JANICE RIVERA

1155 Ripley Street, Silver Spring, Maryland 20910 ▪ 787.579.6000 ▪ janice.rivera5@gmail.com

QUALIFICATIONS PROFILE

Multifaceted, goal-driven, and results-oriented professional, offering comprehensive experience in management, data and technical analysis, program scope and development, and clinical and scientific research. Armed with expertise in quality management, budgeting, audits, molecular biology, immunoassays, and writing development. Expert at developing and driving innovative projects; implementing process improvement strategies; analyzing and resolving issues; and improving overall staff performance and timelines. Offering knowledge of FDA, GxP, CLIA, CAP and NYSDOH regulatory standards. Bilingual in English and Spanish. Proficient with Microsoft applications (Excel, Word, Outlook, PowerPoint, SharePoint, Project, Visio).

EDUCATION

Dec 2010	**Master of Science in Biotechnology** (GPA 3.96) JOHNS HOPKINS UNIVERSITY – BALTIMORE, MD
May 2009	**Bachelor of Science in Medical Technology** (cum laude) UNIVERSITY OF PUERTO RICO – SAN JUAN, PUERTO RICO

CERTIFICATION

2009	**Medical Laboratory Scientist,** American Society of Clinical Pathologists (ASCP)

LEADERSHIP EXPERIENCE

ACELL, INC – COLUMBIA, MD

2018–present **Manager of R&D Laboratory**

- Managed a budget of over 350K to facilitate operations for all testing and research in R&D.
- Established a relationship between R&D and Finance to establish budget codes improving the correct allocation of charges.
- Worked closely with the Quality department to improve compliance and quality of results in accordance to FDA regulations and the organization's Quality Management System (QMS).
- Participated in internal and external audits while developing CAPAs to address noncompliance.
- Improved and observed strict adherence to timelines in regards to projects, equipment maintenance and data reporting by developing a schedule for each task and test performed.
- Performed feasibility, verification and characterization of devices and developed a training plan for each test performed.
- Participated in the qualification of test methods and equipment as well as the implementation of test method training plans to ensure personnel is qualified to conduct tests.
- Assisted in maintaining all areas of the company in a safe state by participating as a member of the Safety Committee and conducting unannounced inspections.
- Managed all changes to product and processes by addressing and incorporating them to the Change Control Management program.
- Documented deviations to processes and quality events in accordance to the company's QMS.
- Assessed the budget and requirements to implement a cleanroom in the laboratory while addressing the feasibility of the project.

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Career Highlights

- ✓ *Implemented a system for inventory control and management to address last minute orders while lowering shipping costs by minimizing next day order requests.*
- ✓ *Recognized as 'most improved' by the Safety Committee after reorganizing the laboratory structure to be compliant with company and safety guidelines.*
- ✓ *Established strong reputation in improving laboratory organization, compliance and processes in accordance with FDA regulations.*

BIOCERNA, LLC – FULTON, MD

2014–2018 **Manager of Laboratory Operations**

- Worked closely with the director in improving quality and safety effectiveness of the laboratory.
- Administered laboratory budget and communicated with vendors and manufacturers.
- Facilitated two successful regulatory inspections and internal audits for CLIA, CAP and NYSDOH.
- Observed strict compliance with project timelines in collaboration with senior management while accomplishing special projects.
- Co-created scientific procedures and techniques in support of current assays improvement, as well as the validation protocols in line with regulatory guidelines.
- Established the Quality Management Team in making regulatory decisions and investigations to address issues and execute necessary corrective actions.
- Reviewed and revised over 200 guidance documents, policies, and procedures in accordance to federal and state laws.
- Keenly assessed laboratory risks and discussed findings and issues that required a corrective action by conducting weekly meetings.
- Managed laboratory operations and designed study methods in ensuring accurate, precise, and timely performance of tests and efficient and productive use of all equipment and supplies.
- Fulfilled human resource functions, including staff recruitment, training, and performance evaluation to meet organization's needs, culture, and guidelines.
- Aided physicians in selecting the appropriate treatment for patients through in vitro diagnostic assays in over 200 samples weekly, such as SNP genotyping and chemistry assays.
- Communicated with employees and upper management regarding the use of current technology during formulation and application of new scientific methods and regulatory guidance.

