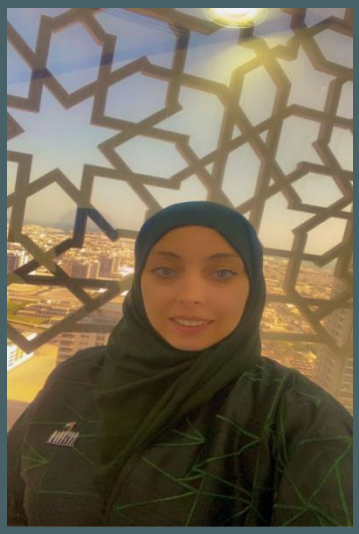

Samah Elbakrawi

CONTACT

Address: Dubai, UAE

Phone :+201050008139

: +971561233541

: +966 562793129 whatts

Email : Samahbakrawy@gmail.com

SKILLS

Regulatory Affairs
Medical Devices
Medicines , Food supplement, cosmetics
Management
Training
Logistics
Marketing
Business Development
SFDA
QPPV

PROFESSIONAL SUMMARY

I am a **pharmacist with 7 years' experience** in the medical products and services different sectors along with management skills.
I am looking for a position in a reputable company to be a part of its success and to enrich my career by applying my experience as a **Regulatory Affairs Manager and Business Development.**
Challenge is my Passion and Success is my Target.

WORK HISTORY

General Manager 02/2021 to Current
LEPTIR Regulatory Solution and Consulting services
RAK , United Arab Emirates.

Business Development 01/2020 to 01/2021
NOOR ELQAMAR Medical company- Riyadh, Saudi Arabia

QPPV Qualified Person for PV 01/2020 to 03/2021
Life Pulse Medical Company - Riyadh, Saudi Arabia

QPPV Qualified Person for PV 01/2020 to 03/2021
Safety Science Medical Company - Riyadh, Saudi Arabia

Regulatory Affairs Manager 03/2017 to 03/2021
Life Pulse Medical Company - Riyadh, Saudi Arabia

Regulatory Affairs Manager 03/2017 to 03/2021
Safety Science Medical Company - Riyadh, Saudi Arabia

Office Head Manager 10/2016 to 03/2017
Continuous Pioneering Consulting Office (CPC) - Riyadh, Saudi Arabia

Regulatory Projects Director 10/2016 to 03/2017
Continuous Pioneering Consulting Office (CPC) - Riyadh, Saudi Arabia

Regulatory Affairs Consultant 10/2016 to 03/2017
Continuous Pioneering Consulting Office (CPC) - Riyadh, Saudi Arabia

Regulatory Affairs Supervisor 08/2016 to 08/2016
Sulinda Sole Trade Company - Riyadh, Saudi Arabia

Regulatory Affairs Supervisor 09/2015 to 08/2016
Future Pharma Company - Riyadh, Saudi Arabia

Marketing Supervisor 09/2015 to 08/2016
Future Pharma Company - Riyadh, Saudi Arabia

Logistics Coordinator 09/2015 to 08/2016
Future Pharma Company - Riyadh, Saudi Arabia

Inpatient Pharmacy 07/2014 to 07/2015
Dr. Bakhsh Hospital - Jeddah, Saudi Arabia

Quality Assurance 05/2013 to 05/2014

Abu Sultan Pharmaceutical Factory - Abu Sultan, Egypt

Community Pharmacist 01/2005 to 05/2014
Community Pharmacy - Ismailia, Egypt

Pharmacy Manager 01/2005 to 05/2014
Community Pharmacy - Ismailia, Egypt

Medical Representative 05/2012 to 12/2012
EIPICO Pharmaceutical Company - Cairo, Egypt

CERTIFICATIONS

Bachelor Degree in Pharmaceutical Science (B.SC.Pharm), 06/2004
Faculty of Pharmacy, **Suez Canal University** - Ismailia, Egypt
Grade: Very Good with Honor

Certificate of Completion Clinical Pharmacy Course, 06/2008
Faculty of Pharmacy, **Suez Canal University** - Ismailia, Egypt

