Asma M. Hammad

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CAREER OBJECTIVE

Ambitious with 11 years of experience in Regulatory Affairs, Pharmaceutical Industry, Project Management and RIMS. Appreciates dynamic work environment and innovative thinking style, aspires to extend and apply my experience in a challenging work environment that offers a new horizon for excellence in business development, licensing and regulatory fields.

EDUCATION

June 2006	**Bachelor of Science in Pharmacy** University of Jordan, Amman, Jordan GPA: 3.58/4.0
July 2001	**High School - Scientific Stream** Jawharat AL-Oroba School, Amman, Jordan Final Grade: 95.6%

PROFESSIONAL EXPERIENCE

March-2017-Present

Strategy and planning Regulatory Affairs Manager
Hikma Pharmaceuticals
MENA Division

March 2014 – March-2017

Regulatory Affairs Manager
Hikma Pharmaceuticals
MENA Division

Key Responsibilities

- Acting as key member of the Corporate Regulatory Affairs leadership team, this role involved establishing the strategic direction and execution of regulatory strategies for Hikma's portfolio within MENA (Middle-East and North Africa) region.
- Acting as key responsible member for setting and revising the 2020-BP from RA perspective to reflect the new RA strategies for submissions.
- Collaborating with senior management to provide planning, development and implementation of appropriate regulatory strategies /processes to ensure ongoing compliance with regulatory requirements for the targeted markets.
- Providing regulatory expertise and ensures appropriate regulatory guidance and support is provided to development teams across the region.
- Being outstanding member of MENA Injectable, oncology & biosmliar business team representing corporate and local regulatory affairs personnel for MENA region, ensuring regulatory activities are aligned with commercial priorities.
- Providing leadership and driving functional aspects of the corporate regulatory process to ensure timely filing and approval of new products and maintenance of existing products in the territories of responsibility in accordance with business objectives.
- Directly managing Branded RA team based in Amman and cross functionally overseeing and working with MENA regulatory professionals teams located in Hikma's sites.
- Serving as primary regulatory liaison for all territories of responsibility to other Hikma entities, ensuring corporate consistency for the key development initiatives.
- Project management for key strategic Regulatory projects with cross functional teams.
- Preparing key quarterly and annually RA performance management reports to be discussed during the business management meetings.
- Providing insights and continual research into future direction of corporate Regulatory Affairs and how to best prepare, trends, regulations and changes, enabling Hikma to take a proactive approach and proactive planning to future business requirements.

- Acting as a business process owner for RIMS project.
- Working on regulatory intelligence analysis and data base.
- Setting the KPIs and executing sites visits for Hikma's agents and local RA teams in MENA.
- Overseeing in-licensing RA activities, key mile stones and agreed deliverables with the licensors.

Key Achievements in 2017, 2016, 2015 & 2014 :

- A record in the coordination to achieve the full alignment with relevant stakeholders in the central corporate functions and the teams in the local sites mainly GCC, Algeria, Morocco , Tunisia, to submit around 200 product and get the approval for 300 product. 2015-2017.
- Assigned as the principal coordinator for the committee group meetings between the central functions and local sites managements in the strategic markets (Algeria, Egypt and KSA) to assess the main gaps and agree on the short, medium and long term strategies and needed action plans.
- Lead the Kick off for the main regulatory activities and initiatives related to strategic business segments e.g Biosimilar business, CHC business.
- Achieved record in cross functional team management represented by the successful launch of RIMS project in Hikma Jordan sites. 2014-2015
- Represented Hikma as Main speaker in the 2015 -Be the Expert annual life science conference in Portugal.
- Achieved Record in mapping Hikma's processes mainly RA department processes represented by the successful launch of RIMS with the regulatory affairs reporting intelligence module that tracks the submission and work flow from the wish list phase to the launch/2014.
- Achieved record in managing the GCC and braded team to achieve more than 1000 successful submissions /2014.
- Achieved record in managing the GCC and braded team to achieve more than 500 successful submissions /2013.
- Achieved records in setting the agent's KPIs and more than eight sites visits across MENA to assess the agent's and local RA team's performance and set the needed action plan to bridge the gap.2016/2017
- Achieved record challenging local regulations and changing submission strategies for key markets due to gaps in the guidelines which opened the window for more than 60 submissions to build new pipeline. 2014-2017.
- Achieved record in negotiating with heath authorities key challenges and being able to appeal successfully against the official cancellation of more than 30 key strategic products. 2014
- Achieved records in getting approvals on new submissions for more than 30 submissions from the same market. 2017.
- Achieved record in managing the Biosimilar RA team who filed the submission of the first biosimilar product in MENA countries.2014-2017
- Achieved record in managing the team who filed the first e-CTD submission for Hikma in KSA through RIMS. 2014.
- Achieved record in setting the BP plan verification key milestones and managing the pipeline submissions through systemized process. 2015-2017

