

# Natasha R Gibson

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## JOB PROFILE

Master's of Business Administration with 20 years of Pharmaceutical experience working with GMPs, SOPs, ISOs. Over 10 years of diverse experience in the area of Quality Assurance and Quality Control. Investigating customer complaints to determine failure and root cause. Inspecting and trending proper dispositions to all incoming and outgoing raw material and APIs. Technical review and approval of finished product Batch Records, Validation reports for equipment and manufacturing process, and CAPAs. Assist in generation, revision, updating and approval of SOP, master batch records and user guides. Lead root cause investigation in the effort to improve and/or develop standard work practices.

## CAREER HISTORY

Home Marketing Systems, Inc., Kalamazoo, MI (Sept 2014 – Present)

### Real Estate Assistant

- Handling sales calls
- Coordinating property showings
- Handling the sale of rental and investor properties
- Updating listing on the Flexmls website
- Advertising land contracts on Craigslist
- Locating property owner using the city assessors website

Stryker Instruments (JBL Resources), Kalamazoo, MI (Nov 2013 – July 2014)

### Complaint Investigator, Post Market Compliance

- Determined product failure, root causes and evaluated risk of failures
- Documented investigation results
- Investigated related failures, design, and manufacturing history of failed devices
- Documented investigation results in Trackwise
- Determined trend results to input into post market product failure data
- Provided input into regulatory reporting decisions
- Identified, entered and investigated complaint related nonconformities
- Initiated non-conformances in Trackwise
- Entered new complaints and product return into Trackwise
- Coordinated with customers along with sales reps for complaint information and product return
- Prepared and sent out a weekly update of the backlog for both domestic and international complaints
- Tracked product returns and closed them out in Trackwise
- Updated information in Trackwise
- Identified duplicate complaints and entered the duplicates into the Sharepoint website

Caraco Pharmaceuticals Laboratories, LTD., Detroit, MI (March 2012 – Oct 2013)

### Quality Assurance Compliance Specialist – Customer Complaints

- Conducted, documented and reviewed complaint investigations
- Tracked all incoming complaints and closure of complaints in a timely manner
- Cross functional communication between other areas and sites to aid in product complaint resolution
- Confirmed complaint sample in ERP to ensure customer receives replacement or credit
- Received communication from various sources related to customer complaints
- Coordinated and received complaint samples from the complainant
- Handled controlled substance complaints and performed inspection of all complaint samples
- Performed monthly and annual trend analysis
- Performed testing on sample complaints
- Maintained complaint files and monitored the status of each complaint through a tracking system
- Tracked and monitored incidents, CAPAs, PEs and Change controls to closure

Torrent Pharma, Inc., Kalamazoo, MI (Aug 2011 – May 2012)

### Consultant/Supply Chain Administrator

- Managed product returns from various customer locations
- Reviewed and approved customer return requests
- Lead root cause investigations of all customer order issues encountered
- Directed implementation of corrective action strategy as result of investigations
- Conducted customer distribution audits to render release of customer recompense
- Audited 3<sup>rd</sup> party carrier distribution practices and procedures to certify accuracy of customer delivery
- Researched pricing information against the return authorizations to determine the amount of credit

Mossberg Labs, Kalamazoo, MI (June 2011 – Aug 2011)

### Production Professional

- Coordinated process line preparation for Histology, Cytology and Hematology stain and reagent products.
- Processed packaging request

- Conducted quality inspections of packaging labels
- Coordinated, reviewed, and approved of SOPs, packaging specifications and work orders

Pfizer Inc. (Coretech), Kalamazoo, MI (Oct 2010 – Dec 2010)

**QO Document Control/Stability Labeler**

- Managed document retention of reports utilizing Reserve system
- Prepared to transfer documentation that exceeds the five year in-department guidance to record storage department for archiving
- Prepared stability samples prior to entering the stability chambers and responsible for removing the products from stability chambers as directed by the stability protocol
- Labeled products to be tested on different conditions then placing that product on condition

Corium International Inc., Grand Rapids, MI (Aug 2007 – Nov 2008)

**Quality Assurance – Document Control Specialist**

- Reviewed production records to determine compliance
- Approved and released product for distribution after documentation completed.
- Maintained quality system library of reference material
- Updated and maintained the organizations training records
- Archived all documentation and made available for online viewing
- Worked with other units to resolve observations so the product can be released in a timely manner

Alkermes Inc., Wilmington, OH (Jan 2006 – Aug 2007)

**Supply Chain Technician/Production Planning Associate**

- Tracked and distributed raw materials to ensure release times met production need
- Prepared a summary of rejected raw materials on a monthly basis
- Tracked the bulk yield for all finished product
- Coordinated and updated training for three departments
- Reconciled API usage for one finished product
- Updated the monthly and quarterly metrics for all products on a monthly basis
- Implemented and completed change control requests
- Implemented changes using the Electronic Change Control system (ECC)

**Quality Assurance Professional**

- Reviewed batch records against approved SOP's
- Reviewed and approved SOP's, Protocols and Final Reports
- Tracked batch records with the use of Excel spreadsheets for monthly metrics
- Reviewed and released raw materials in Oracle system
- Performed triage functions in the Trackwise deviation system
- Reviewed and approved IQ, PQ, and OQ's
- Reviewed and approved label artwork

Pfizer Inc., Kalamazoo, MI (Aug 1993- Dec 2005)

**Quality Assurance Technician for PGRD (Pfizer Global Research & Development)**

- Provided GMP manufacturing support in the review and approval of clinical API manufacturing documentation
- Afforded guidance during safety review meetings
- Participation in FDA Inspection and Internal Auditing readiness efforts
- Utilized the quality systems approach during deviations investigations, OOS, and product quality issues
- Followed through with any deviation to ensure they were properly documented and completed
- Encouraged maintenance/quality interactions to improve cGMP compliance of API facility
- Strengthened improvement of equipment and instrument change control compliance
- Implemented routine quality inspections of GMP API manufacturing plant
- Assisted in authoring Master Batch Records for API material

**EDUCATION AND PROFESSIONAL DEVELOPMENT**

**Real Estate License**

Major: Real Estate

Greater Kalamazoo Association of Realtors, Kalamazoo, MI

License received: August 2014

**Masters of Business Administration**

Major: Business

University of Phoenix, Phoenix, AZ

Graduated: April 2007

**Bachelor of Business Administration**

Major: Business

Davenport University, Kalamazoo, MI

Graduated: December 2003

**NOTEABLE SKILLS**

Experience with interpretation pivot tables, TrackWise, AS400, Oracle, vast experience with Microsoft products (Excel, Access, Project, etc) and expertise in SAP, MRP, ERP, Flexmls and the city assessors website