Dr. Mansi Shah PharmD

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Objective: Dedicated PharmD graduate with a strong academic background and extensive pharmacy experience, seeking a position in the pharmaceutical or healthcare industry. Proven ability to contribute to research, clinical trials, and patient care. Ready to leverage skills and knowledge to make a positive impact.

CERTIFICATIONS, LICENSES & TRAINING

Pharmacy Based Immunization Delivery Certificate, American Pharmacist Association (January 2021– Present)
Good Clinical Practice Certificate, Bayer (April 2023 – Present)
Surgeon General Executive Team (SGET) & Prevention through Active Community Engagement (PACE), Opioid
Overdose Response Training (April 2023 – Present)
Mental Health First Aid Adult Certificate, USA Mental Health First Aid (September 2020 – September 2023)
HIPAA Privacy and Security Certification, Pharmacist Letter (August 2019 – Present)
CPR and AED Training Certification, American Heart Association (August 2019 – Present)
Cybersecurity Readiness Certificate, Kean University (March 2019 – Present)
Best Practices for Co-Prescribing Naloxone in your agency, Rowan University (September 2020 – Present)
Responsible Conduct of Research (RCR), CITI Program at Kean University (February 2019 – February 2022)

- Record ID 30491761

Registered Pharmacy Technician, New Jersey State Board of Pharmacy (July 2022 – August 2024)

- License No. 28RW03225100

PROFESSIONAL EXPERIENCE

Bayer, Whippany, NJ, Contract **January 2022 - Present**

• Timely submission of registration updates to ClinicalTrials.gov on behalf of the clinical team, adhering to global regulatory timelines.
• Regularly updating and maintaining study trackers to ensure current and accurate information, with weekly reviews.
• Collaborating with various stakeholders, operations leads, statisticains, clinical trial physicians, clinical scientists, among others to ensure precise and consistent trial registrations aligned with protocol requirements and in adherence to NIH guidelines.
• Ensuring timely and accurate posting of high-quality information on clinical trial registries such an ClinicalTrials.gov and EU client.
• Contributed in the submission process for New Drug Application (NDA) approval to the U.S. Food and Drug Administration (FDA).
• Helped selecting a site and get it approved for the trial.
• Attended meetings nationally and internationally (Germany)

Hikma 503B, Dayton, NJ, Intern **January 2021 – March 2022**

• Organized and managed supplier quality information and questionnaires, maintaining detailed records in Excel and document folders.
• Completed FDA-sponsored training courses on Investigations, Corrective & Preventive Actions, and Supplier/Contractor Qualification and Management.
• Updates Excel sheets related to Error Reduction Factor (EFR) and Major Issue Report (MIR) for human error root causes.

• Compared and analyzed the evolution of USP <797> standards, including the 2008, 2019,and 2022 versions.
• Developed and delivered a presentation on the top five 503B citations from FDA 483s.
• Revised presentation and training materials on Good Documentation Practices, incorporating current examples.
• Actively participated in various meetings and training sessions related to operations planning, compliance, quality systems, and process optimization.

CVS Pharmacy, East Brunswick, NJ **August 2019 – Present**

- Prescription management and prioritization
- Medication therapy management (MTM)
- Communication with healthcare professionals
- Inventory management
- Patient care calls and follow-ups

Summit Oaks Hospital, Summit, NJ **August 2021 – Present**

- Floor stock management
- Medication formulary support
- Controlled medication delivery
- Inspection preparation

EDUCATION

Fairleigh Dickinson University (FDU) School of Pharmacy, Florham Park, NJ August 2019 – May 2023

- Doctor of Pharmacy GPA 3.75/4.0

Kean University, Union, NJ September 2017 – June 2019

- Bachelor of Science in Cell and Molecular Biology GPA 3.8/4.0

Middlesex County College, Edison, NJ September 2015 – June 2017

- Associate in biology GPA 3.9/4.0

SKILLS

- Medication therapy management
- Clinical trials and research
- Inventory management
- Communication with healthcare professionals
- Vaccine administration
- Data analysis and presentation
- Regulatory compliance
- Good Clinical Practice (GCP)
- CPR and AED certified

References available upon request.