Chris Wubbolt

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Curriculum Vitae

SUMMARY

Quality Assurance professional with over 20 years' experience in quality assurance, regulatory compliance, and computer validation positions both as a consultant and an employee. A recognized industry leader specializing in GxP compliance and validation, including conducting GMP, GCP, GLP audits, assessments, and compliance activities, providing regulatory compliance training, six sigma quality system improvement projects, computer validation, and project management services. Guaranteed compliance and validation results.

EXPERIENCE

NERCSQA, President (2013)

President, New England Region Chapter Society of Quality Assurance

MARSQA, Vice President (2013)

Vice - President, Mid-Atlantic Region Society of Quality Assurance

MARSQA CSV Chair (2013)

MARSQA Computer Systems Validation Committee Chair

QACV Consulting

(2001 – present)

Quality Assurance, Compliance and Validation Consulting to FDA regulated industries. Experience/projects include:

- Provide GxP Training, including GCPs, GMPs, 21 CFR Part 11, Computer Validation, and GLPs
- Conduct GCP Audits, including Central Laboratories, Institutional Review Boards, Contract Research Organizations, Trial Master Files, Investigator Sites, Sponsors
- Quality Systems Development, Implementation, and Improvement
- Quality Assurance responsibilities, including product complaint handling, internal GMP audits, and supplier/vendor audits.
- Computer Systems Compliance, including Computer Validation
- Audits and Assessments
  - Internal GMP Audits
  - Contract Manufacturers and Packagers Audits
  - Active Pharmaceutical Ingredient Manufacturer Audits
  - Excipient Supplier Audits
  - Data Center Audits
  - Computer Validation Audits
  - Supplier Audits
  - Laboratory Audits
- QSR Audits and Assessments
- Good Laboratory Practices (GLP) audits
- Good Tissue Practices Quality Support

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- Development of Policies and Standard Operating Procedures
- Part 11 Assessments and Remediation
- Project Management
- System Retirement and Decommissioning
- Systems experience includes EDC, CDMS, IVRS/IWRS, Learning Management Systems, Complaint Handling, CAPA, EDMS, Pharmacovigilance, ERP, LIMS, laboratory and manufacturing control.

Hoffmann-La Roche (2004)
Group Leader, Supplier Audit and Product Complaints

Management of product complaint department, including evaluation and approval of product complaint files. Responsibilities included receipt and evaluation of critical complaints and escalation to management technical review committees for potential field alert reporting. Redesigned product complaint processes and procedures to improve compliance and efficiencies.

Management of supplier audit department, including scheduling and prioritization of audits, performing audits, and reviewing audit reports. Initiated redesign of supplier audit processes to assure comprehensive audit coverage of suppliers.

Supervised eight personnel including contractors in both departments.

Glemser Technologies Corporation (2000 – 2001)
Senior Consultant

Software validation, supplier auditing, quality system development, compliance auditing, and electronic records / electronic signatures assessments. Responsibilities include development of computer system related procedures, validation documentation (specifications, protocols, and reports), execution of validation protocols, conducting supplier and compliance audits, conducting Part 11 assessments and evaluations, providing computer validation and Part 11 training, and quality consulting.

Aventis Pasteur (1998 – 2000)
Computer Validation Manager, Quality Assurance

Development of computer validation policies and procedures based on FDA requirements and expectations. Audit lead in performing audits and evaluations, including development of audit plans, conducting audits, and authoring audit reports, of computerized system suppliers. Validation of information systems, including Laboratory Information Management Systems (LIMS), Enterprise Resource Planning (ERP) systems, Electronic Document Management Systems (EDMS), Clinical Data Management Systems, and other regulatory related systems. Validation of automated manufacturing and laboratory equipment, including data acquisition systems, Programmable Logic Controllers (PLCs), Supervisory Control and Data Acquisition Systems (SCADA), and Distributed Control Systems (DCS). Training of personnel in Computerized System Validation and 21 CFR Part 11 requirements and procedures. Development of policies and procedures on 21 CFR Part 11 administrative controls, assessments and remediation plans. Development and implementation of company-wide change control procedures.

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McNeil Consumer Products Company (1996 – 1998) Senior Validation Specialist, National Quality Assurance	Review and approval of computer validation documentation through all phases of the system life cycle, including requirements, specifications, protocols and reports. Interpretation of regulatory requirements for validation of information systems and automated manufacturing equipment. Support of computer validation activities at all McNeil sites. Performing computerized system supplier audits, including development of audit plans, checklists, and reports. Providing computer validation and Part 11 awareness training.
Lancaster Laboratories, Inc. (1992 – 1996) Quality Assurance Specialist III/Coordinator	Approval of validation protocols, reports and other computer validation deliverables. Perform computerized system vendor audits and evaluations. Conduct GMP/GLP compliance audits. Review GLP study protocols, data, and reports. Development of SOPs for computer validation and other GMP activities. GMP/GLP training instructor. Company representative during FDA and EPA inspections.
Lancaster Laboratories, Inc. (1989 – 1992) Chemist	Laboratory GC/MS Analysis, including instrument setup, sample and standard preparation. Instrument maintenance, calibration, and troubleshooting. Results verification and reporting. Data auditing.

