Willa Loletia Carter

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Experienced chemist with 25 years of experience in quality control, raw materials, manufacturing, validation, and stability. Experience in pharmaceutical, medical device, cosmetics, and food industries. Former odor panel scientist at Proctor & Gamble as a contractor. Extensive teaching experience. International inspector.

Work Experience

Quality Lead Auditor October 2021-Present
Cannon Quality Group
Danville, CA

- Conducted at least 62 out of 72 audits of medical devices for startup companies.
- Types of facilities include the manufacturing of non-active cardiovascular implants, drug eluting coronary stents, and orthopedic medical devices et.al.
- Other facilities audited include quality control laboratories (testing of raw materials, in-process, and final components), clean rooms and sterilization facilities using ethylene oxide, and E-Beam Sterilization.

Quality Lead Auditor January 2018-October 2018
SGS North America
Rutherford, NJ

- Conducted over 300 audit days of inspecting materials such as active pharmaceutical ingredients, raw materials, excipients for use in the final product. Assessed manufacturing equipment such as kettles, and mixers et. al. Reviewed records for compliance of the processes for the manufacturing of components including chemical synthesis, fermentation, chromatography, and plant extraction et. al.

- Inspected warehouses for environmental conditions such as temperature and humidity to ensure the appropriate storages for components according to the Food and Drug Administration and ISO (International Organization for Standardization).

Assessor April 2015-October 2018

British Standards Institute
Herndon, VA

- Supervised and conducted over sixty-eight (68) Rx 360 Audits/ ISO Audits in the USA, Mexico, New Mexico, Italy, London, Brussels, Frankfurt and Ludwigshafen, Germany, Netherlands, Belgium, Paris, Basel, and Sissle Switzerland, Luxembourg, Barcelona and Portugal, Dominican Republic, Puerto Rico, Guadeloupe, El Salvador, Panama City, Panama, Budapest, Hungary
- Types of audits conducted; supply chain security, packaging, active pharmaceuticals, excipients, cGMP, GDP, GLP, Raw Materials/Basic Chemicals, and oil/gas. Conduct audits that include classification of medical devices, safety, and effectiveness requirements, application for medical device licenses, foreign manufacturers, the obligation to inform, distribution records, recalls and implant registration data tracking, serialization, SAP, and ERP systems.
- Prepare assessment reports and approve corrective active and preventative action plans.

Scientist/Chemist March 2014-April 2015
Alcon-Johns Creek, GA

- Peer-reviewed and prepped for audit readiness of the laboratory.
- Conduct quality control and in-process tests as needed.

Chemist April 2012-March 2014
Johnson & Johnson
Athens, GA

- Conducted tests within a quality control laboratory according to various methods per the United States Pharmacopeia, European Pharmacopeia, and validated test methods by the organization. Instruments (not all inclusive) to test material are Karl Fischer used to determine moisture in the component, High Performance Liquid Chromatography, and Gas Chromatography used for determination of concentration and impurities in material.
- Approved and reviewed stability testing for control substance schedule I, II, and III
- Investigated and wrote investigations determining root- cause and implemented CAPAs.
- Approved test results using a variety of chemistry-specific software programs (Empower 3), Laboratory Information Management Systems (LIMs)

Raw Material Chemist/Quality Systems Analyst October 2008-April 2012
Qualitest Pharmaceuticals
Huntsville, AL

- As Raw Material Chemist conducted laboratory tests determining impurities, concentrations of materials for used in the manufacturing of final products.
- Wrote and evaluated annual product reviews and graphed scientific data.

- Maintained compliance with DEA, EPA, and FDA.
- Wrote root-cause investigations and implemented corrective and preventative actions, including documentation of any effect or impact on the product.
- Maintained required regulatory documentation as current, legible, readily understood, complete, and accurate to ensure compliance with procedures and specifications.

Chemist/Quality System Analyst October 1999-October 2008
Thermofisher (Formerly known as Patheon Pharmaceuticals)
Cincinnati, OH

- Coordinated and conducted tests methods using European, Japanese, British, the United States Pharmacopeia and the Food Chemical Codex.
- Tests methods from the United States/European Pharmacopeia et. al. included testing to determine moisture, impurities, concentrations, and safety etc. for the materials used in manufacturing to produce the final products.
- Lead routine and non-routine quality investigations on plant processes and development activities using instrumentation such as FTIR, Karl Fisher, Wet chemistry, etc. Conducted validation using technical customer packages and validated methods from the United States Pharmacopeia, European, British/Japanese Pharmacopeia, and Food Chemical Codex.
- Assisted in hosted FDA audits and internal quality laboratory audits.

