

CURRICULUM VITAE ANTOINETTE AZEVEDO

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Email AAzevedo@e-SubmissionsSolutions.com
Web site <http://www.e-SubmissionsSolutions.com/>

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 publishing systems selection, implementation and validation.
- eCTD submission publishing services
- eCTD submission publishing staff augmentation
- Electronic Document Management System (EDMS) selection, implementation and validation
- MS Word templates, toolbars, and user training for eCTD document authoring
- EndNotes implementation, configuration, and training
- Label conversion to Structured Product Labeling (SPL) standards for drug, biologic, device, veterinary, and over-the-counter products

Virtual Technical Infrastructure

- **Coming soon: Microsoft Office Sharepoint Server (MOSS) hosted document management.**
- EMC eRoom for document exchange and collaboration.
http://software.emc.com/products/software_az/erom_net.htm?hlnav=T
- EXTEDO eCTD Manager for paper and electronic submission publishing
<http://www.extedo.us/>
- LORENZ Archiv-Systeme GmbH docuBridge.ASP for paper and electronic submission publishing <http://www.docubridge.com/dbasp.cfm>
- Adobe Acrobat Professional 7.x and 8.x for PDF manipulation and preflight
<http://www.adobe.com/products/acrobat/index.html>
- Image Solutions Inc. ISIToolbox Pharma edition for PDF manipulation and preparing submission-ready documents
<http://www.isitoolbox.com/Default.aspx?tabid=724>
- Enfocus PitStop Professional for PDF troubleshooting and preflight
<http://www.enfocus.com/product.php?id=855>
- GlobalSubmit eCTD Validate+Review for eCTD validation
<http://www.globalsubmit.com/>

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- Sage Submissions LLC MS Word templates for regulated product submissions <http://www.sagesubmissions.com/>
- Microsoft Office Professional 2000, 2003, and 2007
- Microsoft Windows XP, 2003, and Vista/2007

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.

Professional Experience

Sage Submissions, LLC, Louisville, CO (a Colorado corporation)

February 2007 to present. Managing Partner

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

e-Submissions Solutions.com, San Diego, CA. (a California 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
- SPL/PLR consulting and conversion services
- Submission publishing services – paper and electronic submissions, including eCTD
- Training and technical support services – EDMS and submission publishing systems
- Electronic submission & EDMS strategy and corporate standards; vendor selection & implementation/validation

ANTOINETTE AZEVEDO CURRICULUM VITAE

ESPS, Inc. (now Lipient), 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 Lipient 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.

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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): Documentum, QUMAS, OpenText, Hummingbird/PC DOCS, FileNET, Lotus Notes/Domino, Lorenz DocuBridge, MasterControl.
- eCTD Publishing: Lorenz DocuBridge. Image Solutions, Inc. eCTDXpress, EXTEDO eCTD Manager.
- eCTD Validation: GlobalSubmit and GECCO review and validation tools.
- Submission Publishing: Liquent CoreDossier, kPublisher, kPortal and EZsubs. Xerox XDA/XDP.
- Adobe Acrobat family of products: Professional, Distiller, Catalog, 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

- Datafarm, Inc., <http://www.datafarminc.com/>
- EXTEDO, Inc., <http://www.extedo.us/>
- GlobalSubmit, <http://www.globalsubmit.org/>
- Image Solutions, Inc. <http://www.imagesolutions.com/>
- Liquent, Inc., <http://www.liquent.com/>
- LORENZ Archiv-Systeme GmbH, <http://www.lorenz.cc/>
- Octagon Research Solutions, Inc., <http://www.octagonresearch.com/>
- Sage Submissions, LLC, <http://www.sagesubmissions.com/>

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/>
- Moonbay Technology, <http://www.moonbaytech.com/>
- NextDocs Corporation, <http://www.nextdocs.com/>
- OpenText, <http://www.opentext.com/>

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- QUMAS <http://www.qumas.com/>
- Zorch <http://www.zorchsoftware.com/>

Memberships

- Association for Imaging and Information Management (AIIM). <http://www.aiim.org/>
- BIOCOM/San Diego. <http://www.biocom.org/>
- Clinical Data Standards Interchange Consortium (CDISC). <http://www.cdisc.org/>
- CRIX International Association. <http://www.crixinternational.org/> Member of North America Advisory Council (NAAC). Chair of Regulatory Submissions Special Interest Group.
- Drug Information Association (DIA). <http://www.diahome.org/> Member of Special Area Interest Committees (SAIC) on Biotechnology, Document Management, and Electronic Submission Publishing.
- Health Level 7. <http://www.hl7.org/>
- Implementation of Regulatory Information Submissions Standards (IRISS). <http://www.iriss-forum.org/>
- Orange County Regulatory Affairs Discussion Group. <http://www.ocra-dg.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.

Life Sciences Regulatory Skills Summary

- eCTD/CTD publishing
- FDA CDER eNDA, NDA, IND, ANDA, CTOC for eIND
- FDA CBER eBLA, BLA, eIND, IND
- EU MAA, CTA/IMP
- Canada TPP NDS, CTD/eCTD, CTA

Education

1975 -- BA, 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

2008 (to be published) *eCTD Vendor Survey*.

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2008 (to be published), *Preparing Compliant Electronic Submissions in the eCTD Format*.

2008 (to be published), *A History of Biopharmaceutical Electronic Submissions: Regulatory, Technological, and Cultural Convergence*.

2007 *eCTD 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

2008

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

FDANews, “Navigating the FDA’s New Requirements for eCTD Submissions,” Philadelphia, PA, July 28-29, 2008. <http://www.fdanews.com/>

DOCTRIN 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

FDANews, “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.

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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.

FDANews, “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.

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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.

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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

2008

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.

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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.

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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.