EDUCATION

MS, Temple University, 1997, Quality Assurance and Regulatory Affairs in Pharmaceuticals

BS, Millersville University, 1988, Physics/Computer Engineering with a minor concentration in Mathematics

Certified Six Sigma Black Belt, 2005, Villanova University

Certified Six Sigma Green Belt, 2004, Villanova University

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MEMBERSHIPS

- Drug Information Association
- Society of Quality Assurance
- British Association of Research Quality Assurance
- ISPE
- Parenteral Drug Association
- Mid Atlantic Region Society of Quality Assurance
- New England Region Society of Quality Assurance
- Midwest Region Society of Quality Assurance
- Former Member J&J Computer Validation Forum

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CONTINUING EDUCATION

- Quality Assurance Audits, Inspections, and Responsibilities, West Coast Quality Training Institute, sponsored by NERCSQA, 2012
- CBIs 7th Annual Forum on Manufacturing Execution Systems (MES), CBI, 2012
- FDA Combination Products: An FDA Discussion on Regulating Combination Drugs, Devices, and Biologics, FDA Small Business REdI Conference, 2012
- 28th Annual Society of Quality Assurance Conference, SQA, 2012
- AOPO Annual Quality Council Meeting, AOPO, 2012
- Good Clinical Practice Training, New England Region Society of Quality Assurance, 2011
- CDER Small Business Assistance Industry Workshop, Clinical Trials and Electronic Submissions, Food and Drug Administration, 2011
- CBI's 6th Annual Forum on Manufacturing Execution Systems, CBI, 2011
- Clinical Auditing Forum, Barnett International, 2011
- 12th Annual IVT Computer Validation Conference, IVT, 2011
- 27th Annual Society of Quality Assurance Conference, SQA, 2011
- FDA Clinical Trial Requirements, Regulations, Compliance and GCP, FDA and SoCRA, 2010
- SQA Quality Conference Symposium, SQA, 2010
- Advance Good Clinical Practices, PERI, 2010
- 5th Annual Manufacturing Execution Systems, CBI, 2010
- 26th Annual Society of Quality Assurance Conference, SQA, 2010
- ShareFEST Conference, NextDocs, 2010
- Advanced Good Clinical Practices, PERI, 2009
- 45th Annual DIA Conference, DIA, 2009
- Advanced Good Clinical Practices, PERI, 2008
- Project Management for Phase 1 & 2 Clinical Trials, The Center for Professional Innovation and Education, 2008
- GAMP 5 Launch, ISPE, 2008
- ISO 13485:2003 Training, Caliso, 2008
- Bioanalytical Instrument Qualification & Validation Symposium, SQA, 2008
- Advanced Good Clinical Practices, PERI, 2007
- Advanced Good Clinical Practices, PERI, 2006
- Good Laboratory Practices, PERI, 2006

- Good Laboratory Practices, PERI, 2005
- 10th Annual Computer Validation and 3rd Annual IT Conference, DIA, 2005
- Computer Systems and Software Validation, Institute of Validation Technology, 2005
- Clinical Data Management, Temple University, 2005
- Components of a Compliant Stability Program – A Global Perspective, International Pharmaceutical Academy, 2005
- Six Sigma Black Belt Certification, Villanova University, 2005
- Good Clinical Practices, Temple University, 2004
- Auditing the Excipient Supplier, International Pharmaceutical Excipients Auditing, Inc., 2004
- Validation and Qualification Compliance Requirements, John Lee, PharmaNet, Inc., 2004
- Six Sigma Green Belt Certification, Villanova University, 2004
- Global Complaint Management Workshop, Hoffmann-La Roche, 2004
- Global Auditor Workshop, Hoffmann-La Roche, 2004
- Pharmaceutical Authentication and Forensic Analysis, American Chemical Society, 2004
- 5th Annual FDA and the Current Challenges of GMPs, University of Rhode Island, 2003
- Computer and Software Validation & Electronic Records and Signatures, IVT, 2003
- TrackWise Training, Hoffman-La Roche, 2003
- Network Infrastructure Qualification and Systems Validation, IVT, 2002
- Good Laboratory Practices Seminar, IQPC, 2002
- ISPE Washington Conference, GAMP 4 Launch, ISPE, 2002
- Oracle Clinical Training, CSS, 2002
- Introduction to Good Clinical Practices, James H. Weir, M.D./Columbia-Presbyterian Medical Center, 2002
- GAMP Americas Forum, ISPE / GAMP, 2001
- Vendor Audit and Supplier Certification Programs, Barnett International, 2001
- Computer Products Supplier Auditor Training, PDA, 2000
- Public Conference on Technical Implementation of Part 11, PDA/FDA, 2000
- Advanced Computer System Validation in a Regulatory Environment, Raskasky Group, 2000
- Change Control – System Elements, Problems and Implementation Points, ISPE/GMP Institute, 1999
- Developing the Technical Expert, SkillsPlus, 1999

