

MIKE A. BRANNON, VALIDATION, DOCUMENTATION AND PROCESS SPECIALIST

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SUMMARY

18 years of extensive system validation and documentation experience. A wide variety of projects in both system validation and technical writing spheres, including several positions involving team leadership and project management.

RELATED EXPERIENCE

Validation and Documentation Specialist, Brannon Consulting Services LLC (*May 2011– Present*)

- Engagement with Eli Lilly, *Sep 2014 – Present*: edited and processed over 200 standards, practices, resource, periodic reviews, compliance reports and references for the Global Quality Services Organization.
- Engagement with Elanco, *Jan 2012 – Sep 2014*: planned, and documented seven production validation projects for the Clinton Plant.
- Engagement with Transcend Medical, *May 2011 – Oct 2011*: planned, executed and documented an extensive ePRO/EDC system.

Lead Validation Specialist, REGISTRAT-MAPI (*April 2007 – March 2011*)

- Specialized in Late Phase Pharmaceutical Studies.
- Validated and tested protocols for computer automated systems.
- Directed, documented and completed fifty major validation projects, specializing in 21 CFR Part 11 Compliance.
- Extensive experience writing Validation Plans, Installation and Operational Qualifications, and User Acceptance Tests.

Senior Technical Writer, Exstream Software (*January 2005 – April 2007*)

- Extensive work both in documentation of the Dialogue product as well as designing and authoring seven training courses.
- Consistently assigned the most technically advanced topics documented by the department.
- Designed and developed Flash computer based training courses.

System Validator, Analysts International (*May 2004 – December 2004*)

- Contracted as a system validator in the Indianapolis area.
- Directed, documented and completed four validation projects for Eli Lilly and Company.
- Directed, documented and completed three validation projects for Disetronic.

Senior Technical Writer, Ontario Systems (*April 2002 – May 2004*)

- Led a project team documenting the Artiva line of products.
- Worked extensively in XML-based online documentation.

Documentation Department Director, Avaya Communication (*March 2000 – March 2002*)

- First Director of the Professional Services Documentation Department.
- Duties included software documentation, business writing, press release authoring, quality assurance testing, and library science.
- Managed a team of six technical writers.

Process Engineer and Documentation Specialist, Lucent Technologies (*June 1997 – March 2000*)

- Member of the award-winning Business Development Team.
- Led fifteen Process Improvement Initiatives within Lucent.
- Built and maintained the BDIS Process Web Tool, a Process Development Tool that won the President's Team Award.

INDUSTRIES

System Validation (Pharma, Manufacture, Software), Technical Writing, Software Documentation, Process Engineering, Quality Assurance, Public Relations, Information Technology, Project Leadership, Publishing, Audit Preparation, Instructional Design

TECHNICAL WRITING

FrameMaker, InDesign, Scribus, FrontPage, Epic, Photoshop, SnagIt, RoboHelp, Sharepoint

QUALITY AND VALIDATION

FDA (*21 CFR Specialty*), WHO, ISPE, ICH, ISO, TL9000, MBQ, HIPPA, PQMI, SAP, Lilly, Elanco, Validation Plans, Validation Reports, Installation Qualification, Operational Qualification, Production Qualification, Traceability Matrices, Software Development Lifecycle, Corrective Action Reports, Findings Analysis,

BUSINESS TOOLS

All Microsoft Office applications, Regulus, Epic, Artiva, CentreVu, MySQL, Bugzilla, Captivate

AWARDS

Pinnacle Quality Award (REGISTRAT-MAPI, 2010)
Department Excellence Award (Exstream Software, 2005)
Professional Services Quarterly Excellence Award, Silver Achievement (Avaya, 2000)
President's Team Achievement Award, Gold Level (Lucent, 1999)
Lucent GROWS Award (1999)
Lucent Silver Achievement (1997)

EDUCATION

M.S. Technical Communication, University of Colorado at Denver (1999 – 2001)
B.A. English and Writing, University of Colorado at Denver (1993 – 1997)