Career Highlights

- ✓ *Initiated a system to verify employee performance in a yearly basis, thus enhancing employees' motivation and focusing work toward organizations' goals.*
- ✓ *Established strong reputation in improving turnaround time of testing and reporting organization-wide.*
- ✓ *Maximized staff productivity through effective training and counseling, which helped them to accomplish and start new projects.*
- ✓ *Received fast-tack promotion to department lead and laboratory manager in two years of tenure by demonstrating outstanding performance within the biotechnology startup environment.*

RESEARCH EXPERIENCE

UNITED STATES DEPARTMENT OF DEFENSE – SILVER SPRING, MD

2011–2013 **Medical Technologist,** Molecular Systems
(Multidrug-resistant Organism Repository and Surveillance Network, WRAIR)

- Supported the data collection and monitored quality and timeliness of generated data daily.

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- Capitalized on industry expertise in fulfilling the following tasks:
  - Extraction of high-molecular weight DNA from bacteria and assessment of DNA sample concentration and quality;
  - Maintenance of regulatory compliance through monitoring of laboratory documentation, proper specimen handling, and assessment of generated data;
  - Validation of equipment and tests after the use of new instrument, lot, and panel type;
  - Completion of monthly surveillance of multidrug-resistant organisms for clinically relevant antibiotic resistance and virulence-associated genes;
  - Development of 20 optical maps to produce an ordered whole genome restriction map; and
  - Maintenance of three different automated equipment for phenotypic characterization of bacteria.
- Guaranteed confidentiality of protected health information through shredding, physical security, and other approved methods of institution guidelines

Career Highlights

✓ *Trained nine co-workers on standard operating procedures, while formulating policies and procedures to streamline laboratory processes in compliance with regulatory guidelines, which resulted to CAP accreditation with zero deficiencies.*

HARTFORD HOSPITAL – HARTFORD, CT

2008 **Transplantation Laboratory Intern**

- Handled cell typing through immunoassays, such as ELISAs along with molecular diagnostic procedures to reduce immune rejection by the recipients.
- Facilitated a study of the clinical significance of pre-transplant detection of HLA antibodies through solid-phase microsphere-based assays and antibodies assessment on Luminex.
- Demonstrated broad knowledge in accomplishing diversified tasks:
  - Development of the outcome of solid organ transplantation through testing, crossmatches, cell typing, PCR and electrophoresis;
  - Comparison of graft survival and antibody detection to identify statistical significance; and
  - Isolation of T and B cells and HLA Class I cells to determine viability.

GENOMAS, INC. – HARTFORD, CT

2008 **Laboratory of Personalized Health Intern**

- Carried out DNA extraction and quantification from whole blood of Hispanic patients under anticoagulant treatment through high throughput technology equipment.
- Performed genotyping of DNA samples for major CYP2C9 and VKORC1 Single Nucleotide Polymorphisms (SNPs) using Luminex.
- Kept the Warfarin DNA database with details and sought common patterns of 56 patients.

Career Highlights

✓ *Made key contribution to the following studies and implementations:*
  - *DNA as a predictor of Warfarin metabolism on patients with heart disease by assessing obtained data to create graphs and tables for result presentation;*
  - *Profile of frequency of SNPs in determining effective therapeutic dose through pharmacogenomics.*

Earlier Position Held

UNIVERSITY OF PUERTO RICO – SAN JUAN, PR

2006–2007 **Oncology Research Technician**

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PROFESSIONAL DEVELOPMENT

2019	Leadership Training for People's Managers
2019	PMP Boot Camp Certification Course
2019	First Aid/CPR/AED Training

AWARDS AND HONORS

2010	**AAP Scholarship Assistant Grant Award**, Johns Hopkins University
2007	**1st Place,** XXVII Investigation and Education Annual Forum, University of Puerto Rico

POSTER PRESENTATIONS

Rivera, J. (2007). *MDM2 levels in serum of patients with prostate cancer: A better marker?* XXVII Investigation and Education Annual Forum, UPR, Medical Sciences Campus, San Juan, PR.

Rivera, J. (2011). *Preventing injury and promoting healing through creative partnerships: Infection control for the military working dog*. Military Working Dog Veterinary Services, WRAIR, Silver Spring, MD.