DEVON BROSCH

Indianapolis, Indiana 46256 **317-517-5904**
www.linkedin.com/in/devonbrosch devon@brosch.org

REGULATORY COMPLIANCE PROFESSIONAL
Establishing and Maintaining Regulatory Compliance of Direct Impact and Indirect Impact Systems

Working to successfully produce Objective Evidence and Supporting Documentation for the Regulatory Compliance of Laboratory Equipment, Production Machinery, and Software. Authored documentation has been scrutinized in several internal and external audits with no observations made.

Validated systems including the following:

- Software: Custom SAS / C++ / Oracle 10g based software, Access Database based software, COTS software, Configured spreadsheets with/without Visual Basic Macros.
- Laboratory Equipment: Analytical and Top-Loading Balances, Rheometers, Tensiometers, Mixers, Microscopes, Pipettes, Fume hoods, Spectrophotometers, pH meters, Sonicators, Hot Plates, Magnetic stirrers, Thermohygrometers.
- Manufacturing Equipment: Custom Automated and Networked Machinery for the Production and Packaging of Glucose Testing strips.

GDP | GMP | GLP | 21 CFR Part II

TECHNICAL SKILLS

Platforms: Windows (9x, WinNT/2000, 2003, 2008, XP, Vista, 7, 10), Mac OS.
Languages: SQL, HTML, CSS, DOS.
Databases and Tools: ValGenesis, SAP, Softech ProductCenter, Oracle 10g, Microsoft Access, Microsoft Office Suite.

PROFESSIONAL EXPERIENCE

Roche Diabetes Care, Inc., Indianapolis, Indiana 2007 to May 2017

Validation Engineer **2007 to May 2017**

Writing and executing testing protocols and change controls for the creation of objective evidence which demonstrates compliance with FDA regulations. Leading validation projects and coordinating the efforts of teams of SMEs, quality representatives, laboratory, and manufacturing personnel.

- Validated custom software application from Design Verification and Development through PV, allowing its use in production of saleable product, and continued to successfully support through Change Control.
- Conducted Commissioning and Validation testing of an Automated and Networked Production Machine from design schematic through PV and continued to successfully support via change controls while in production of saleable product.
- Validated laboratory equipment, software instances, and custom test stand equipment in Ponce, Puerto Rico for the purposes of manufacturing capacity expansion, which was all released for use in production.
- Performed Periodic Quality Evaluations (Periodic Reviews) on every critical manufacturing and packaging system and supporting software system in the facility, including the Manufacturing Execution System itself, fulfilling regulatory requirements.
- Conducted Cleaning Validation Risk Assessments and Manufacturing Materials Classifications for production line machinery and manufacturing laboratory equipment, fulfilling regulatory requirements.

- Conducted Commissioning and Validation testing of automated and networked packaging quality control machine, which was approved for use in production.
- Relocated validated laboratory equipment, including environmentally isolated analytical balances, from one laboratory facility to another, which were released for use in production.
- Validated spreadsheets which, for example, performed calculations for Analytical Chemistry Test Methods and Cpk/Ppk, which were then used in quality testing of product and capability testing of production machinery.
- Conducted System Retirements of custom production machinery, custom software applications, and laboratory equipment, which were successfully removed from the facility.

Adecco –Roche Diagnostics, Indianapolis, IN 2005 to 2007

Contract Technical Writer **2005 to 2007**
Wrote and executed testing protocols and supporting documentation for custom software applications and laboratory equipment. Edited and proofread SOP, DOP, UM, and FMEA.

- Wrote and executed installation and operational qualifications for software and laboratory equipment which allowed their use in production of saleable product.
- Wrote requirements documents, Project Validation Plans, Trace Matices, and equipment classification documents, which fulfilled regulatory requirements.
- Edited and corrected User Manuals, Standard Operating Procedures, software requirements, software design documentation, software unit and integration testing protocols, and failure mode and effects analyses, which completed the development phase of custom C++/Oracle 10g/SAS software application.

Adecco –Roche Diagnostics, Indianapolis, IN Summer 2005

Intern **Summer 2005**
Took meeting minutes which familiarized myself with the custom software development process, in a regulated environment. Edited and proofread SOP, DOP, UM, and FMEA.

EDUCATION

Bachelor of Science (BS), Biology, Purdue University, West Lafayette, Indiana
(Completed 76 credit hours)

Bachelor of Arts (BA), Professional Writing, Indiana University, Fort Wayne, Indiana

Professional Development Course, Pharmaceutical Regulatory Affairs II: Devices and Combination tech, LeHigh University, Distance Learning

JavaScript Cohort, Eleven Fifty Academy