iJOBS Career Panel

Ileana Marrero – Berrios FDA Biological Reviewer 09/24/2024

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Career Path





2006-2012

Dual BS Industrial Biotechnology and Microbiology

> University of Puerto Rico, Mayagüez



2013

Doctoral Studies:

Biomedical

Engineering

Rutgers

University

Oct 2013

Joined Yarmush Lab

Biotechnology Training Program Celgene

2017

Global Regulatory Summer Internship Celgene 2019

Bristol Myers Squibb

Finished PhD!
Regulatory CMC
Contractor

Celgene (now BMS)

Oct 2021

Biological Reviewer

CBER/OTP/CTB

FDA

Feb 2022 -Present

Biological Reviewer

CBER/OTP/TEB

FDA

Current Role: Biological Reviewer

- Chemical, Manufacturing, and Controls Reviewer at the Tissue Engineering Branch (TEB), OTP/CBER/FDA
 - Review cell and tissue engineered products (TEPs) Quality/Manufacturing information from clinical trial applications and marketing applications (licensure)
 - Review Cell/TEP-based devices and manufacturing equipment
 - Develop guidance/policy for TEPs
 - Review Focus on:
 - Materials/reagents
 - Starting material origin
 - Manufacturing process
 - Quality control (process controls, quality attribute testing, adventitious agent testing, biocompatibility, facility controls, etc.)

Advice: What can you do?

- You do not need previous regulatory experience to become a reviewer!
- Network talk to individuals in the profession (you are here!)
- Join a professional society (e.g., RAPS)
- Look for internship opportunities
- Attend regulatory-focused courses
- Apply!
 - Full-time reviewer
 - Staff Fellow
 - Regulatory Reviewer
 - Regulatory Researcher/Reviewer

Jobs and Training at FDA | FDA

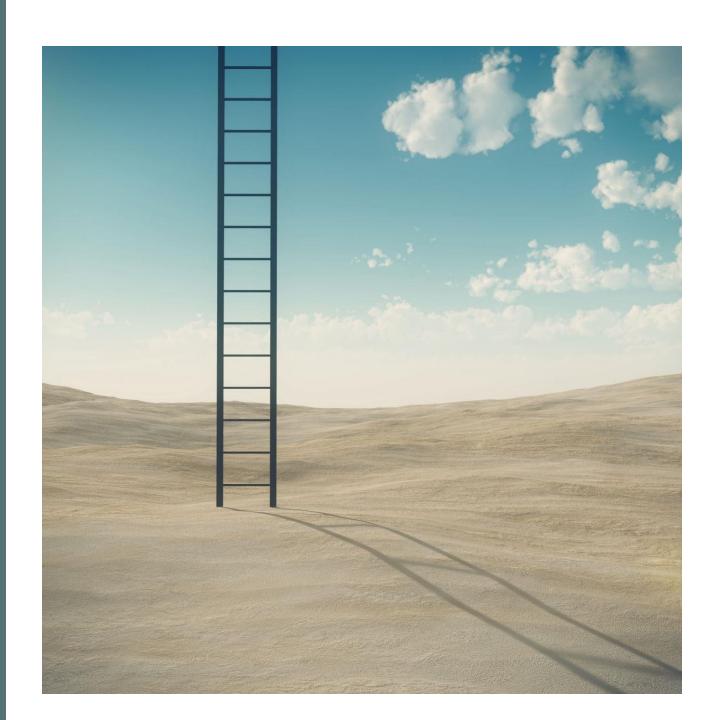
<u>USAJOBS - The Federal Government's</u> <u>official employment site</u>

Rasika Hudlikar

https://www.linkedin.com/in/rasikahudlikar13/

CAREER PATH

- Ph.D.: Advanced Centre for
 Treatment, Research and Education
 in Cancer (ACTREC), Mumbai,
 India
- Postdoctoral research: Rutgers
 University, NJ, USA
- Senior Postdoctoral Scientist:
 NCI, NIH, Bethesda, MD, USA.
- Research Scientist: Walter
 Reed Army Institute of Research,
 MD, USA



Current role: Research Scientist, WRAIR, USA

- Assists in designing, developing, executing, and implementing scientific research
- Collecting and handling the clinical trial samples from the HIV vaccine clinical trials
- Managing collaborations, proposal budgets, purchasing.
- Assist with the preparation of data for presentations at scientific meetings and for publication in journals.
- Training postdoctoral fellows, research assistants for their projects.





Research

Advise for the transition



Informational interviews



Networ k

Start applying Be patient Stay positive

Miriam Schachter

Research Scientist 1/Program Manager, Newborn Screening Laboratory

NJ Department of Health

Miriam.Schachter@doh.nj.gov

Career Path

- PhD in Biomedical Sciences from the Icahn School of Medicine at Mount Sinai
- Brief post doc in thesis lab while trying to figure out next steps
- Post doc in the NJ Newborn Screening Laboratory (APHL Fellowship)
- Entry level Research Scientist position in Virology and then NBS (3 years total)
- Research Scientist 1/Program Manager, Newborn Screening Laboratory

Current Role – Program Manager, NBS

- Oversee all laboratory operations for the NBS Lab
 - Hiring and staffing and staff logistics (total of 38 staff)
 - Purchasing and budgets
 - New assay development and validation
 - LIMS
 - Outreach
 - Day to day operations of specimen receiving, data entry, and testing (staff split into 5 testing units and 4 support units)
 - Results reporting
 - Legal

Advice

- Be open minded
- Learn about other ways to apply the lab skills you have learned
- Network and be open you never know who will set you up with your first job
- Public health and clinical labs exist and need experienced scientists

DR. NIRMALA T. MYERS, PHD

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH
(NIOSH)

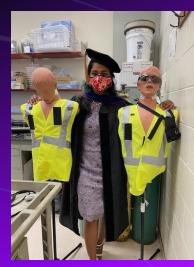
IJOBS PANEL 09/24/2024 EMAIL: NMYERS@CDC.GOV

CAREER PATH

- Bachelor of Technology Biotechnology engineering,
 SRM University, Chennai, India class of 2014
- Graduate School Ph.D. in Exposure Science from Rutgers University – graduated in 2020
- Postdoctoral Fellowship NIH funded at EOHSI,
 Rutgers University completed in May 2022
- First job outside Academia CDC NIOSH
 Morgantown from June 2022









CURRENT ROLE

- Research Epidemiologist in CDC/NIOSH/RHD
 - 80% Epidemiology Exposure Assessment and Hazard Surveillance
 - Acute inhalation injuries in all industry sectors
 - Acute injuries of women miners
 - Exposure surveillance of WTCHP participants
 - Exposure diagnosis codes in electronic health records
 - 20% Aerosol Sampling Health Hazard Evaluation Program and Industrial Hygiene projects

CAREER ADVICE

- Begin your job search at least one year before your graduation or the end of your fellowship.
- Enhance online presence and do targeted networking
 - Contact by official email
- Consider applying for multiple opportunities simultaneously, even if you don't meet all the requirements.
 - Filter by location of interest, remote/hybrid positions, job descriptions

