eDMS Vendor Survey.
- 1994, *<SGML> Competitors & Markets, Products & Applications, 1994-1998*, Antoinette Azevedo and David Henry Goodstein with M. Elizabeth Hunter, European Supplement by Hans Andriese, 1994, InterConsult, Inc. Arlington, MA.

Speaking Engagements

2013

Regulatory Affairs Professional Society, "Advanced eCTD Submissions," Washington, DC, August, 2012. http://www.raps.org/s_raps/index.asp

University of California, San Diego, Extension, "Electronic Submissions - Planning for Success," July 1, 2013 through August 2013, 9 weeks, delivered online.

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions - ANDA, 505(b)(2), DMF and ASMF," Rockville, MD, May, 2013. http://www.raps.org/s_raps/index.asp

The ShareFest 2013 Conference, "Fast-Tracking a Regulatory Submission System Implementation at a Global Healthcare Products Company," Philadelphia, PA, April 25, 2013. http://www.sharefestconference.com/

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, April 15-16, 2013. http://www.raps.org/s_raps/index.asp

Drug Information Association, Medical and Scientific Communications 2013 Annual Forum, panelist on Device, Diagnostic, and Biotech Submissions, "FDASIA 2012 and the 'UFAs:' A Brave New World of Electronic Submissions," March 20, 2013. The Sheraton Wild Horse Pass Resort & Spa, Chandler, AZ. March 18-21, 2013 http://www.diahome.org/en-US/Flagship-Meetings/MedComm2013.aspx

Regulatory Affairs Professional Society, webinar series "Electronic Submissions for INDs and IDEs - Electronic Copy Compilation and Validation," Rockville, MD, March 4, 2013. http://www.raps.org/s_raps/index.asp

FDAnew, webinar "eCTD Requirements Under FDASIA: FDA to Require eCTD Submissions for New Applications," February 14, 2013. http://fdanews.com/conferences/audio

Regulatory Affairs Professional Society, webinar series "Electronic Submissions for INDs and IDEs - eCTD Compilation and Validation," Rockville, MD, February 4, 2013. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, webinar series "Electronic Submissions for INDs and IDEs - Creating, Checking and Fixing PDF Files," Rockville, MD, January 7, 2013. http://www.raps.org/s_raps/index.asp

2012

FDA*News,* "Preparing for the New Electronic Submission Mandates: Mastering the Tools and Strategies," Raleigh, NC, December 6-7, 2012. http://www.fdanews.com/

Regulatory Affairs Professional Society, webinar series "Electronic Submissions for INDs and IDEs - Using MS Word to Create PDF Files for Electronic Submissions," Rockville, MD, December 3, 2012. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, webinar series "Electronic Submissions for INDs and IDEs - Electronic Submission Requirements for CDER, CBER and CDRH," Rockville, MD, November 5, 2012. http://www.raps.org/s_raps/index.asp

Drug Information Association meeting DIA/FDA Industry PDUFA V Conference, Hilton Crystal City, Arlington, VA, October 18-19, 2012. http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=30392&EventType=Meeting&FlagshipMeetingFlag=False

MasterControl Masters Summit, co-presenter on "Overview of the Regulatory Suite and the Clinical Suite and the Role of the EDM Reference Model and TMF Reference Model," Canyons Resort, Park City, UT, October 16-18, 2012 http://www.cvent.com/events/2012-masters-summit/event-summary-45ed49e042c0409198003aab54922ea9.aspx

Drug Information Association meeting EDM and the ERS/eCTD: The Content Continuum from Document Authoring through Submission Delivery, exhibitor, Baltimore Hilton, Baltimore, MD, October 9-11, 2012. http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=27425&EventType=Meeting&FlagshipMeetingFlag=False

American Medical Writers Association 72nd Annual Conference, panelist on "eSubmissions: A Brave New World for the Medical Writer," Sacramento Convention Center, Sacramento, CA. October 6, 2012. http://www.amwa.org/default.asp?id=548

