Dalya Rizk

Technical Regulatory Affairs Supervisor

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Professional Technical Regulatory Affairs Supervisor with experience 17 years in Technical & Regulatory affairs Business with Passion and continuously strive to raise the standard of excellent Regulatory Affairs mission through accuracy, efficiency, and finding solutions for product development and lifecycle management.

Having a GCC Residency and Ready to Relocate to any Gulf Country.

Experience:

May 2017: Present

Technical Regulatory Affairs Supervisor

Middle East Pharmaceutical Industries Co. Ltd. (AVALON PHARMA) – KSA

- Communication and Collaboration with internal departments for requirements of regulatory information.
- Revision of internal documentation to ensure accuracy, synchronization and compliance with international regulations and standards.
- Developing and implementing RA Good Documentation System.
- Gathering, evaluating, organizing, managing and collating information in a variety of formats according to requirements of Health Authorities.
- Directing Registration files preparation and submission of (New, Renewal, Variations, Agency applications, Reports, or Correspondence) on General Requirements, CTD, eCTD Format according to implemented guidelines for Health Authorities.
- Preparing Pricing & Reimbursement application, price negotiation with price Committees in Drug Control Authorities.
- Ensure Successful Submission of New & Renewal Registration files for Products to Drug Control Authorities.
- Ensuring that quality standards are met, and submissions meet strict deadlines
- Training and leading Regulatory affairs Team to perform Tasks.
- Supporting Sales and Marketing Team in all technical and regulatory aspects.
- Liaising with regulatory authorities, to keep up with Updates in regulatory legislation and guidelines.

Experience:

Jun 2015: Nov 2017	**Technical Regulatory Affairs Supervisor** *SEDICO Pharmaceutical Company – Egypt*

- Communication and Collaboration with internal departments for requirements of regulatory information.
- Directing Registration files preparation and submission of (New, Renewal, Variations, Agency applications, Reports, or Correspondence) on General Requirements, CTD, eCTD Format according to implemented guidelines for Health Authorities.
- Preparing Pricing & Reimbursement application, price negotiation with price Committees in Drug Control Authorities.
- Ensure Successful Submission of New & Renewal Registration files for Products to Drug Control Authorities.
- Training and leading Regulatory affairs Team to perform Tasks.
- Supporting Sales and Marketing Team in all technical and regulatory aspects.
- Liaising with regulatory authorities, to keep up with Updates in regulatory legislation and guidelines.
- Member of Internal Audit Team.

May 2014: Jun 2015	**Quality Control Documentation Unit Head (Rotation Period)** *SEDICO Pharmaceutical Company – Egypt*

- Prepare and review of SOP (Standard Operating Procedure) for Quality Control Department.
- Member of Internal Audit Team.

Jan 2011: May 2014	**Technical Regulatory Affairs Unit Head** *SEDICO Pharmaceutical Company – Egypt*

- Registration files preparation and submission of (New, Renewal, Variations, Agency applications, Reports, or Correspondence) on General Requirements, CTD, eCTD Format according to implemented guidelines for Health Authorities.
- Preparing Pricing & Reimbursement application.
- Training and leading Regulatory affairs new interns to perform Tasks.

Dec 2002: Jan 2011	**Technical Regulatory Affairs Specialist** *SEDICO Pharmaceutical Company – Egypt*

- Registration files preparation and submission of (New, Renewal, Variations, Agency applications, Reports, or Correspondence) according to implemented guidelines for Health Authorities.

Education:

Bachelor's degree in Pharmaceutical Science
Zagazig University – Egypt
Graduation MM/YYYY: May 2002

Skills:

- Acknowledged track record and expertise in this specialist field.
- Exceptional ability to conceptualize, develop and manage timelines.
- Excellent negotiation skills.
- Good understanding of the drug/biologics development process.
- Excellent written and verbal communication skills.
- Excellent communication (oral, written) and presentation skills necessary for interaction health authorities, senior leaders across AVALON, and cross-functional teams.
- Demonstrated ability to form strong working relationships across functional boundaries.
- Excellent planning and organizational skills.
- Strong interpersonal skills.
- Ability and willingness to travel internationally.

Languages:

English ***Proficient*** 

Arabic ***Proficient*** 

Achievements:

UAE:
+50 Products Registration in UAE MOH (Conventional – GSL – Medical Devices)
+20 Cosmetic Products Registration in ESMA (Q)
+20 Cosmetic Products Registration in Dubai Municipality

GCC Countries:
+50 Products Registration in SFDA, Omani MOH, NHRA – Bahrain, Kuwait MOH, Yemen MOH.

Egypt:
+50 Products Registration in UAE MOH (Pharmaceuticals – Biologicals – Dietary Supplements)

CIS Countries / East Europe:
+20 Products Registration in Belarus, Azerbaijan, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Uzbekistan and Romania.

African Countries:
+20 Products Registration in NMPB-Sudan, EFDA-Ethiopia, NDA-Uganda, Tanzania, Nigeria.

Levant Countries:
+20 Products Registration in Jordan FDA, Lebanon MOH, Palestine MOH and Iraq MOH.

References:

Mr. Nilay Khan	Mob: +971 506445191	Muscat Pharmaceutical Trading LLC- Dubai
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Dr. Mohamed El Menyawi	Mob: +966 549463656	AVALON PHARMA – KSA / Dubai