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# Eric J. Silva

eric@ericssilva.org | 484-619-3742 | 129 Beechwood Dr., Birdsboro, PA 19508

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## SUMMARY

I have more than 14 years enterprise application development and architecture experience, and more than 17 years in web design experience. I have effectively functioned in various roles, including Project Manager, Lead Developer, Developer, and Chief Architect. I have spent the last 13 years designing and developing GxP validated applications and I am extremely comfortable working in a heavily regulated environment.

## TECHNICAL SKILLS

### Languages

- Proficient in: Java/J2EE, EJB, Java Server Pages (JSP), C#, ASP.NET, PHP, SQL, PL/SQL, XML, XSLT, VoiceXML, JavaScript, CSS, JQuery, and JSON.
- Familiar with: Python, Ruby, Visual Basic, and Active Server Pages (ASP)

### APIs and Frameworks

- Java
  - Spring, Hibernate, XA Transactions, JUnit, JDBC, Struts (MVC), Google Web Toolkit (GWT), AspectJ (AOP), and iText (PDF).
- .NET
  - Spring.NET, NHibernate, NUnit, ASP.NET MVC, PostSharp AOP
- PHP
  - Yii, FPDF
  - Wordpress plugin and theme customization

### Methodologies

- Problem Domain Modeling in Color
- Feature Driven Development
- Scrum
- Waterfall (traditional and modified)
- Peer Code Review

### Operating Systems

- Windows XP and Windows 7
- Windows Server 2003 & 2008
- UNIX (Solaris 8 and 9)
- Linux (Ubuntu and RedHat)
- Mac OS X (10.x)

### Software

- Database: Oracle 8i-11g, Microsoft SQL Server, MySQL, and Microsoft Access
- Platforms: Windows, Windows Server, Solaris, Linux, DOS, and MacOS
- Development Tools: Eclipse, Visual Studio 2005+, IntelliJ IDEA, WebLogic Workshop, Borland JBuilder, NetBeans, Together, and Macromedia Dreamweaver
- Web and Application Servers: Oracle WebLogic 8.1/10, JBossAS 7+, Tomcat 5.x, Apache2, and IIS 5+
- Graphics: Adobe Photoshop, Adobe Illustrator, and Macromedia Fireworks
- Mobile: Experience developing applications for Android devices.
- Content Management Systems: Wordpress, Drupal, Joomla
- Cloud/PaaS: Amazon AWS/EC2, Microsoft Azure, RedHat OpenShift

### Hardware

- I have an extensive knowledge of PC hardware, peripheral devices, troubleshooting, networking, and Windows Server Administration.
- I have practical experience in analyzing, optimizing, and tuning the performance of the Java Virtual Machine (JVM).
- I have excellent analytical skills which enable me to efficiently troubleshoot system issues and architect effective solutions

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## EXPERIENCE

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### *Senior Enterprise Architect, Cytel Inc.*

#### *July 2010 – Present*

- Responsible for design and architecture of enterprise caliber solutions that scale and can be deployed in a centralized hosted environment to minimize the infrastructure footprint for our clients.
- Provide technical support service to our staff and clients as needed.
- Lead Architect and Product Manager for Access Control Execution System (ACES).

#### **Access Control Execution System (ACES)**

- Designed and developed base infrastructure for ACES using UI→PD←SI design.
- Used NHibernate, Spring.NET, PostSharp AOP, and ASP.NET MVC.
- Led team of developers to develop new functionality and product releases.
- Managed SaaS (hosted) platform for all clients.

#### **SOP Remediation**

- Led a team of writers to completely overhaul and bring up-to-date the existing SDLC and Quality Management System (QMS) SOPs.
- Existing SOPs were not written to support the development of GxP applications.
- Identified the problem areas in existing SOPs and devised the project plan to make the necessary changes to comply with regulatory requirements.

### *Data Migration of Legacy Wyeth Randomization and Clinical Supplies Systems*

#### *Pfizer, June 2011 – November 2011*

- Worked as a contractor to Pfizer to support the migration of application data from legacy Wyeth subject enrollment and clinical supplies tracking systems to Pfizer Enterprise Systems.
- Wrote custom Java utilities and SQL queries for data migration using Java 5/6, SQL, and Oracle RDBMS.
- Wrote custom SQL for report generation to aide management in understanding data migration scope.

### *Senior Technology Lead, Pfizer Inc.*

#### *October 2009 – July 2010*

- Primary responsibilities were to design and develop integration strategies and projects to allow for the smooth transition of Wyeth Clinical R&D applications to Pfizer R&D applications.
- Technical lead for migration of Wyeth Clinical Supplies systems to Pfizer systems.
- Created utility applications in Java and SQL to automate and expedite the process for extracting clinical supply and genealogy data from legacy Wyeth systems in preparation for input to Pfizer applications.
- Used Java 6, SQL, PL/SQL, and Oracle RDBMS.