Lorenz Life Sciences Group, userBridge.12, Table Tutorial co-presenter on "LORENZ authorBridge," Hotel Clontarf Castle, Dublin, Ireland, September 25-27, 2012. http://lorenz.cc/Community/events/userBridge/

Drug Information Association meeting Unwrapping FDA's 2012 UFA Package: What's Inside the Statute, What's Next? Westin Washington DC City Center, Washington, DC, September 20, 2012. http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=30228&EventType=Meeting&FlagshipMeetingFlag=False

Food and Drug Administration, Public Meeting on eCTD Module 1, Silver Spring, MD, September 18, 2012. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm

ExpertBriefings.com, "UFA Requirements for eCTDs," online webinar, September 12, 2012. http://www.expertbriefings.com/events/breaking-regulatory-update-for-life-science-firms-ufa-requirements-for-ectds-sept-12-2012-2-330-pm-edt-azevedo/

Extedo, Inc., "Regulatory Considerations for Life Sciences Firms," September 12, 2012, Embassy Suites, La Jolla, CA. http://www.extedo.com/

San Diego Regulatory Affairs Network, "eCTD: Background and Current Regulatory Status," San Diego, CA, August 16, 2012. http://www.sdran.org/

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, August 14-15, 2012. http://www.raps.org/s_raps/index.asp

University of California at San Diego, course instructor, "Electronic Submissions – Planning for Success," eight-week online course, fall 2012. http://extension.ucsd.edu/

American Medical Writers Association, 72nd Annual Conference. Panelist on e-submissions with Greg Cuppan of McCulley/Cuppan LLC, October 4-6, 2012, Sacramento, CA. http://www.amwa.org/default.asp?id=548

Drug Information Association, 2012 Annual meeting. Panelist SIAC Showcase for Document and Records Management, EDM Submission Reference Model, "Introduction and Recent Expansions," June 24-28, 2012, Philadelphia, PA. http://www.diahome.org/

Regulatory Affairs Professional Society, "Advanced eCTD Submissions," Washington, DC, May 2-4, 2012. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, March 28-29, 2012. http://www.raps.org/s_raps/index.asp

Thompson Publishing Group, Inc. "Electronic Trial Master File: Creation, Implementation, and Management," online webinar, March 26, 2012. http://www.thompsoninteractive.com/site/index.jsp?cat=FOODDRUG&upcoming=yes&x=87&y=25

American Medical Writers Association, "Good/Bad Authoring Practices and the Impact on eCTD Quality and Compliance," speaker for Pacific Southwest Chapter Meeting, January 28, 2012, Doubletree Hotel, Irvine, CA.

2011

Drug Information Association, 10th Annual Electronic Submissions Conference: Moving into the Next Generation of Electronic Submission Standards, San Diego, CA, 2010, November 16-17, 2011. http://www.diahome.org/

FDA*News*, "eCTD Requirements Under PDUFA V: INDs, NDAs and BLAs in eCTD Format Will Be Required," online seminar, November 16, 2011. http://www.fdanews.com/

Drug Information Association, Medical Writing SIAC Shared Learning Session, "The Medical Writer – Cornerstone of eCTD Success," online seminar , October 6, 2011. http://www.diahome.org/

ExpertBriefing.com, "How to Avoid the Dreaded Refuse-to-File, Plus 2012 eCTD Mandate from Congress," online seminar, September 6, 2011. http://www.expertbriefings.com/

Regulatory Affairs Professional Society, "Advanced eCTD Submissions," Long Beach, CA, July 20-22, 2011. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Long Beach, CA, July 18-19, 2011. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, "Medical Device Submission & Compliance Strategies for the US Market," speaker on the topics of "e-Submissions and eSubmitter: an Overview," "Managing for Success: Issues Regarding the Content of an Electronioc Submission," and "Best Practices in the Use of MS Word and Adobe Acrobat Professional," Rockville, MD, July 9, 2011. http://www.raps.org/s_raps/index.asp

Drug Information Association, 47th Annual Meeting: Convergence of Science, Medicine, and Health. Panelist "SIAC Showcase for Document and Records Management," June 21, 2011, Chicago, IL. http://www.diahome.org/

