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| Nicole RIVERA |  |
| Career dRIVEN High Professionalism Adaptable Versatile |
| (407)398-2092 ▪ NICOLERIVERAPR94@GMAIL.COM ▪ Rockville ▪ https://www.linkedin.com/in/nicole-rivera |  |

SUMMARY

* Life Sciences professional with published research and acquired knowledge in the pharmaceutical & biological sciences.
* Recognized for working with diligence and due awareness of impact to industrial operations, project timelines and customer deliverables.

Competencies in the areas of:

* Small & Large Molecule Product Manufacturing
* Bioinformatics, Statistics, Pharmacology & Computer Programming Courses
* Process Qualification (Validation Studies)
* Organic/Analytical Chemistry & Laboratory Instrumentation
* Technical Writing
* Quality Assurance, Data Integrity, and Compliance
* Knowledge in Quality Systems & Investigational Tools
* Bilingual: English & Spanish

**Investigative Specialist, Production System (Biologics)** ▪ Oct 16, 2019 – Dec 1, 2020

GlaxoSmithKline ▪ Rockville, MD

* Led cross-functional team meetings, performed root cause analysis, assessed material effect, and developed corrective and preventive action plans per QRM strategy.
* Utilized production control systems including Delta-V, CCDARTS, Unicorn, and Manufacturing Enterprise Resource Planning to obtain, generate, and evaluate data.
* Worked with quality assurance, operational, process science, and engineering individual contributors throughout deviation lifecycle demonstrating learning agility.
* Presented investigational findings to group of peers in support of continuous improvement activities in two of three operational value streams at site plant.
* Managed stakeholders and deviation records (from creation to approval) to achieve on-time closure of investigations and support disposition of product batches.

**Validation Engineer, QA Validation (Biologics)** ▪ Aug 20, 2018 – Mar 19, 2019

Delta Project Management, Client: Regeneron ▪ Albany, NY

* Supported process qualification activities (cleaning) for drug processing equipment and CIP/SIP systems.
* Generated protocols, coordinated activities, collected samples, investigated events/deviations, and reported conclusions of cleaning validation studies.
* Investigated events for impact and presented technical reports with FMEA.
* Verified CPPs of cleaning procedures and addressed changes/CAPAs through change control program.
* Utilized business managing systems including SAP Process Compliance and Blue Mountain Regulatory Asset Manager.

**Cleaning Validation Specialist (Small Molecule)** ▪ Oct 13, 2016 – Apr 19, 2018

Catalent Pharma Solutions ▪ St. Petersburg, FL

* Supported validation, verification and periodic review activities and collaborated within cross-functional team.
* Resolved inefficiencies of equipment sampling process to reduce equipment idle time factor.
* Trained additional personnel on protocol execution regarding collection of rinse and swab samples.
* Demonstrated excellent time management skills providing reliable analytical results of samples taken from equipment.
* Strengthened skills in instrument monitoring, troubleshooting, and analytical method performance. Regularly utilized HPLC, GC, and FTIR including checking system suitability to ensure system performance.
* Used wet chemistry techniques, performed mathematical calculations for sample/ standard preparations, and analyzed chromatographic data using Empower, TotalChrom, and Chemstation. Performed validated limits test methods placed on API, or drug residue.

**Chemistry Technician, Chemistry (Food & Beverage)**

▪ Jan 1, 2015 – Dec 30, 2015

ABC Food & Beverage Research Laboratories ▪ Gainesville, FL

* Performed wet chemistry on samples requiring attention to detail, problem solving skills, and knowledge of techniques and materials involved.
* Helped set up GC & HPLC analytical instrument for assays of extracted samples.

**Organic Chemistry Research Scientist** ▪ Aug 1, 2013 – May 30, 2014

ARKAT USA, Florida Center for Heterocyclic Compounds ▪ Gainesville, FL

* Worked with scientists and mentors to provide research, publishing, and teaching services to the scientific community on the subject of heterocyclic compounds.
* Conducted research of heterocyclic compounds with specific potential as novel drug candidates and prepared corresponding research reports to be submitted for publishing journals.

EDUCATION

University of Florida

April 29, 2016 ▪ Bachelor of Science, Biotechnology

* Completion of Organic Synthesis Research Program University of Florida, Gainesville, FL.

University of Maryland

August 29, 2020 ▪ Master of Science, Pharmacometrics (Online)

* Currently attending. Learning the applications of pharmacology (PKPD), modeling and simulation (computer programming), and statistics in drug development. Graduation in April 30, 2022.

MEMBERSHIPS

ISPE, Chesapeake Bay and Boston ▪ 2018-Present

**Active Member**

Project Management Institute ▪ 2017-Present

**Active Member**

Student National Pharmaceutical Association▪ August 01, 2012 - February 20, 2015

**Head of Newsletter Committee**

▪ Gainesville, FL

* Authored informative articles on pharmacy topics covering issues such as new legislations, new drugs on the market, and health awareness information.

PUBLICATIONS

* Synthesis of Glucosamine-NSAID Bioconjugates. Rachel A. Jones, Yann Thillier, Nicole Rivera Rosario,…. 2014/ The Royal Society of Chemistry
* Chemical modification of 5α-steroids with N-protected amino acids. Nana N. Barbakadze, Rachel A. Jones, Nicole Rivera Rosario,…. 2014/SYNLETT and SYNTHESIS Thieme Chemistry Journal & Tetrahedron

CONFERENCES

* “Synthesis of protected NSAID-Amino Acids with Carbohydrate,” I-Cubed: Graduate Research Day 2014 (Book of Abstracts pdf, page 164), Gainesville, FL, October 2013.

CONTINUING EDUCATION

* Certificate of Completion for ‘AAPS Regulatory Affairs 101: Essentials of Regulatory Affairs for Pharmaceutical Scientist eLearning Series’, St. Petersburg, FL, Completed on July 16, 2017.