

HEATHER F. FISHER-CLARKE

191 Leland St. Rockville, MD.

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[LinkedIn Profile](#)

Career Profile

An energetic, driven and team-oriented professional with 8 years in progressive food and clinical quality management roles. Specializing in assessing risk, root cause analysis, auditing, GMP, CAPA and continuous improvement.

Certifications and Education

03/16 – 02/17 Professional certifications

- Certified in HACCP and Certified HACCP Auditor (GMP and hazard analysis) -ASQ
- Certified Quality Process Analyst (statistics, project and quality management)-ASQ
- Certified Food Safety Preventative Controls Individual (risk assessment).

08/04 – 05/09 Virginia Polytechnic Institute and State University — Blacksburg, VA.

- Bachelor of Science, Human Nutrition, Foods, & Exercise: Consumer Foods Option
- Minor, Food Science and Technology: Independent quality research projects 2007 – 2009

Quality Management and Laboratory Experience

11/15-5/17 Quality Analyst. Spectrum Brands: Pet, Home and Garden– Blacksburg, VA.

- Served as the second in command to the Quality Manager for decision making and approvals.
- Directed investigation actions for out-of-specification materials per FDA regulations.
- Managed the implementation of statistical process control(SPC) software on the production floor.
- Audited suppliers for qualification, risk categorization and generated comprehensive reports.
- Effectively lead teams in risk assessments, root cause analysis (RCA) and the implementation corrective and preventative actions/changes (CAPA).
- Designed a CAPA system compliant with FDA regulations and trained management.
- Lead cross-functional teams in procedure development and training, raw material management, microbiological lab validation, and other continuous improvement initiatives.
- Served as a process, quality, food safety, document control, and training subject matter expert in multiple successful NSF, FDA and client audits.
- Prepared/approved deviations justifying release after thorough investigations for use during audits.
- Independently solved routine issues and collaborated with multiple departments to resolve quality issues in a timely fashion by leading the weekly deviation meetings.

4/15-11/15 Quality Specialist. Spectrum Brands: Pet, Home and Garden– Blacksburg, VA.

- Assisted in the preparation, execution, reporting, and CAPAs for internal and external audits.
- Completed batch reconciliation, file preparation, review and release of clinical products.
- Reviewed/Developed validation protocols and testing results for clinical products.
- Facilitated internal training on QA policies and procedures and GMP on the production floor.
- Developed the validation and change management policies and provided training.
- Independently completed monthly complaint trending/ investigations per FDA requirements and process performance metrics (KPIs) for corporate presentations.
- Completed traceability exercises and internal quality and GMP audits.
- Served as a liaison between departments by completing necessary tasks for CAPA, audit preparation, change control and product release to meet deadlines.

1/13-4/15 Laboratory Specialist. VT Food Analysis and Control Lab – Blacksburg, VA.

- Developed, troubleshoot, updated, and adhered to SOPs and trained new employees
- Prepared/processed food raw material samples for nutrition analysis.
- Inspected materials per acceptance criteria and prepared reports for testing plans.
- Assisted R&D and operation managers in determining appropriate CAPA.

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- 8/10-4/14 Quality Control and Assurance Consultant. Maxx Performance Inc – Roanoke, VA.
- Designed a hazard plan(HACCP), GMPs, SOPs, and corporate quality policy.
 - Developed SOPs/forms and provided training for sanitation procedures and hazard prevention.
 - Conducted problem-solving meetings for the development of SOPs and continuous improvement.
 - Audited the production floor in accordance with cGMPs and regulations.
- 11/11-9/13 Quality Control Laboratory Technician. Inorganic Ventures – Christiansburg, VA.
- Conducted analytical testing and managed records for release per ISO/NIST standards.
 - Identified/implemented method of data/technology transfer of analytical results to eliminate errors.
 - Regularly identified, troubleshoot, and corrected quality issues.
 - Adhered to SOPs with keen attention to detail, while critically evaluating scientific analysis results.
 - Investigated complaints to determine validity, root cause, and implement CAPA.
- 8/09-9/11 Shop leader/Assistant Manager. VT Dining Services – Virginia Tech; Blacksburg, VA
- Trained and managed employees on regulatory guidelines and SOPs.
 - Designed and implemented process improvements during fast pace production.
 - Maintained /audited product and sanitation records and recorded corrective action.
 - Received employee and customer feedback in a considerate and timely matter daily.
 - Received 100% on all health inspections by ensuring employee adherence to regulations.

Performance Milestones

- ◆ Slashed costs of testing, accumulation of stock inventory, and sales cuts by over \$200,000 annually by initiating and leading team efforts for in-house microbiological testing validation. –Spectrum Brands.
- ◆ Lead raw material management team's efforts in resolving inventory discrepancies, improving supplier relationships, preventing the consumption of expired chemicals, and saving \$15,000 annually by retesting good materials for prolonged use – Spectrum Brands.
- ◆ Developed/implemented an FDA and ISO compliant document control system - Spectrum Brands.
- ◆ Created a SQF certified Quality Management System from the ground up – Maxx Performance, 2010-2014.
- ◆ Created/Provided insight for the development of 4 HACCP plans for successful audits – Maxx Performance and Spectrum Brands.

Applicable Skills, Training and Affiliations

- ◆ Attended a FDA Root Cause (RC) Analysis and CAPA class focused on pharmaceutical industry.
- ◆ Active member of The American Society of Quality (ASQ).
- ◆ Currently studying for Pharmaceutical GMP Professional and Quality Auditor Certifications (ASQ).
- ◆ Comprehensive understanding and experience with application of FDA cGMP/GCP/GLP, EU regulations, ISO standards and Lean 6 Sigma Process improvement methodologies.
- ◆ Expert in Microsoft office suite: Word, Excel, Outlook, Visio, One Note and Project.
- ◆ Experienced using various QMS, Trending, and Inventory systems: Minitab, SAP, LIMS, SharePoint. etc.
- ◆ Experience in handling sensitive information and passing ISO, NSF, FDA, and client audits.
- ◆ Well versed in various scientific assays in the fields of microbiology, instrumental, and wet chemistry.
- ◆ Displays flexibility, eagerness to learn, and strong interpersonal and communication skills.
- ◆ Certified First Responder in Adult and Pediatric CPR/AED and First Aid.