**Ayanah Tunis, MS**

Plantation FL, 33324 | Mobile: + (954) 707-3272 | tunisayanah@yahoo.com

**PROFILE:**

* Regulatory Affairs Associate with four (4) years of pharmaceutical industry work experience. Proven success in leading multiple product submissions, including FDA and EMA filings, in a complex matrix environment. Demonstrates excellent project management abilities, including facilitation, organization, and time management. Highly skilled at providing regulatory support for new product development, ensuring compliance with regulatory guidelines, and achieving timely approvals. Seeking to expand my experience by contributing to regulatory strategy in pharmaceuticals, medical devices, or cosmetics.

**CORE COMPETENCIES:**

* Submissions (IND, NDA, ANDA, BLA, 510(k), PMA)
* Compliance/QA (GMP, GCP)
* Risk Mitigation
* Digital/Data Systems
* Health Authority Engagement (IR)
* Reports (LDD, APQR, AR)
* Change Controls, CAPAs Deviations

**EXPERIENCE:**

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| **ADMA BIOLOGICS, Boca Raton, FL**  ***Regulatory Affairs Associate*** | **September 2023 – July 2024** |
| **Change Controls and Compliance:**   * Processed change controls in accordance with CMC Guidance, ensuring compliance with regulatory requirements and maintaining product quality standards. * Reviewed and assessed FDA guidelines before executing tasks, ensuring accuracy in lot distribution data (LDD) reports before FDA transmission and compliance with regulatory standards. * Managed assessments and reports for Change Controls, CAPAs, and Deviations as needed, collaborating with subject matter experts to address compliance issues.   **Regulatory Submissions and Documentation:**   * Managed the preparation of Annual Reports for BLA and IND submissions, evaluated impacted change controls, and ensured timely transmission and submission of regulatory documents. * Gathered, organized, and analyzed data, preparing regulatory documents for FDA submissions, providing submission strategy guidance, and transmitting submissions via DocuBridge and WebTrader. * Prepared board slides for FDA inspections to ensure readiness and compliance with regulatory expectations.   **Product Quality and GMP Compliance:**   * Managed Annual Product Quality Reviews (APQR) in alignment with Good Manufacturing Practice (GMP) standards, facilitating quality assurance, trend analysis, and informed decision-making on manufacturing processes. * Understood, adhered to, and updated SOPs to ensure compliance with FDA-required cGMPs.   **Data Analysis and Training:**   * Gathered, trended, and analyzed scientific data using systems like SoftExpert and Laboratory Information Management System (LIMS). * Engaged in continuous training and compliance activities to stay current with regulatory standards and practices. | |

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| **GLOBOSCIENCE, Boston, MA**  ***Regulatory Affairs Associate*** | **June 2021 – September 2023** |
| **Regulatory Documentation and Submission:**   * Collected and coordinated information for regulatory documentation, preparing submissions to FDA, Health Canada, CHMP, and other regulatory agencies. Provided guidance on submission strategy for various projects. * Acted as the primary contact for external ex-US regulatory consultants, developing plans and preparing country-specific regulatory submission documents for clinical trial applications, regulatory annual reports, and compliance documents. * Liaised with external CROs and vendors to ensure the efficient transfer of clinical trial regulatory submission documents and managed the in-house submission of FDA Agency electronic documents.   **Compliance and Research:**   * Maintained up-to-date knowledge of FDA and international regulations, guidance, and standards to ensure submissions met all relevant regulatory requirements. * Participated in research of regulatory issues, disseminating information to product and technical teams, as well as senior management, to address regulatory concerns and maintain compliance.   **Cross-functional Support and Collaboration:**   * Provided functional area support for specific projects, assisting with regulatory filings and documentation on a global scale. * Collaborated with senior RA team members and project teams to accomplish regulatory projects and assignments, ensuring smooth execution and compliance across departments. | |

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| **BLACKBOARD, Summerset, KY**  ***Financial Student Aid Advisor*** | **June 2020 – Aug 2021** |
| * Responsible for offering financial aid programs, application procedures, budget development, and debt management advice and guidance to students, prospective students, parents, staff, and the community. * Aiding, guiding, and completing electronic paperwork such as FAFSA, FERPA Release forms, MPN’s. * Monitored financial aid award notices through service desk. | |

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| **WALGREENS PHARMACY, Ft. Lauderdale, FL  *Intern, Pharmacy Technician*** | **Sept 2015 – May 2017** |
| * Worked under the guidance of a pharmacist to guarantee that patients' understood drug health warnings, find, distribute, pack, and label a patient's prescribed medication, which is then verified by a pharmacist for correctness before being dispensed to the patient. * Properly track and dispose expired medication and replace them with new inventory. | |

**EDUCATION:**

**NORTHEASTERN UNIVERSITY**

* **Master of Science for Regulatory Affairs,** Boston, MA | 2023

**FLORIDA A&M UNIVERSITY, School of Science and Technology,** Tallahassee, FL | 2021

* **Bachelor of Science in** **Biology** | **Concentration:** Pre-Medicine

**MC FATTER TECHINCAL COLLEGE/HIGH SCHOOL**, Ft. Lauderdale, FL | 2017

* **Certification in Pharmacy Technician** | **Concentration:** Pharmaceutical

**TECHNICAL EXPERTISE:**

* **Artificial Intelligence:** ChatGPT
* **Microsoft Suite:** Word, PowerPoint, Teams Microsoft Publisher
* **Regulatory Systems:** eCTD, Veeva Vault, DocuBridge, WebTrader
* **Compliance Standards:** FDA 21 CFR Parts 11, 210, 211, ICH Guidelines (Q1-Q12), ISO 13485, EU MDR
* **Data Analysis:** Excel, Google Analytics, Smartsheet

**REFERENCES:** Available upon request.