FDA*News,* "Preparing for the New Global Requirements for eCTD and Regulated Product Submissions: Mastering the Tools and Strategies," Boston, MA, May 24-25, 2011. http://www.fdanews.com/

ExL Pharma, "Regulatory Information Management," Philadelphia, PA, May 16-17, 2011. Pre-conference workshop leader, May 16: Process Re-Engineering for Small and Medium-sized Regulatory Operations: Leveraging Existing Infrastructures and Gaining Control of Service Relationships. Conference chair: May 16-17. http://exlpharma.com/events/regulatory-information-management

Regulatory Affairs Professional Society, "Drug Master File (DMF) and Active Substance Master File (ASMF)" webinar with Hans van Bruggen of eCTDconsultancy.com, April 14, 2011. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, March 23-24, 2011. http://www.raps.org/s_raps/index.asp

ERA 2011, Speaker: "eCTD Publishing: Effective Strategies for Creating Compliant Documents," February 28, 2011, Loews Portofino Bay Hotel, Orlando, FL. http://eracon.org/?page_id=154

Drug Information Association, The 24th Annual Conference for Electronic Document Management: The Intersection of Data, Documents and Submissions. Panelist "Fill it to

the RIM: Regulatory Information Management," Topic: "Metadata — Curse or Salvation?" February 15, 2011, National Harbor, MD. http://www.diahome.org/

2010

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Brussels, Belgium, November 15-17, 2010. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, "Advanced eCTD Submissions," Del Mar, CA, September 29-October 1, 2010. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Del Mar, CA, September 27-28, 2010. http://www.raps.org/s_raps/index.asp

ExpertBriefing.com, "Top 12 Issues to Avoid Under FDA's New Requirements for eCTD Submissions," online seminar, August 18, 2010. http://www.expertbriefings.com/

MMS Holdings, Inc., Scientific Advisory Board, "eCTD Do's and Don'ts," Canton, MI, August 3, 2010. http://www.mmsholdings.com/

OCRA, FDA-Educational Conference, "e-MDR: The Industry Perspective," Irvine, CA, June 17, 2010, http://www.ocra-dg.org/

CfPIE, "CTD-eCTD – Building the Marketing Application Throughout Clinical Development," Irvine, CA, June 14-16, 2010. http://www.cfpie.com/

ExpertBriefing.com, "Top 12 Issues to Avoid Under FDA's New Requirements for eCTD Submissions," online seminar, June 8, 2010. http://www.expertbriefings.com/

FDA*News,* "Preparing for the New Global Requirements for eCTD and Regulated Product Submissions: Mastering the Tools and Strategies," Raleigh, NC, May 13-14, 2010. http://www.fdanews.com/

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Brussels, Belgium, May 5-7, 2010. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, "Advanced eCTD Submissions," Rockville, MD, April 19-21, 2010. http://www.raps.org/s_raps/index.asp

ShareFEST The SharePoint Conference for Life Sciences, presenter on "Total Quality Submissions (TQS),"and panelist on "The DIA Reference Models in SharePoint," Philadelphia, PA, April 9-10, 2010 www.sharefestconference.com

CfPIE, "CTD-eCTD – Building the Marketing Application Throughout Clinical Development," Malvern, PA, March 10-12, 2010. http://www.cfpie.com/

Drug Information Association, The 23rd Annual Conference for Electronic Document Management: Global Content Management in an Electronic World, Panel Chair:

"Progress Report – The Business Case for the DIA EDM Reference Model," February 16-19, 2010, National Harbor, MD. http://www.diahome.org/

ExL Pharma, The 2nd Leveraging Global eCTD Efficiencies: eCTD Submission Management and Standards for a Global Regulatory Landscape. Pre-conference workshop leader, "eSubmissions 101 -- Regulatory Information Management: Leveraging Efficiencies and Improvements Provided by the Use of eCTDs". January 11-12, 2010, Washington, DC. http://www.exlpharma.com/events/leveraging-global-ectd-efficiencies

2009

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, December 7-8, 2009. http://www.raps.org/s_raps/index.asp