Scientist September 1999-October 1999
Proctor & Gamble
Sharonville, OH

Administrator/Owner September 1994-September 1999
Living Waters Family Assisted Living
Huntsville, AL

- Managed, planned, budgeted, and scheduled all work task**.**
- Implemented and wrote Standard Operating Procedures, marketing, negotiating, and contracts.
- Monitored/Consulted with others and helped open a new elderly care facility.
- Planned budgets, cost savings, and facility and transportation activities.
- Consulted for other health care associates to open family assisted living facilities for the elderly.

Associate Engineer September 1994-June 1995
Qore Property Sciences
Huntsville, AL

- Test asphalt, gravel, and soil for building specifications

Social Worker April 1993-September 1994
Huntsville Housing Authority
Huntsville, AL

- Social Worker for single mothers

Crisis Counselor January 1992-April 1993
Bradford Parkside
Huntsville, AL

- Crisis Counselor for Substance and Alcohol Abuse

Education

Florida Institute of Technology
Masters of Project Management-May 2015
Melbourne, FL

Oakwood University
Bachelor of Science in Chemistry-April 27, 1996
Huntsville, AL

Professional Societies and Committees

- 1999-2008 American Chemical Society

Teaching Experience

- Silicon Dioxide, Auburn, Alabama-Introduction to 21 Code Federal Regulation Part 210 Current Good Manufacturing Practice in Manufacturing Processing, Packing, or Holding of Drugs - May-June 2019-Various dates.

- Silicon Dioxide, Auburn, Alabama -Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals- May-June 2019-Various dates.

- L Brands, Columbus, Ohio- ISO 22716:2007 Cosmetics-Good Manufacturing Practices (GMP)-Guidelines on Good Manufacturing Practices-Internal Auditor Training-August 08-09, 2019

- L Brands, Columbus, Ohio -ISO 22716:2007 Cosmetics-Good Manufacturing Practices (GMP)-Guidelines on Good Manufacturing Practices-Awareness Training-August 08-09, 2019

- Silicon Dioxide, Auburn, Alabama-Introduction to Good Laboratory Practices Based on ISO 17025:2017-May-June 2019-Various dates.

- Cannon Quality Group, Danville, California-Integrated Management Systems ISO 9001:2015 Quality Management System, ISO 13485:2016 Medical Devices-Quality Management Systems Requirements Products-Particular Requirements for the Application of ISO 9001: 2015, Current Good Manufacturing Practice (cGMP)-On Going

Certifications

- TUV SUD North America ISO 13485: 2016 Medical Device-Quality Management System Internal Audit-Issued January 27, 2022-No Expiration
- TUV SUD North America Medical Device Regulation (MDR)-Issued November 18, 2021/(EU) 2017/745-No Expiration
- TUV SUD North America Medical Device Single Audit Program (MDSAP)-Issued November 28, 2021-No Expiration
- Rianne Tooten Clinical Research Professional ISO 14155:2020 Clinical Investigation of Medical Devices for Human Subjects-Good Clinical Practices-Issued March 30, 2022-No Expiration
- Basics of Gamma Radiation Sterilization Process Requirements-Issued June 2022-No Expiration
- Food Safety Preventative Controls for Human Food (FSMA-Food Safety Modernization Act) Certificate of Training Issued June 06, 2018-No Expiration
- Global Food Safety Initiative (GFSI) Remote Auditor Training Issued August 10, 2020-No Expiration
- EFfCI (European Federation for Cosmetic Ingredients) GMP Auditor Certification December 17, 2018-No Expiration
- IATA (International Air Transport Association) Audit Quality and Risk Management for Temperature Controlled Cargo (classroom five days) March 20-March 24, 2017-No Expiration
- SGS ISO 22716:2007 Cosmetics Good Manufacturing Practices Auditor Training According to ISO 19011-Issued September 25, 2019-No Expiration
- SGS ISO 9001:2015 Quality Management Systems -Issued June 22, 2019-No Expiration
- COVID-19 Remote Auditing Training-Issued March 18, 2020-No Expiration
- Lean Six Sigma Yellow Belt Certification-2012-No Expiration