Heather Carroll

Cell: 551.804.6692 430 E. Lancaster Ave, Apt. E23. Wayne, PA 19087 hcarroll127@gmail.com

SUMMARY OF SKILLS

Dedicated, accomplished, hardworking professional with over 6 years of pharmaceutical experience, focused on attention to detail and company success. Energetic and motivated individual capable of successfully leading teams or projects, with the ability to organize and simplify complex concepts for ease of use. Master of Science Degree in Applied Statistics drives a strategic approach to analytics and data review. Accountable, ethical, analytical and loyal individual with success in the following areas:

- Team Metrics
- Stakeholder Support
- SAS Programming
- Mathematical Modeling (e.g. Stochastic SIR Model)

WORK EXPERIENCE

Shire Pharmaceuticals, now part of Takeda Exton, PA

Senior Quality Assurance Specialist April 2019 – Present

- In addition to responsibilities as a QA Specialist II, QA Specialist I, and QA Specialist, role was expanded to include:
  - Maintaining CMO Quality Agreements by performing periodic reviews and updates as required.
  - Performing comprehensive reviews of analytical test methods, method validations, and stability protocols as they pertain to IMP.

Quality Assurance Specialist II April 2017 – April 2019

- In addition to responsibilities as a QA Specialist I and QA Specialist, role was expanded to include:
  - Ensuring complaints are fully investigated and adequate responses are provided to complainants.
  - Generating and updating (as appropriate) Shire SOP's with input from key stakeholders.
  - Participating in CMO audits.
  - Preparing Product Specification Files.

Quality Assurance Specialist I January 2015 – April 2017

- In addition to responsibilities as QA Specialist, role was expanded to include:
  - Conducting Annual Mock Recall.
  - Performing person-in-plant and QA oversight at CMO's.
  - Contributing actively in project and team meetings.
  - Communicating effectively with CMO's/suppliers regarding technical information and queries.
  - Collaborating with other members of QA Team to improve quality systems.
  - Navigating Electronic Quality Management System to progress and close records.

Quality Assurance Specialist (Kelly Services - Contractor) September 2013 – January 2015

- Provides QA support for the manufacturing, packaging and control of clinical trial materials by:
  - Ensuring compliance with cGMP's, IND, clinical protocol, company policies, and domestic/global regulatory standards.
  - Ensuring all deviations, change controls, and out-of-specification results are properly investigated.
  - Reviewing and approving master batch records and executed batch records.
  - Releasing IMP for clinical use in Shire's inventory system.
  - Reviewing and approving Clinical Label Text.
- Generates and reviews with QA Management on regular basis team metrics of key performance indicators.
- Manages and writes internal/external deviations.
- Upholds the strict confidentiality of on-going clinical programs.
- Collaborates with QP's to ensure compliance with EU GMP's.
- Prioritizes and manages strict clinical deadlines
- Ensures all GMP training is current and completed on time.

Novartis Suffern, NY

Packaging Operator (Kelly Services - Contractor) Summer 2013

- Contributed as member of high-speed controlled substance packaging line team responsible for:
  - Operating packaging equipment based on company safety specifications.
  - Adhering to Good Manufacturing Practices and up to date Standard Operating Procedures.
  - Maintaining quality control while achieving productivity goals.

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EDUCATION AND CERTIFICATIONS

SAS Certification
Base Programming Specialist In-Progress
- Programming 1: Essentials
- Programming 2: Data Manipulation Techniques

Villanova University Villanova, PA
Masters of Science in Applied Statistics May 2016
- Cumulative GPA: 3.4

Muhlenberg College Allentown, PA
Double Major: Mathematics and Art History B.S. May 2013
- Cumulative GPA: 3.7 (Graduated Magna Cum Laude)
- Mathematics GPA: 3.71 (Graduated with Honors in Mathematics)

RELATED TRAINING

Quality Assurance/ Quality Control for Biologics and Biopharmaceuticals – *CfPIE* October 2017
Auditing Fundamentals - *ASQ* November 2016
Quality Metrics - *Compliance Training Panel* June 2016
Aseptic Processing in the Manufacture of Biotech and Pharmaceutical Products - *CfPIE* May 2016
The Manufacturing Process – *Techceuticals: The Solid Dose Experts* January 2016
GMPs in Clinical vs. Commercial Manufacturing - *Tungsten Shield Group* November 2015
Meeting the Regulatory GMP Requirements during Clinical Manufacturing - *Pharma Webinars* October 2015
GMP for IMP Manufacture – *GMP Services* September 2015

AWARDS AND ACHEIVEMENTS

Shire Pharmaceuticals
- **Celebrate Awards**: Recognized multiple times by colleagues and stakeholders for exceptional contributions.
- **Recognizing Excellence Awards**: Recognized multiple times by key stakeholders for exceeding responsibilities on multiple projects.
- **Kelly Services Employee of the Month:** Recognized by Kelly Services and colleagues at Shire for outstanding dedication and service.

Muhlenberg College
- **Pi Mu Epsilon**: Accepted into the Muhlenberg Chapter of the National Mathematics Honors Society.
- **Miriam Koehler Mathematics Scholarship:** Awarded to a freshman or sophomore mathematics major for excellence in mathematics.
- **Muhlenberg College Dean's List (8 of 8 Semesters):** Selected to the Dean's List every semester, for a semester GPA of 3.5 or greater.
- **Muhlenberg College Presidential Scholarship:** Awarded a four-year Presidential Scholarship for High School Academic Excellence.

LEADERSHIP

Shire Pharmaceuticals
- **Disposition Harmonization:** Contributed on team to create one disposition process for Clinical Small Molecule, Large Molecule, API, and Plasma.
- **Shelf Life Allocation Process:** Developed Shelf Life Allocation and Expiration Date Assignment Process for Clinical Small Molecule QA Team.
- **Metrics Development:** Since 2014, created tools for capturing Clinical QA key performance indicators such as tracking receipt of all batch records, batch record review time, batch disposition time against deadlines. Review metrics weekly with QA Management to ensure visibility.
- **Acquired Product Integration**: Drove integration activities for acquired product to ensure compliance and timely integration resolution.