Drug Information Association, The 8th Annual Electronic Submissions Conference. eCTD: The Adventure Continues. "Case Study: Using the EDM Reference Model to Close the Gap Between Regulator/Industry Requirements and EDM Architectural Constraints," San Diego, CA, November 17-19, 2009. http://www.diahome.org/

FDA*News,* "Navigating the FDA's New Requirements for eCTD Submissions," Las Vegas, NV, November 16-17, 2009. http://www.fdanews.com/

CfPIE, "CTD-eCTD – Building the Marketing Application Throughout Clinical Development," Berlin, Germany, November 2-4, 2009. http://www.cfpie.com/

ExpertBriefing.com, "Document Management Systems to Support eCTD Success," online seminar, October 15, 2009. http://www.expertbriefings.com/

ExpertBriefings.com, "Organization of Clinical Datasets in eCTD Submissions," online seminar, September 29, 2009. http://www.expertbriefings.com/

CfPIE, "CTD-eCTD – Building the Marketing Application Throughout Clinical Development," Malvern, PA, September 14-16, 2009. http://www.cfpie.com/

Regulatory Affairs Professional Society, "Advanced Course: Preparing Compliant eCTD Submissions," Rockville, MD, August 20-21, 2009. http://www.raps.org/s_raps/index.asp

ExpertBriefings.com, "Best Practices in the Use of MS Word to Assure Compliance of Documents for eCTD Submissions," online seminar, July 30, 2009. http://www.expertbriefings.com/

FDA*News,* "Navigating the FDA's New Requirements for eCTD Submissions," Boston, MA, June 9-10, 2008. http://www.fdanews.com/

ExpertBriefings.com, "Organization of Clinical Datasets in eCTD Submissions," online seminar, May 20, 2009. http://www.expertbriefings.com/

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," West Coast location to be announced, May 7-8, 2009. http://www.raps.org/s_raps/index.asp

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, March 19-20, 2009. http://www.raps.org/s_raps/index.asp

ExpertBriefings.com, "Top 12 Issues to Avoid Under FDA's New Requirements for eCTD Submissions," online seminar, April 1, 2009. http://www.expertbriefings.com/

Drug Information Association, 22nd Annual Conference for Electronic Document Management: "Addressing Challenges in an Electronic World," February 10-13, 2009, Philadelphia, PA. Member of DIA ESM/DM SIAC Reference Model Working Group. February 11, 2009, Reference Model Vendor Showcase.

ExpertBriefings.com, "Understanding SharePoint as a Platform for Life Sciences Document Management," online seminar, February 5, 2009. http://www.expertbriefings.com/

ExL Pharma, Emerging Global Electronic Submission Standards: Operational Preparation for eSubmission Requirements, January 22-23, 2009, National Harbor, MD. January 22. Pre-Conference Workshop leader: eSubmissions 101: The Building Blocks for Ensuring a Compliant eCTD

2008

FDA*News,* "Navigating the FDA's New Requirements for eCTD Submissions," Raleigh, NC, December 8-9, 2008. http://www.fdanews.com/

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, December 3-4, 2008. http://www.raps.org/s_raps/index.asp

ExpertBriefings.com, "Best Practices in the Use of MS Word to Assure Compliance of Documents for eCTD Submissions," online seminar, December 1, 2008. http://www.expertbriefings.com/

Drug Information Association, eCTD: The Adventure Continues. San Diego, CA, November 5-7, 2008. Panel Chair: "Assuring Compliance of Nonclinical and Clinical Study Reports and Datasets for eCTD Submissions. Panelist "Preparing Clinical Datasets for the eCTD," November 7, 2008. http://www.diahome.org/

LORENZ Archiv-Systeme GmbH, user.Bridge.08, "Soup to Nuts: How to Get Started on the road to eCTD." Lisbon, Portugal, September 23-25, 2008. http://www.lorenz.cc/

ExpertBriefings.com, "Organization of Clinical Datasets in eCTD Submissions," online seminar, September 11, 2008. http://www.expertbriefings.com/

