Lama M. Hammoud

REGULATORY AFFAIRS • QUALITY ASSURANCE • PHARMACOVIGILANCE

Seasoned Regulatory leader (15+ years) with expertise across innovative medicine, generics, and biosimilars. Championed quality assurance, people development, and accelerated approvals through collaboration with Health Authorities. Expertise including product registration, license maintenance, quality audits, investigations/corrections, and compliance; deep understanding of registration requirements and regulations in Middle East countries. Proven ability to build trust and effective communication with stakeholders at all levels. Fluent in English, French, and Arabic. US permanent resident. Areas of strength include:

Regulatory Submissions • Labeling • Regulatory Guidelines/Requirements • Pricing

Innovative Medicines • Biotechnology • Generics • Policy Advocacy • Pharmacovigilance

• Reporting • Strategic Planning

Audits/Compliance • Corrective Action/Preventative Action (CAPA) Plans • Documentation Preparation

Good Manufacturing/Distribution/Warehousing/Laboratory Practices (GMP/GDP/GWP/GLP)

Technology Transfer • Project Management • Quality Assurance

PROFESSIONAL EXPERIENCE

AstraZeneca FZ LLC, Dubai, United Arab Emirates **2023 - Present**

HEAD OF DRUG REGULATORY AFFAIRS, GULF

(UNITED ARAB EMIRATES, KUWAIT, OMAN, QATAR, BAHRAIN)

Leading and executing strategic regulatory initiatives to ensure successful product launches, life-cycle management, and efficient submissions for AstraZeneca products across the five (5) therapeutic areas (Oncology, Rare Disease, Vaccines and Immunology, Respiratory, and Cardio-Vascular, Renal & Metabolism) in the Gulf market.

Key highlights

- Lead the development and execution of regulatory strategies for the entire AstraZeneca product portfolio across the Gulf region.
- Influence Regulatory Landscape through proactively engage with regulatory agencies and trade associations to shape regulatory policies and secure favorable outcomes for AstraZeneca products.
- Leverage deep knowledge of local and global trends to anticipate upcoming regulations and guide strategic planning.
- Streamline Regulatory Processed by implementing innovative strategies to optimize the efficiency and quality of regulatory submissions and license maintenance.
- Empower cross-functional teams through providing expert guidance and training to product teams, skill groups, and global functions, ensuring seamless navigation of evolving regulatory requirements.
- Foster team development, provide effective performance coaching to promote highly performing teams.
- Champion industry collaboration and represent AstraZeneca on key committees within relevant trade associations, advocating for industry-wide solutions and advancing best practices.

Galderma Middle East FZ LLC, Dubai, United Arab Emirates **2022 - 2023**

HEAD OF DRUG REGULATORY AFFAIRS, QUALITY ASSURANCE AND PHARMACOVIGILANCE MIDDLE EAST

(KINGDOM OF SAUDI ARABIA, UNITED ARAB EMIRATES, KUWAIT, OMAN, QATAR, BAHRAIN, EGYPT, LEBANON, JORDAN, IRAQ)

Directed and executed comprehensive regulatory strategies for a diverse product portfolio encompassing pharmaceuticals, medical devices, and cosmetics. Provided strategic vision while ensuring project success and alignment with business goals. Built high-performing regulatory teams and optimized resource allocation for efficient operations.

Key highlights:

- Streamlined regulatory processes, delivering high-quality, timely submissions for new product registrations and license maintenance.
- Represented Galderma in cross-functional teams and interactions with regulatory authorities, ensuring product compliance throughout the lifecycle.
- Championed regulatory excellence, maintaining a deep understanding of industry trends and proactively adapting strategies for business growth.
- Cultivated a collaborative environment, fostering team development and providing effective performance coaching.
- Supported the project for legal entity formation in United Arab Emirates, Kingdom of Saudi Arabia and Kuwait through regulatory intelligence gathering, establishing key milestones, and driving compliant and timely project execution.
- Managed critical aspects like promotional material review, packaging amendments, and pharmacovigilance activities.
- Oversaw quality assurance compliance with local, regional, and corporate standards.
- Analyzed service provider contracts and distribution agreements.