- FDA Inspection Preparedness Training, Quintiles Consulting, 1999
- Electronic Document Management Conference, DIA, 1999
- Industry Training Session on 21 CFR Part 11; Electronic Records; Electronic Signatures, FDA, 1999
- Electronic Signatures & Batch Records, PDA/FDA Joint Conference, 1998
- Computer & Software Validation Processes, The Validation Institute, 1998
- Validating Programmable Logic Controllers, Confidence in Software, 1997
- SAP R/3 Basis Technology, SAP, 1997
- SAP R/3 Overview, SAP, 1997
- First Annual 'GMP by the Sea' Bio-tech/Pharmaceutical Conference, University of Rhode Island, 1996
- Microbiological QA for Pharmaceutical Products, PDA, 1996
- Training the Trainer, Fred Pryor Seminars, 1995
- 19th International GMP Conference, University of Georgia, 1995
- Laboratory GMPs, FDA and NDMA, 1995
- CGMPs for QC Laboratory Personnel, Center for Professional Advancement, 1994
- Computer System Validation in a Regulatory Environment, Raskasky Group, 1993
- 17th International GMP Conference, University of Georgia, 1993

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ADDITIONAL INFORMATION

- Speaker, CBIs 7th Annual Forum on Manufacturing Execution Systems, CBI, 2012
- Webinar Presenter, Quality and Compliance Considerations for Cloud-Based Systems, in collaboration with UL EduNeering, 2012
- Speaker, MARSQA Introduction to Computer Validation, MARSQA, 2012
- Speaker, 28th Annual Society of Quality Assurance, Auditing Software as a Service and Cloud Computing, SQA, 2012
- Co-Author, "Considerations for Validation of Manufacturing Execution Systems" Winter 2012 edition of The Journal of Validation Technology, Chris Wubbolt, John Patterson, Sr. Director of IT Compliance at Merck & Co.
- Speaker, Annual Quality Council Meeting, Considerations for Implementation of Electronic Donor Management Systems, AOPO, 2012
- Webinar Presenter, Validation vs. Verification, Association of Organ Procurement Organizations, AOPO, 2011
- Speaker, New England Region Society of Quality Assurance Good Clinical Practice Training, 2011
- Workshop Chair, Advanced Integration with Global MES Platforms, 6th Annual Manufacturing Execution Systems Conference, CBI, 2011
- Chapter Chair and Editorial Board, Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts (The 'Peach'), published 2011
- Speaker, Clinical Auditing Forum, Barnett International, 2011
- Webinar Presenter, Introduction to 21 CFR Part 11, Association of Organ Procurement Organizations, 2011
- Speaker, 12th Annual IVT Computer Validation Conference, IVT, 2011
- Co-Author, "Certified Copies of Electronic Records", Northern Highlights, NERSQA, December 2010 edition; Chris Wubbolt, Jennifer Bravo
- Speaker, SQA Quality Conference Symposium, SQA, 2010
- Speaker, Advanced Good Clinical Practices, Pharmaceutical Education and Research Institute, September 2006, 2007, 2008, 2009, 2010
- Workshop Chair, Considerations for Validation of Manufacturing Execution Systems, 5th Annual Manufacturing Execution Systems Conference, CBI, 2010
- Speaker, Midwest Regional Chapter Society of Quality Assurance, Computerized Systems Used in Clinical Trials, July 2010
- Speaker, Good Laboratory Practices, Pharmaceutical Education and Research Institute, November 2005

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- Guest Speaker, Wyeth First Annual Analytical Laboratory Instrumentation Users Group Meeting, October 2005
- Speaker, 10th Annual Computer Validation and 3rd Annual IT Conference, DIA, August 2005
- Guest Speaker, Midwest Complaint Discussion Group, May 2004
- Instructor, Pharmaceutical Education and Research Institute, Good Laboratory Practices Training, November 2003
- Speaker at IQPC Good Laboratory Practices Seminar, Achieving Part 11 Compliance Workshop, and Part 11 Guidance Documents, July 2002
- Contributing Member: GAMP Laboratory Systems Special Interest Group
- Speaker at Barnett International Vendor Audit and Supplier Certification Programs Seminar, Planning for Effective Vendor Audits, June 2001
- Certified PDA Computer Products Supplier Auditor, 2000
- Guest speaker at Mid-Atlantic Region Society of Quality Assurance (MARSQA) Spring 1995 Meeting.