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, August 7-8, 2008. http://www.raps.org/s_raps/index.asp

FDA*News,* "Navigating the FDA's New Requirements for eCTD Submissions," Philadelphia, PA, July 28-29, 2008. http://www.fdanews.com/

ExpertBriefings.com, "Top 12 Issues to Avoid Under FDA's New Requirements for eCTD Submissions," online seminar, July 9, 2008. http://www.expertbriefings.com/

DOCTRAIN Life Sciences, "Preparing Compliant eCTD Submissions," June 24, 2008, Indianapolis, IN. http://www.doctrain.com/life/program_table/

OPENeCTD Forum, "Role of Templates in eCTD Process," June 10, 2008, Hamburg, Germany. www.openectd.org

Expert Briefings, "eCTDs -- Efficient and Affordable Approaches to Document Management," Live Webinar, May 20, 2008. http://www.expertbriefings.com/

Thompson Interactive, "INDs in eCTD Format: Your Roadmap for Electronic Submission Requirements," Live Webinar, May 6, 2008. www.thompsoninteractive.com

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," South San Francisco, CA, May 1-2, 2008. http://www.raps.org/s_raps/index.asp

Compliance Online, "Preparing Compliant eCTD Submissions," Live Webinar, February 6, 2008. www.complianceonline.com

FDA*News,* "Navigating the FDA's New Requirements for eCTD Submissions," Emeryville, CA, March 3-4, 2008. http://www.fdanews.com/

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Rockville, MD, January 31-February 1, 2008. South San Francisco, CA, May 1-2, 2008. Rockville, MD, August 7-8, 2008. http://www.raps.org/s_raps/index.asp

2007

Expert Briefings, "The FDA's New Requirement for eCTD Submissions," November 20, 2007.

Octagon Research Solutions, Inc., "Managing Content Across the Organization," La Jolla, CA, November 13, 2007.

Regulatory Affairs Professional Society, "Preparing Compliant eCTD Submissions," Vancouver, BC, October 25-26, 2007.

LORENZ user.Bridge.2007 User Group Meeting, "docuBridge ASP: Practical Experience," Nice, France, September 18-22, 2007.

FDA*News,* "Navigating the FDA's New Requirements for eCTD Submissions," Waltham, MA, September 17-18, 2007; San Diego, CA, October 1-2, 2007.

San Diego Regulatory Affairs Network, program moderator, "Getting Started with eCTD Submissions, Part 2", San Diego, CA, May 24, 2007.

OPENeCTD Forum, workshop on "Preparing Compliant eCTD Submissions," Budapest, Hungary, May 14, 2007.

San Diego State University Center for Distance Learning Interwork Institute. Guest Speaker on "Electronic Submissions" of RA774 Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices on the topic of Electronic Submissions, May 2007.

RAPS webcast, "Electronic Submissions Techniques," April 25, 2007.

RAPS Horizons 2007, San Francisco, CA. Moderated panel on "Electronic Submissions Update and Case Study," March 2007.

FOI Teleconferences, "Electronic Submissions: Will FDA Require eSubs & Outsource eSub Infrastructure," guest speaker assisting featured presenter, Joshua Sharlin, Ph.D., January 18, 2006.

2006

FOI Teleconferences, "Electronic Submissions: Will FDA Require eSubs & Outsource eSub Infrastructure," guest speaker assisting featured presenter, Joshua Sharlin, Ph.D., December 21, 2006.

"Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management; Public Hearing," [Docket No. 2006N-0464], December 18, 2006.

LORENZ user.Bridge.2006 User Group Meeting, "Preparing to Submit an eCTD: Key Steps to Take Before a Submission," Berlin, Germany, September 2005.

Bay Area Biotechnology Consultants Network. Guest Speaker, "Nightmare or Blessing (or both)? - Electronic Document Systems and Submission Publishing Management." El Rancho Hotel, Millbrae, CA, May 2006.

San Diego State University Center for Distance Learning Interwork Institute. Guest Speaker on "Electronic Submissions" of RA774 Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices on the topic of Electronic Submissions, May 2006.