Certificate of Mini MBA, 05/2015
Faculty Commerce, Ain Shams University - Cairo, Egypt

Certificate of Human Resources Management Program, 05/2015
Faculty Commerce, Ain Shams University - Cairo, Egypt

Total Management Program, 05/2015
Faculty Commerce, Ain Shams University - Cairo, Egypt

Certificate of attendance of the Third Arab Conference for Food, Drug and Medical Devices, 04/2018
Gulf Health Council - GCC

Course certificate in Introduction to pharmacovigilance, 04/2020
Uppsala Monitoring Centre, (online) - Sweden

Course certificate in Statistical reasoning and algorithms in pharmacovigilance, 04/2020
Uppsala Monitoring Centre, (online) - Sweden

Course certificate in Signal detection and causality assessment, 04/2020
Uppsala Monitoring Centre, (online) - Sweden

Certificate of attendance of Regulated Bioanalysis Workshop, 06/2020
US FDA (online) - USA

Certificate of attendance of Pharmacovigilance and Risk Management Conference, 05/2020
US FDA (online) - USA

Certificate of attendance of Pharmacovigilance training course, with grade of Excellent ,09/2020
Giza pharmacists syndicate head, Egypt

Certificate of attendance of Training Program For Licensing Stability Centers,
07/2021, EDA, Egypt

LICENSING STABILITY CENTERS WORKING EXPERIENCES

· **EDAAccount:**
o regulations for licensing new stability center
o Documents required for licensing new stability center and Licensing procedures
o Procedures for Licensing renewal.
o Annual audit procedure.

MEDICAL DEVICES AND IVDS WORKING EXPERIENCES

· **SFDA Account:**
o Opening account of the new SFDA Medical Devices system (GHAD system)
o Solving issues relate to old data transfer from the old to the new system
o Update of account information when needed
· **Low Risk devices:**
o Complete report for the regulatory requirements and fees for product registration approval
o Registration of low risk medical devices in SFDA new GHAD system based on several Jurisdictions (KSA, USA, EU, Canada, Australia, Japan)
· **Medium and High-Risk Medical Devices and IVDs:**
o Complete report for the regulatory requirements and fees for product registration approval
o Medical Devices Marketing Authorization (MDMA) registration of Medium and high-risk medical devices and IVDs in SFDA, based on several Jurisdictions (KSA, USA, EU, Canada, Australia, Japan)
o Renewal of higher risk medical devices and IVDs in SFDA
o Bundling of products in one application to save the registration fees and time
o Complete discussion with the manufacturer by planning for the registration process including and not limited to adding extra products to the same application even no needed to be marketed immediately, to save the fees and time of registration
o Updating of the current MDMA registration for adding new products in the same application and avoid payment of new complete fees and spending new time in the new registration
o Transfer of MDMA registered products from the old AR to the new assigned AR
o Revision of the technical file including Artwork and IFU data for compliance with SFDA requirements
o Direct contact and communication with SFDA for follow up the registration process and solving any inquiry
· **Authorized Representative:**
o Fast Authorized representative (AR) registration and renewal in SFDA with solutions for the AR mandate legalization
o Revision of the AR mandates for compliance with SFDA requirements
· **MDEL:**
o Fast registration and renewal of MDEL for the importer warehouse
o Different solutions for the agent warehouse availability
o Preparing the warehouse and company SOP's related to MDEL approval (Storage, Handling, Transportation, Recall, Traceability,... etc.)
o Stuff training on the related SOP's
o Preparing the corrective action plan for SFDA MDEL inspection visit
· **NCMDR:**
o Preparing the Field Safety Corrective Actions (FSCA) for received Field Safety

Notifications (FSN) by SFDA NCMDR
o Ensuring the implementation of the FSCA and ensuring of FSN closure by SFDA
· **MDIL Import Permission:**
o Import permission approval when requested for the products
o Communication and preparing the file needed by different authorities approval (e.g. National Security)
· **Borderline products:**
o Registration approval for borderline products between SFDA Drug and Medical Devices Sectors
· **Updated guidelines and announcements:**
o Follow up SFDA website for the continuous updates in the new guidelines and announcements
o Updating the manufacturers and agents with the new guidelines and announcements
o Communication with SFDA stuff for any clarifications related to the new guidelines to ensure complete understanding
· **VAT:**
o As Medical devices are subjected for 0% VAT, communication is done with ZAKAT and SFDA to add the HS Code of the related devices in ZAKAT 0% VAT table
· **Tenders and Direct Purchasing:**
Cooperation with the related departments in preparing the tender and product evaluation file

