BIOMEDICAL QC/QA SCIENTIST
Profile

Conscientious and result-oriented biomedical engineer with pertinent field experience. Have been working in FDA/ISO regulated industry within QC-QA-Manufacturing departments for the last three years. Extensive experience with quality control testing of finished products, and calibration as well as generating engineering change orders (ECO) to address CAPAs, writing test method validation protocols & reports and updating FMECA/SOPs as needed. Evaluate/Resolve customer complaints. Ability to work alone, good team player, co-ordinate, prioritize, and meet deadlines. Creative, reliable, efficient, diligent with excellent communication and interpersonal skills.

Dedicated [job title] with excellent technical, analytical and communication skills demonstrated by [number] years of experience.

Hard-working, entry-level [job title], looking to apply my education and experience to a job in [job category]. Areas of proficiency include [skills].

Results-driven Mechanical Engineer with solid product engineering and QA experience.

Skills

- Training program implementation
- The Mathworks MATLAB
- Quality control
- Team player
- Excellent quantitative skills
- Critical thinker
- Detail oriented
- Microsoft Word, Excel, PowerPoint
- Planning/coordinating
- Team leadership
- Lab equipment calibration
- Lab equipment setup
- Pipetting
- Fluent in Turkish, Karachay
- Center for Biology Education
- Species 2000
- Species 2000
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- Species 2000

Accomplishments

Statistical Analysis

- Performed data collection and statistical analysis that resulted in sound recommendations that were adopted by department.

Quality Control

- Saved 8% on supply costs by working closely with suppliers to ensure components met department quality standards.

Testing, Evaluation and Analysis: Â

- Tested equipment to ensure compliance.
- Analyzed data and provided recommendations which resulted in adoption of new cost-saving equipment.

Organizational Design Â

- Prepared plans and layouts for equipment or system arrangements and space allocation.

Professional Experience
Maricopa Unified School District July 2011 to Current Biomedical QC/QA Scientist
Maricopa , AZ

- Write protocols/reports for new test method validations.
- Assist with FMECA and Standard Operating Procedure (SOP) updates.
- Perform validation/precision tests for new materials to be used.
- Collect data; analyze results in order to improve testing/calibration methods.
- Evaluate/resolve FDA priority#1 complaint cases in junction with R&D.
- Evaluate/resolve complaints for returned instruments in junction with Service Department. Biomedical QC/QA Technologist II / I
- Perform testing of finished goods per SOP.
- Review and release product related data ensuring accuracy and compliance.
- Perform testing as required for product validation using correct GMP regulations
- Maintain testing database and perform relevant analysis with associated product.
- Conduct training of new technologists using SOPs.
- Perform calibration of ITC in-process units (Avoximeter=Co-Oximeter) as well lab reference (IL-682=Co-Oximeter).
- Perform QC-Verification tests on all ITC devices for release.

Rutgers University-Enhanced Classroom Support Service January 2007 to May 2010 Technology Technician
City , STATE

- http://classrooms.rutgers.edu/)
- Assist professors with technical problems. Configure/reconfigure the users' systems.
- Responsible for repair of minor malfunctioning systems and/or equipments

Clifton Health Department July 2009 to August 2009 Health Specialist/Inspector Intern
City , STATE

- Familiarize with local Health Department Services and N.J.A.C. 8:24,26 and 7:A
- Inspect retail/recreational food/bathing institutes and factories under 2005 FDA Food Code
- Embargoed, witnessed voluntary destruction and legal sampling
- Recalled products along with State inspector, FDA inspector and microbiologists Project

Research-Rutgers University Research Dr. Drewiecki-Mathematical modeling of blood vessels, relating hypertension to area.

- Worked on fitting data into a model using numerical methods Research-Rutgers University Dr. George Shoane - Designing a noninvasive device to detect and alert drowsy drivers.
- Studied physiological changes of drowsiness and researched ways to detect these changes.
- Prototyped such a device, ran trials and collected data
- Presented the project at the end of the year at the senior design conference Skills/ Current knowledge of GLP, GDP, cGMP. MS Word, Excel, Power Point, Trackwise, JDE

Education and Training
Rutgers University B.S. : Biomedical Engineering City , State , US Rutgers University - New Brunswick, NJ B.S. in Biomedical Engineering May 2010
Affiliations
Activities Turkish Student Association Treasurer (-). Member of SWE and SHPE
Skills

Biomedical, Fda, Calibration, Cases, Database, Fmeca, Gmp, Qa, Service Department, Sop, Sops, Testing, Training, Change Orders, Eco, Engineer, Engineering Change Orders, Iso, Method Validation, Quality Control, Team Player, Writing Test, Cgmp, Drivers, Excel, Glp, Jde, Ms Word, Retail, Retail Marketing, Sampling, Trackwise, Word