2005

LORENZ User Group Meeting, Vienna, Austria, September 2005.

San Diego State University Center for Distance Learning Interwork Institute. Guest Speaker on "Electronic Submissions" of RA774 Investigational and Marketing

Applications for Drugs, Biologics, and Medical Devices on the topic of Electronic Submissions, May 2005

RAPS Horizons 2005, San Francisco, CA. Moderated panel on "CTD/eCTD Submissions," March 2005

Liquent West Coast User Group, Emeryville, CA. Delivered presentation "Challenges Leading up to CTD/eCTD Publishing," March 2005

FDA public meeting on CDISC and Study Data Tabulation Model (SDTM), Rockville, MD, February 2005

2004

San Diego Regulatory Affairs Network, San Diego, CA. Delivered presentation "Tools for Electronic Submissions Publishing and Electronic Record Keeping."

University of California at San Diego, Extension, San Diego, CA. Guest lecturer on IT Requirements in FDA-Regulated Industries, addressing electronic document management and electronic submission publishing.

2003

San Diego Regulatory Affairs Network, Del Mar, CA. "What you need to know about the IND Process 2002," moderated a panel on electronic INDs and the FDA CBER electronic review process

Barnett International, Philadelphia, PA. "Electronic Regulatory Submissions," presented on the topic of Explore Accepted Technologies for Electronic Submissions.

San Diego State University Center for Distance Learning Interwork Institute. Guest Speaker for Week 9 of RA774 Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices on the topic of Electronic Submissions.

2002

DIA EDMS Conference, Philadelphia, PA. Speaker on panel concerning implementation timelines for electronic submission publishing.

CALBIOsummit2002, San Diego, CA. Speaker on panel concerning implementation of electronic document and data collection technologies from patient bedside to regulatory submission.

San Diego Regulatory Affairs Network. Moderator for panel presentation on preparing for electronic submissions.

2001

DIA EDMS Conference, Philadelphia, PA. Speaker on panel concerning options for publishing and document management solutions for regulatory submissions.

2000

PhRMA Conference on Biostatistics. Speaker on panel concerning electronic submissions standards, Baltimore, MD.

1999

DIA Annual Meeting, Baltimore, MD. Speaker on panel concerning electronic submissions standards.

Conference/Seminar Attendance

2012

eRegulatory Affairs 2012, March 19-21, 2012, exhibitor, Loews New Orleans, New Orleans, LA. http://www.extedo.com/eventdetails/era-2012-electronic-regulatory-affairs-conference/

2011

Drug Information Association 2011, 47th Annual Meeting: Convergence of Science, Medicine, and Health, Chicago, IL, June 19-23, 2011. http://www.diahome.org/DIAHOME/FlagshipMeetings/Home.aspx?meetingid=27170

2010

Drug Information Association, 9th Annual Electronic Submissions Conference: Working Together Towards a Global Strategy, San Diego, CA, 2010, October 28-29, 2010. http://www.diahome.org/

Drug Information Association, 1st Annual DIA-FDA CDER/CBER Computational Sciences Meeting, Bethesda, MD, March 22-23, 2010.

Drug Information Association, 23nd Annual Conference for Electronic Document Management: "Addressing Challenges in an Electronic World," February 17-19, 2010, Philadelphia, PA. Panel chair on Business Case for EDM Reference Model.

2009

Drug Information Association, eCTD: The Adventure Continues. San Diego, CA, November 18-19, 2009. Panelist "The Business Case for the DIA EDM Reference Model," November 7, 2008. http://www.diahome.org/

Drug Information Association, Annual Meeting, San Diego, CA, June 21-25, 2009.

Drug Information Association, 22nd Annual Conference for Electronic Document Management: "Addressing Challenges in an Electronic World," February 10-13, 2009, Philadelphia, PA. Member of DIA ESM/DM SIAC Reference Model Working Group. February 11, 2009, Reference Model Vendor Showcase.

