

THEDA MAHEDY

Regulatory Affairs Specialist

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PROFILE

Results-driven Regulatory Affairs Specialist with 2 years of experience in ensuring compliance with industry standards and government regulations. Adept at managing documentation, analyzing data, and collaborating with cross-functional teams to develop and implement strategies for regulatory submissions. Expertise in guiding product development and navigating complex regulatory environments, contributing to the successful launch of products in the market. Strong communication skills and a commitment to staying informed on regulatory updates, ensuring adherence to best practices and continuous improvement in regulatory processes.

LINKS

[linkedin.com/in/thedamahedy](https://www.linkedin.com/in/thedamahedy)

SKILLS

Compliance monitoring

Risk assessment

Policy analysis

Documentation management

Regulatory intelligence

Stakeholder communication

Submission preparation

LANGUAGES

English

EMPLOYMENT HISTORY

Regulatory Affairs Specialist at GlaxoSmithKline (GSK), PA

May 2023 - Present

- Successfully led the approval process for a new drug application (NDA) resulting in a 25% faster approval time by the FDA, contributing to an estimated \$50 million in additional revenue for GSK.
- Managed the submission of 100+ regulatory documents within a year, ensuring 95% compliance with both internal and external guidelines and significantly reducing the risk of non-compliance penalties.
- Developed and implemented a streamlined regulatory affairs training program for new hires, reducing onboarding time by 30% and increasing overall team efficiency by 15%.

Associate Regulatory Affairs Specialist at Johnson & Johnson, PA

Aug 2021 - Mar 2023

- Successfully managed the submission of 5 major regulatory applications for new medical devices within a year, resulting in a 100% approval rate and contributing to a 15% increase in annual revenue for the company.
- Streamlined the regulatory documentation process by implementing an efficient tracking system, reducing the time spent on document management by 30% and increasing overall department productivity.
- Led a cross-functional team to address and resolve 10 FDA inspection findings within a 3-month period, significantly improving the company's compliance rating and preventing potential fines or delays in product approvals.

EDUCATION

Bachelor of Science in Regulatory Affairs at Temple University, Philadelphia, PA

Aug 2016 - May 2021

Relevant Coursework: Regulatory Compliance, Quality Assurance and Control, Risk Management, Clinical Trials, Pharmacovigilance, Medical Device Regulations, Biostatistics, and Pharmaceutical Law and Ethics.

CERTIFICATES

Regulatory Affairs Certification (RAC)

Jan 2022