Feb 2013 – Feb. 2014

Regulatory Affairs Senior Supervisor
Hikma Pharmaceuticals
Regulatory Affairs Department-MENA Division
Key Responsibilities

- Supervises the activities and work of subordinates to ensure that all work within a specific area is carried out in an efficient manner and in compliance with the set policies, processes and procedures.
- Participates in the process of developing department procedures and contributing to the development of policies for the development of the department work and activities.
- Follow up regularly with authorities, internal departments and agents on related submissions and files to ensure meeting deadlines and negotiate with health authorities regarding the registration requirements to enhance execution of Hikma's planned submission strategies.
- Review, analyze and approve reports.
- Handles complex projects to insure project targets are met properly.
- Provide feedback in the 5-YBP on registration pathways, timelines and risks in relevant supervised territories.
- Generate annual registration plans covering new product registration and all maintenance of registrations required per territory.
- Generate and monitor the monthly plan execution.
- Evaluate agent performance from Regulatory point of view.
- Update and train concerned department on new regulations relevant to marketing authorization procedures.
- Set the KPIs for the agents and evaluate their performance.
- Implement a robust due diligence review cycle for under license products and companies to provide regulatory risk analysis.
- RIM business Process Owner with following responsibilities:
    1. Provide leadership to the core team
    2. Identify the internal resources needs and ensure timely resolving them.
    3. Review business process input from core team and ensure accuracy, completeness and alignment with business objectives
    4. Participate in Business Process Workshops.
    5. Promote and maintain focus of project outcomes with respect to realization of key business objectives.
    6. Facilitate Change Management by providing inputs to induced changes because of process or system change.
    7. Assists in gap analysis and helps approve optimal solutions for gaps, whether business process redesign, system customization or other.
    8. Compiling overall business test plan, business test cases for integration and user acceptance testing and signoff.

July 2011 - Feb 2013

Regulatory Affairs Supervisor
Hikma Pharmaceuticals
Regulatory Affairs Department-MENA Division
Key Responsibilities

- Supervises the activities and work of subordinates to ensure that all work within a specific area is carried out in an efficient manner and in compliance with the set policies, processes and procedures.
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- Review, analyze and approve reports.
- Handles projects to ensure project targets are met properly.
- Generate annual registration plans covering new product registration and all maintenance of registrations required per territory
- Generate and monitor the monthly plan execution

Apr. 2009 – Jul. 2011

Regulatory Affairs Supervisor
Dar Al Dawa Development and Investment Co.
Regulatory Affairs Department
Key Responsibilities

- Evaluate the agent's performance from Regulatory point of view.
- Liaise between export markets and heads of departments of the manufacturing facility to organize for the company inspection visits.
- Trains and coaches subordinates to develop their work skills and motivate them to work to their best potential.
- Manage projects in terms of resources, plans, under supervision of RA Supervisor/Manager.
- Evaluate tenders for GCC in terms of technical aspects and fulfilling the requirements.
- Generate annual registration plans covering new product registration and all maintenance of registrations required per territory.
- Generate and monitor the monthly plan execution

Dec. 2009 – May. 2010

Regulatory Affairs Team Leader - business in-licensing projects
Dar Al Dawa Development and Investment Co.
Regulatory Affairs Department
Key Responsibilities

- Set the registration annual submission & approval plans for different markets and follow on the registration processes to ensure being the first to register and the first to market.
- Audit in-licensing files from different licensors, prepare the due diligence reports to steer the decision making and contact the responsible departments to fulfill the needed requirements as per the agreed action plan.
- Trains and coaches subordinates to develop their work skills

and motivate them to work to their best potential.

- Collecting and evaluating data for the aim of preparation of more complex reports.
- Manage projects in terms of resources, plans, under supervision of RA Supervisor/Manager

Sep. 2006 – Apr. 2009

Regulatory Affairs Executive
Dar Al Dawa Development and Investment Co.
Key Responsibilities

- Handling Technical verification exercise for submission documents i.e. BE studies, analytical method validation, DMF, quality agreements, etc. to ensure its compliance with the regulatory requirements with the objective of decreasing the expected deficiencies part of handling the deficiencies initiative.
- Follow up regularly with authorities, internal departments and agents on related submissions and files to ensure meeting deadlines.
- Responsible for all activities related to registration, renewal and post approvals of planned submissions in MENA region.
- Updates and maintains Database as per latest status to align actual status with the planned.
- Contributes to the development of departmental related procedures.

SKILLS

- Creditability, honesty, and leadership qualities
- Business mind oriented, distinguished with fast learning and thinking qualities.
- Excellent problem solving and data analysis skills.
- Excellent interpersonal and communication skills
- Excellent managerial and leadership qualities with genuine concern to team members.
- Excellent project and time management skills needed to drive multiple complex projects simultaneously.
- Proven track record in identifying and implementing regulatory /compliance initiatives.
- Proven track record in managing Corporate, cross functional projects.
- Ability to function at a very high level of independence within a highly matrixed environment.
- Results driven and team oriented.

REFERENCES

References are available upon request.