Novartis Middle East FZE/Sandoz d.d. Branch Office, Dubai, United Arab Emirates **2017 - 2022**

HEAD DRUG REGULATORY AFFAIRS GULF AND LEVANT

(UNITED ARAB EMIRATES, KUWAIT, OMAN, QATAR, BAHRAIN, LEBANON, JORDAN, PALESTINE, IRAQ, YEMEN)

Provides effective regulatory support to countries and Corporate for product development and license maintenance and acts as a mentor for Regulatory Affairs Associates. Leads key regulatory projects within the region e.g. fast-track registration of Biosimilars, Track and Trace, harmonization/shared packs, process optimization.

Key highlights

- Manage, coach and develop the team of Regulatory Affairs Associates and prepare them for succession plan.
- Lead, drive and execute local and regional regulatory strategies to ensure on-time submission of Sandoz products.
- Coordinate with multiple global and local stakeholders to ensure launch readiness and patient access to Sandoz portfolio.
- Monitor and influence license progress to expedite and optimize the outcome (fast-track registration of biosimilars) and from license grant on, ensure the continuing validity of the license throughout the product life-cycle.
- Contribute to maintenance of various forms of labeling and challenge Corporate drafts, providing the local country standpoint. Creation of local drug information, including Patient Information Leaflets and packaging texts.

- Establish pricing strategies for the region and create price certificate for submission. Support communication with Health Agencies on price approvals and reductions.
- Provide regulatory advice to Corporate and relevant country on all aspects of business development and licensing deals.
- Initiate and lead Health Authority interactions and negotiations including complex interactions.
- Winner of Beacon Award 2019 by Novartis Global Regulatory Affairs for collaborating with courage to ensure Zofran access to patients in Jordan.

Sandoz GmbH, Dubai, United Arab Emirates **2014 - 2017**

QUALITY ASSURANCE MANAGER MIDDLE EAST CLUSTER AND COUNTRY REGULATORY EXPERT

(KINGDOM OF SAUDI ARABIA, UNITED ARAB EMIRATES, KUWAIT, OMAN, QATAR, BAHRAIN, LEBANON, JORDAN, PALESTINE, IRAQ, YEMEN)

Provides leadership in all quality related matters and formulates strategies to ensure that all aspects of the operational business comply with cGMP legal and regulatory requirements and Novartis Quality Manual and Policies. Ensures that all drug products manufactured by Sandoz sites or local third parties are released in accordance with the registered specifications and in accordance with local and international regulations. Manages external (Ministry of Health) inspections, complaints, recalls, counterfeits and quality incident escalations according to Novartis Corporate Quality Manual and local written procedures. Audits third parties activities and ensures that third party manufacturing, (re-) packaging and (re-) labelling, storage and/or distribution of Sandoz products is in compliance with Novartis Standards. Provides regulatory support as country expert for Lebanon in new submissions, variations, renewals, PSURs and reimbursement.

Key highlights

- Implemented Novartis Quality Manual and Modules in Middle East cluster by writing local Standard Operating Procedures and conducting quality training to involved functions.
- Nominated as team leader to facilitate the launch project of Sandoz primary packed products via coordinating the analytical method transfers between receiving and giving sites.
- Released the first Sandoz secondary packed products in Lebanon by reviewing the batch records and monitoring the packaging activities.
- Initiated, reviewed and coordinated with Sandoz Com Ops and Tech Ops all quality agreements required on manufacturing, packaging, testing, release and distribution of bulk and/or finished products.
- Managed recalls, quality incidents escalations, quality complaints, deviations and ensured their close out following investigation.
- Lead several audits and participated as support auditor in several audits conducted by Novartis on third parties in the region.
- Reviewed and approved the CAPA plans developed by auditees.
- Approved artworks and Patient Information Leaflet for new submission product in Middle East.
- Acted as Local Pharmacovigilance Depute for Lebanon.
- Provided technical and regulatory support as country expert for Lebanon in new submissions, company registration, variations, renewals, PSURs and reimbursement.
- Gained GC&A Lead Auditor certification from Novartis Basel and managed the technology transfer project from Sandoz sites to third party in Middle East.

Khalil Fattal Et Fils S.A.L., Beirut, Lebanon **2008 – 2013**

REGULATORY AFFAIRS AND QUALITY ASSURANCE MANAGER, HEALTHCARE DEPARTMENT

Exceeds all expectations as specialist handling all regulatory affairs and quality assurance initiatives for four major multinational suppliers (Novartis, Bayer-Schering, Pfizer, and Bristol-Myers Squibb). Ensures the seamless execution of all medical product registration, importation, and pricing activities by leveraging in-depth knowledge of current Lebanese laws and regulations. Prepares dossiers and submissions for product registration at the Ministry of Public Health and National Social Security Fund; facilitates compliance with invoice preparation/approval from the Ministry of Public Health for proper product quality. Regularly reviews granted export prices, requesting documents for repricing as necessary.

