

ANDREA GAIETTO

QUALITY ASSURANCE SPECIALIST

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SUMMARY

Experienced Pharmaceutical Quality Assurance and Customer Service specialist, looking to join a tech company in a software QA role. Leveraging my current experience implementing Quality Assurance and Control systems for highly regulated pharmaceutical clients to troubleshoot and streamline software applications.

PROFESSIONAL ACCOMPLISHMENTS

- Created testing suite of manual/automated test cases to ensure inventory system stability post vendor updates
- Serve as local administrator of web and desktop based inventory system
- Reduced inventory system errors by automating entry fields
- Currently drafting Electronic Systems Validation Master Plan in accordance with regulatory standards
- Authored organizational Quality Manual
- Overhauled company training program
- Authored organizational Quality Agreement legal template for use with clients
- Implemented company metrics tracking system

PROFESSIONAL EXPERIENCE

Quality Assurance Manager, Kryosphere

2016 – April 2020

Cary, NC

Managed Quality Department for a Biorepository storing research specimens and finished drug products.

- Verify accuracy of documentation prior to client review
- Maintain internal metrics program and present current trends to management
- Perform user onboarding training at client sites for client inventory portal system
- Provide telephone, email, and in person inventory system support to clients and staff
- Host client audits and company tours
- Respond to and manage client concerns and complaints
- Conduct company wide training on SOP and regulatory topics
- Serve as electronic inventory system administrator (BSI software)
- Author new Standard Operating Procedures (SOPs) and approve SOP updates
- Perform internal audits of Kryosphere systems
- Conduct external audits of key Kryosphere suppliers
- Ensure conformance with USA and EU pharmaceutical regulations
- Authored organizational Quality Manual
- Oversee creation of new paper based employee training system
- Participated in major updates to Validation Master Plan (VMP)

Biorepository Technician, Kryosphere**2014 – 2016***Cary, NC*

Performed sample handling, shipments, and temperature monitoring of client specimens and drug product.

- Coordinate directly with clients to arrange safe shipment and/or local transport of temperature sensitive materials
- Validate freezers and refrigerators to place into service
- Remain on call bi-weekly to troubleshoot freezer emergencies and failures
- Inventory material and place into BSI inventory management system
- Train interns on proper execution of SOPs and assign tasks as needed

Receptionist, Hill Creek Veterinary Hospital**2013 – 2014***Pittsboro, NC*

Served as the public face of a local veterinary practice.

- Manage incoming telephone calls and emails
- Maintain paper record system
- Clean patient rooms and front desk areas

Laboratory Technician, Perinatology Research Branch of the NIH**2011 – 2012***Detroit, MI*

Performed immediate sample processing of collected research specimens.

- Processed clinical specimens. Received and sectioned tissue samples for histology purposes. Assisted with tissue embedding and equipment maintenance

Cytotoxicology Technician, North American Scientific Associates**2011***Northwood, OH*

Performed in vitro testing of medical devices and maintained mammalian cell lines.

- Tested medical devices in a GLP environment. Maintained cell lines and adhered to company SOPs

EDUCATION

Programming Fundamentals Certificate – Wake Technical Community College – est. completion May 2021

Global Regulatory Affairs Course – North Carolina State University – 2017

BioWork Process Technician Course – Wake Technical Community College – 2015

Bachelor of Science, Biology – Bowling Green State University – 2009

VOLUNTEER EXPERIENCE

Internal Testing Lead, The Body Literacy Collective

2019-Current

London, UK

Volunteer with a global organization focused on promoting women's reproductive health education as they develop a crowdfunded women's health phone app.

- Draft suite of manual test cases based on initial Requirements Spec documentation
- Perform ongoing testing of application throughout development
- Submit detailed bug reports to developers
- Provide support and guidance to other application testers
- Review app website for functionality and accessibility

RELEVANT TECHNICAL KNOWLEDGE

- Working knowledge of Python
- HTML & CSS
- Selenium
- Jira
- Slack
- Toggl
- Microsoft Office
- Familiar with command line interface (CLI)
- Visual Studio Code

PROFESSIONAL ASSOCIATIONS

- Member of Raleigh Chapter of the American Society for Quality (ASQ)
- Member of the Triangle chapter of Women Who Code