Paula Hill

King of Prussia, PA - Email me on Indeed: indeed.com/r/Paula-Hill/5310bf6d16dfead7

WORK EXPERIENCE

Chemist

Dow Chemical / Kelly Scientific - Collegeville, PA - 2012 to Present

Responsibilities

Provide support to scientists that perform quantitative and qualitative analysis of various compounds using HPLC, UPLC, GC and LC/MS/MS. Primary responsibilities are sample, standard and mobile phase preparation. Skills include wet chemistry and excellent record keeping skills.

Accomplishments

Assisted departmental move from Springhouse to Collegeville.

Skills Used

Performed tasks correctly and in a timely manner.

QC Chemist

McNeil Consumer Healthcare, Research Pharmaceutical Services - Fort Washington, PA - May 2007 to November 2011

McNeil Consumer Healthcare, Ft. Washington Plant,

- Provided testing and technical support in the Analytical QC Laboratory. These functions include: Testing: bulk and finished products (liquids & solids), marketed product stability samples and J&J affiliate samples. (HPLC, Dissolution, UV, Viscosity, KF)
- Experienced in the application of laboratory test methods and specifications, USP/NF, cGMP and other pharmacopoeias.
- Skills include: computer applications, ability to multi-task, with excellent interpersonal and team building experience.
- Compiled Annual Product Reviews with reporting focused toward GAP remediation.
- Assisted Quality Assurance Department with Complaint Investigations which included inspection of consumer return samples, packaging and manufacturing record review and trend analysis.
- Experienced with SAP and Product Quality Management System (PQMS) software.

Compliance Specialist

McNeil Consumer Healthcare, Kelly Scientific - Fort Washington, PA - January 2006 to April 2007

McNeil Consumer Healthcare, Ft. Washington Plant

• Provided compliance support to Liquid Operation Work Centers through line inspections, line clearances, manufacturing incident investigations and nonconformance reports in accordance with company standard operating procedures, cGMP compliance and the Johnson and Johnson Credo.

These functions included:

- In-Process Audits, packaging batch record review and supervision of redress operations. Worked as team to efficiently resolve compliance issues.
- Reviewed and approved Liquid and Solid Manufacturing Requisitions.
- Prepared and trended monthly reports for In-Process Audits, Line Clearance Failures, and Packaging Line Changeovers. Prepared monthly Annual Product Reviews. Ability to revise internal SOP's as needed.
- Revised Liquid Manufacturing Requisitions in accordance with change controls.

- Assisted in the implementation and training of the Liquid Packaging Certified Operator Program.
- Assisted Liquid Operation Work Centers with data entry to resolve process and packaging issues.
- Assisted Quality Engineer Project Manager with preparation of monthly Comp Statistic Presentation.

QA ASSOCIATE, QA Raw Materials, Dept. 138

Centocor, Kelly Scientific - Malvern, PA - June 2005 to December 2005

- Responsible for the inspection, review, disposition and release of components and raw materials used in manufacturing.
- Inspection and review of all documentation according to SOP and internal STM's related to support the disposition of incoming components according to cGMP compliance.
- Apply quality system knowledge to minimize compliance risk while providing opportunities for improvement.
- Current with FDA/EU regulations, guidelines, and quality system practices associated with the Pharmaceutical industry.

ANALYTICAL CHEMIST

Merck, Kelly Scientific - West Point, PA - April 2004 to March 2005

- Provided analytical support for the Sterile Pharmaceutical Development / Chemical Engineering Group.
- Conducted compatibility process development studies on new liquid products exposed to various containers, tubing's, and filters for filling and final packaging. Assessment performed by HPLC and UV/VIS. Manufactured small scale batches of liquid products.
- Conducted compatibility, stability and validation studies on lyophilized products with various container/closure systems. Assessment by Karl Fisher, HPLC, Dissolution and DSC.
- Provided written reports, process development summaries and technology transfers.

TEMPORARY ANALYTICAL ASSOCIATE

DEPT. OF ANALYTICAL CHEMISTRY - West Chester, PA - March 2003 to April 2004

19380 (610-344-0200)

Supervisor: Joe Herman (610-738-6194)

- Bioanalytical preparation and analysis of samples from drug discovery PK studies by LC/MS/MS for high throughput drug screening by turbo-flow chromatography. Operation of Micromass LC/MS/MS system with Masslynx software.
- Assist analytical chemistry with API assay, content, uniformity and related substances from solid and liquid dosage forms by HPLC according to regulatory standards. Assist analytical chemistry with method validation according to GMP, regulatory compliance and internal standard operating procedures.
- General instrument maintenance and standard record keeping.

SENIOR RESEARCH TECHNICIAN, Discovery Development

Protarga, Inc - Exton, PA - September 2000 to November 2002

- Developed and conducted preliminary stability screening studies on new anti-cancer / anti-viral drug candidates.
- Performed extractions from biologicals (liquid/liquid, liquid/solid) and liquid formulations according to GLP conditions. Assessment and assay for content and uniformity was conducted by HPLC, GC and LC/MS, including pre-method development and optimization of analytical methodologies.
- Provided detailed reports of summarized data including statistical analysis for documentation according to regulatory compliance and internal standard operating procedures.
- Investigation, isolation and detection of unknown impurities and/or metabolites by HPLC, LC/MS and UV/VIS.
- Provided analytical support to drug discovery chemists. Preparative and semi-preparative purification by normal / reverse phase chromatography.

• Assisted with the development of novel liquid formulations with assessment by HPLC and dissolution according to GMP compliance.

EDUCATION

Associate of Applied Biotechnology

Athens Technical College - Athens, GA 1993

ADDITIONAL INFORMATION

OTHER SKILLS

- Microsoft Office, Excel, Powerpoint, Access
- Millenium Empower
- Chemstation LC and LC/MS
- Project Quality Management System
- Laboratory Information Management Systems
- Laboratory / Manufacturing Hazardous Material Safety Training
- Current with DEA Regulations