Key highlights

- Established and maintained the company's first quality assurance system in Lebanon within a strict timeline, significantly improving regulatory compliance and supplier audit outcomes from non-satisfactory to satisfactory.
- Established the company's first quality assurance system in Iraq.
- Managed an external audit by Bristol-Myers Squibb USA and three external audits by Novartis AG Switzerland, resulting in a good and satisfactory quality assurance audit outcome.
- Utilized regulatory expertise and strategic planning skills to submit required documentation and achieve product registration in only two months, instead of the normal two years.
- Proactively pursued self-training and knowledge of WHO guidelines on all facets of GMP and GDP/GWP, including site master file and SOP preparation/implementation, control of storage conditions, customer complaint management, pharmacovigilance/adverse events reporting, product recall, and corrective action/preventative action (CAPA) plans.
- Awarded 2009 Employee of the Year for outstanding performance in regulatory and quality management.

Novartis Pharma Services Inc., Beirut, Lebanon **2007 – 2008**

REGULATORY AFFAIRS ASSOCIATE LEVANT AND AFRICA

Deepened knowledge of regulatory affairs in the pharmaceutical industry by assisting senior leadership on all regulatory affairs activities and the organization/preparation of dossiers, including price certificates, Certificates of Pharmaceutical Products requests, plant profiles and GMP certificates/samples, statements, and declaration letters writing.

Key highlights

- Cultivated knowledge of regulatory requirements for Lebanon, Palestine, Iraq, Jordan, Sudan, and Ethiopia.

ADDITIONAL EXPERIENCE

Community Pharmacist, Beirut, Lebanon (2006 – 2007)

EDUCATION • PROFESSIONAL DEVELOPMENT

Diploma in Clinical and Hospital Pharmacy, Saint-Joseph University, Beirut, Lebanon
Bachelor in Pharmacy (with High Distinction), Beirut Arab University, Beirut, Lebanon
Lebanese Baccalaureate II (with High Distinction), Saint-Joseph De l'Apparition, Beirut, Lebanon

SPECIALIZED TRAINING/WORKSHOPS

- "GCC Regulatory Affairs Pharma Summit"-PRA Consultancy (2021-2020-2019-2022-2023)

- “IMPACT” – Novartis (2020)
- “M1 Leading At The Front Line” – Novartis (2015)
- “Novartis GxP Systems Auditing Training” – Novartis Basel (2014)
- “cGMP Training Course” – Novartis (2014-2015)
- “Pharmacopoeial Affairs at Novartis” training – Novartis (2014)
- “Effective Personal Productivity” coaching program – LMI (2013)
- “Operation & Strategic” workshop – Vertone (2013)
- “Creative Problem Solving and Decision Making” program – Meirc Training and Consulting (2012)
- “ISO 9001:2008 Internal Auditor Course – Quality Management Systems” – Sustainable Management Group with Canadian Association Services (2012)
- “Levant Institutional Partnership Program” workshop – Pfizer (2011)
- “Personal Leadership Development” workshop – Milestones s.a.r.l. (2011)
- Training on “Good Manufacturing Practices” – Team International at Fattal (2011)
- Current Regulations on Drug Supply Chain Management Workshop, “How to Establish a GSDP & GCCMP Quality System For Drug Distributors”; “Requirements and Challenges–Part 1” – Naratech Pharmaceutical Consultancy (2011)
- Current Regulations on Drug Supply Chain Management Workshop, ”Good Storage & Distribution Practices and the Good Cold Chain Management Practices” – Naratech Pharmaceutical Consultancy (2010)
- “Treatment Value in Oncology” workshop – Novartis Oncology, under the patronage of the Ministry of Public Health (2010)
- “Training Sessions on Global Policy on Interactions with Healthcare Professionals (GPIHP) & Foreign Corrupt Practices Acts (FCPA)” – Pfizer (2010)
- Training on “Good Manufacturing Practices” – Team International at Fattal (2009)
- “Navigating Your Way to Agreement” workshop – Pfizer (2009)