

- MERNA MAGDY -

Regulatory Expertise | Cross-Regional Coordination | Strategic Planning

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Dedicated and detail-oriented Regulatory Affairs Professional with over 6 years of experience in the META and Gulf regions. Proven expertise in managing regulatory submissions, including eCTD and CTD dossiers, for a diverse portfolio of medical products. Skilled in collaborating with cross-functional teams to ensure compliance with health authority regulations and streamline processes. Recognized for strategic planning abilities and awarded first place in the Global Reward C Recognition Program for exemplary teamwork. Committed to continuous professional development and driving organizational success through effective regulatory strategies.

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| • Regulatory Submissions | • Strategic Planning |
| • Project Management | • Attention to Details |
| • Project Coordination | • Adaptability |
| • Cross-functional Collaboration | • Time Management |
| • Data Analysis | • Problem-Solving |
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PROFESSIONAL EXPERIENCE

Regulatory Affairs Associate META

Acino MEA FZ LLC | Dubai, UAE | Nov 2019 – Aug 2024

In my role as a Regulatory Affairs Associate, I oversaw regulatory activities for multiple products across the META region. This included preparing and submitting eCTD and CTD dossiers, ensuring compliance with Health Authority requirements, and maintaining a robust tracking database for regulatory submissions and inquiries. I worked closely with cross-functional teams to facilitate regulatory processes and stayed updated on legislative changes.

- Managed regulatory activities across the META region, ensuring compliance for renewals, variations, and manufacturing site registrations.
- Prepared and submitted eCTD and CTD dossiers for product renewals and variations in Oman, Bahrain, Qatar, UAE, Kuwait, Jordan, and Lebanon.
- Collaborated with the pricing team to secure necessary price certificates, aligning with Health Authority requirements.

- Developed and implemented a regulatory tracking database, enabling real-time monitoring of over 120 compliance activities across seven countries and saving the team approximately 15 hours weekly.
- Awarded first place in the Global Reward C Recognition Program 2022 as part of a team effort, underscoring my commitment to regulatory excellence.

Regulatory Affairs Coordinator GULF

Merck Serono Middle East Biopharma | Dubai, UAE | Oct 2017 – Nov 2019

As a Regulatory Affairs Coordinator, I partnered with regional and global teams to manage regulatory submissions and ensure compliance across Gulf countries. My role involved preparing eCTD submissions, overseeing labeling updates, and coordinating with various stakeholders to maintain regulatory standards.

- Collaborated with global regulatory teams to formulate regional registration plans, aligning strategies for market entry.
- Prepared and submitted eCTD dossiers for Oman, Bahrain, and Qatar, ensuring timely compliance with local regulations.
- Oversaw labeling updates and the creation of artwork for Gulf markets, maintaining adherence to regulatory requirements.
- Managed Track and Trace and Serialization coding projects across the Middle East, enhancing product traceability.
- Coordinated PSUR submissions with the pharmacovigilance team, ensuring timely and accurate regulatory reporting.
- Monitored local regulations and guidelines, ensuring compliance in all submissions across the Gulf region.

EDUCATION

Degree

- BA of Pharmacy from Misr University for Science and Technology - 2016

Certifications

- Completed Medical Devices Regulation Masterclass (MENA Region) with Dubai Pharmacy Colleague – Dubai – UAE.
- Completed Soft Skills Training at Edoxi Training Institute.
- Completed Project Management Program at Cambridge Education Institute.