### *Senior Technology Lead, Wyeth Pharmaceuticals*

#### *April 2000 – October 2009*

- Primary responsibilities include design and development of applications for Clinical R&D.
- Lead and participated in the gathering and authoring of user and functional requirements specifications.
- Acted as development lead, chief architect, developer, and project manager for various projects over the years.

#### **Third Party Randomization Integration**

- Designed and developed process for receiving subject event data from third party enrollment vendors, and loading that data into Wyeth systems.
- Based upon CDISC ODM XML standards
- Used PL/SQL and Oracle RDBMS

#### **Clinical Trials Subject Enrollment System**

- Designed and developed web-based applications to manage the enrollment and randomization of clinical trial subjects.
- Used Java, EJB, Struts, and VoiceXML using WebLogic and Oracle RDBMS

#### **Clinical Trials Supply Tracking System**

- Designed and developed web-based applications to manage the inventory and shipment tracking of clinical trial materials and supplies.
- Used Java, EJB, Spring, Hibernate, Struts, and VoiceXML using WebLogic and Oracle RDBMS

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## Response-Adaptive Trial Support System

- Designed and developed a web-based application to synchronize the randomization numbers across multiple databases in support of Response-Adaptive Clinical Trials.
- Used Java, Spring, Hibernate, Struts, and XA transactions using WebLogic and Oracle RDBMS

## Clinical Study File System

- Developed an automated server-based MS Word mail merge web service application using C# and ASP.NET which was used by a Java web application to aide in the management of Clinical Study File (CSF) documents related to clinical trial

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## PUBLICATIONS AND PRESENTATIONS

- Silva, Eric. "Interim Analyses Workflow Optimization and Case Studies." 2012 American Statistical Association (ASA) Biopharmaceutical Section FDA-Industry Statistics Workshop [Conference]. Washington, DC. 12-14 September 2012. [Conference]. Washington, DC. 19-21 September 2012. (Presentation)
- Silva, Eric. "Interim Analyses Workflow Optimization and Case Studies." Cambridge Healthtech Institute, Fourth Annual ADAPT Congress [Conference]. Washington, DC. 19-21 September 2012. (Presentation)
- Silva, Eric. "Optimizing Human Interactions and Information Flow during Interim Analysis." International Chinese Statistical Association (ICSA) 2012 Applied Statistics Symposium [Conference]. Boston. 23-26 June 2012. (Presentation)
- "VALOR, An Adaptive Design, Pivotal Phase 3 Trial Of Vosaroxin Or Placebo In Combination With Cytarabine In First Relapsed Or Refractory Acute Myeloid Leukemia." 2012 American Society of Clinical Oncology (ASCO) Annual Meeting [Conference]. Chicago. 1-5 June 2012. [Poster]
- Silva, Eric, Cytel. "ACES – A Cytel White Paper." Cambridge, MA. May 2012 [Paper]  
Retrieved from <http://www.cytel.com/pdfs/ACES-WhitePaper-May2012.pdf>
- Silva, Eric. "Implementing Adaptive Designs: Current Technology to Protect Trial Integrity, Reduce Operational Bias, and Build Regulatory Confidence." SMI, Adaptive Designs in Clinical Drug Development [Conference]. London. 26-27 March 2012. (Presentation)
- Silva, Eric. "Software Solutions to Control and Facilitate Interim Analysis Data Access, Reporting, and Communications Between Sponsors and Data Monitoring Committees." Arena International, End-to-End Clinical Data Management [Conference]. Philadelphia. 21-22 March 2012. (Presentation)
- Chandran, V., Kulthe, S., & Silva, E. "[Paper SD06] Access Control Execution System (ACES)." 2011 PhUSE Annual Meeting [Conference]. Brighton, UK. 9-12 October 2011. (Paper)
- Silva, Eric. "Implementing Adaptive Designs: Better Technology to Protect Trial Integrity, Reduce Operational Bias and Build Regulatory Confidence." Cambridge Healthtech Institute, Third Annual ADAPT Congress [Conference]. Philadelphia. 7-9 September 2011. (Presentation)
- Silva, Eric. "Implementing Adaptive Designs: Using Technology to Protect Trial Integrity, Reduce Operational Bias, and Build Regulatory Trust." Drug Information Association (DIA), 47<sup>th</sup> Annual Meeting [Conference]. Chicago. 19-23 June 2011. (Presentation)
- Mehta, Cyrus, & Silva, Eric. "Combining Design and Execution of Adaptive Trials: Case Studies and Software." International Symposium on Biopharmaceutical Statistics (ISBS), The Second Annual Symposium [Conference]. Berlin, Germany. 2 March 2011. (Presentation)

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## REGULATIONS AND STANDARDS

- Computer System Validation
- 21 CFR Part 11
- Good Clinical Practices
- Good Manufacturing Practices
- Good Documentation Practices
- CDISC Operational Data Model (ODM) and Study Data Tabulation Model (SDTM)

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## EDUCATION

- Attended the University of Phoenix-Philadelphia in 2002 pursuing B.S. in Business/Management
- Attended New Mexico Tech between 1995 and 1997 pursuing B.S. in Computer Science/Business Administration
- Graduated from Alamogordo High School in 1995