2008

Drug Information Association, eCTD: The Adventure Continues. San Diego, CA, November 5-7, 2008. Panel Chair: "Assuring Compliance of Nonclinical and Clinical Study Reports and Datasets for eCTD Submissions. Panelists "Preparing Clinical Datasets for the eCTD," November 7, 2008. http://www.diahome.org/

LORENZ Archiv-Systeme GmbH, user.Bridge.08, "Soup to Nuts: How to Get Started on the road to eCTD." Lisbon, Portugal, September 23-25, 2008. http://www.lorenz.cc/

DIA, "Managing Documents and Records – The Never-ending Process," Philadelphia, PA, February 6-8, 2008.

OPENeCTD Forum, "Progressing the eCTD Standard," June 10-11, 2008, Hamburg, Germany.

2007

DIA "eCTD: The Future is Now," San Diego, CA, November 15-16, 2007.

San Diego Regulatory Affairs Network, "Getting Started with eCTD Submissions, Part 2", San Diego, CA, May 24, 2007.

OPENeCTD Forum, Budapest, Hungary, May 14-16, 2007.

Blue Star Learning. XML: An Introduction, San Diego, CA, March 26-27, 2007.

San Diego Regulatory Affairs Network (SDRAN), "Inspections, 483s, and Warning Letters," program committee, La Jolla, CA, February 14, 2007.

DIA EDM Conference, Philadelphia, PA, February 2007.

2006

DIA "eCTDs: Entering the Mainstream," San Diego, CA, November 2006.

DIA Annual Meeting, Philadelphia, PA, June 2006.

DIA EDM Conference, Philadelphia, PA, February 2006.

2005

DIA SPL Workshop, Washington, DC, August 2005.

ISI eCTDXpress training, Whippany, NJ, August 2005.

QUMAS e-DOC Compliance Training, Florham Park, NH, August 2005.

Lorenz docuBridge training, Philadelphia, PA, June 2005.

DIA Regulatory Affairs I & II, West Chester University, West Chester, PA, May 2005.

DIA EDM Conference, Philadelphia, PA, February 2005.

2004

DIA EDM Conference, Philadelphia, PA

2003

DIA EDM Conference, Philadelphia, PA.

San Diego Regulatory Affairs Network, Del Mar, CA. "What you need to know about the IND Process 2002," moderated a panel on electronic INDs and the FDA CBER electronic review process

Barnett International, Philadelphia, PA. "Electronic Regulatory Submissions," presented on the topic of Explore Accepted Technologies for Electronic Submissions.

San Diego State University Center for Distance Learning Interwork Institute. Guest Speaker for Week 9 of RA774 Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices on the topic of Electronic Submissions.

DIA eCTD Conferences (May, October, December).

2002

DIA Workshop on CBER Electronic Investigatory New Drug Application Guidance, Irvine, CA.

DIA Workshop on CBER Electronic Submissions Review, La Jolla, CA.

DIA Annual Meeting, Chicago, IL.

2001

BIO2001, San Diego, CA.

DIA Annual Meeting, Denver, CO.

DIA European Regulatory Affairs, Boston, MA.

DIA Workshop on CDER Electronic Submissions Review, Philadelphia, PA.

RAPS seminar on electronic submissions, San Diego, CA.

2000

BIOCOM 2000, San Diego, CA.

DIA Annual Meeting, San Diego, CA.

DIA CBER Seminar on eBLA and electronic submissions, Washington, DC.

ICH5, San Diego, CA.

IIR Conference on Common Technical Document (CTD).

PhRMA Conference on Biostatistics. Speaker on panel concerning electronic submissions standards, Baltimore, MD.

San Diego Regulatory Affairs Network Seminar on QSIT, Carlsbad, CA.

1999

BIO1999, Seattle, WA.

BIOCOM 1999, San Diego, CA.

DIA Annual Meeting, Baltimore, MD. Speaker on panel concerning electronic submissions standards.

DIA Seminar on CDER Electronic Submissions, Baltimore, MD.

1998

DIA Annual Meeting, Boston, MA.

DIA Seminar on CDER Electronic Submissions, Washington, DC.

Prior Years

BIO1995, San Francisco, CA.

References

Available upon request.