MANAGEMENT WORKING EXPERIENCES

- Strategic planning for company business scope with setting up short term and log term plans
- Feasibility studies for the project
- Setting up the hierarchy structure within the organization along with the administrative and financial structure
- Preparation of the related job description and tasks for the organization stuff
- Delegation and follow up strategies and plans for the organization stuff
- Evaluation and reporting systems and templates for each employee
- Instant, frequent and periodic training program for each employee
- SOP's defining and organizing the work process within the organization
- Electronic and Hard copy archiving systems
- Documentation and database of each department (annual and monthly plan, SOPs, Achievement track and trace system for all products).
- Ensure adherence to standard operating procedures (SOPs), work instructions (WIs), quality of designated deliverables and to project timelines
- Ensure overall project efficiency and adherence to project timelines and financial goals; report project and organization performance metrics and out of scope activities as required.

MARKETING AND TRAINING: WORKING EXPERIENCES

- Preparation of the marketing data and marketing materials related to the products
- Marketing related training for the medical representatives based on the scientific product data
- Coordinate all marketing activities internally and externally.

- Collaborate with other teams to promote offerings and meet marketing strategy.
- Update clients and prospects of products and services through creative marketing strategies
- Track performance of all marketing campaigns
- Regulatory related training for different regulatory officers

COMMUNICATION WITH SFDA AND GCC DEPARTMENTS EXPERIENCES

- Direct coordination between the manufacturer, the agent and the authorities for all aspects related to the product registration
- Direct communication and meetings schedules with SFDA related departments to overcome any obstacles and/or clarifications related to the product registration

LOGISTICS SERVICES WORKING EXPERIENCES

- Imported products (Drugs, Herbal, Health, Food supplements, Foods, Cosmetics, Medical Devices) regulatory and logistics requirements, permissions and follow up with customs and health authorities till final clearance
- Complete follow up with the customs broker for the right HS codes and its related customs fees and VAT.
- Overcoming pending shipments clearance by providing solution along with direct communication with SFDA departments
- SASO electronic system (SABER) submission and approval for different products types

PHARMACOVIGILANCE WORKING EXPERIENCES

- Establishment and Maintenance of the Pharmacovigilance system for the products (PSMF)
- Overview of medicinal product safety profiles and any emerging safety concerns, when possible
- Maintain awareness of Pharmacovigilance regulatory requirements and developments
- Identify, collect and report adverse events (ADRs, SAEs, SARs, SUSARs)
- Ensure the conduct of pharmacovigilance activities and the submission of all pharmacovigilance-related documents (e.g. ISCRS, SUSARs, DSURs RMPs) is in accordance with the legal requirements and GVP
- Provide input into the preparation of regulatory action in response to emerging safety concerns (e.g. variations, urgent safety restrictions, and communication to patients and healthcare professionals)
- Read and acknowledge all necessary Company standard operating procedures (SOPs) and customer SOPs as required
- Creation and maintenance of pharmacovigilance agreements. Maintain a local register of all incoming PV related information and all correspondence in relation to Pharmacovigilance activities with agencies and customers based on signed agreements

PHARMACEUTICAL DRUG PRODUCTS WORKING

EXPERIENCES

- Complete regulatory pre-registration study for the new products, including and not limited to:

o Latest updated guidelines and requirements
o Suggested solutions to overcome registration obstacles
o List of all fees required by the authorities
o List of competitors registered within the authority

- Pricing study for the product before submission and providing the expected retail price to be issued by the authorities before submission
- Repricing study and submission for registered products
- ECTD registration file formatting and submission as per SFDA and GCC requirements
- Revision of Modules 1 to 5 content for compliance with SFDA and GCC latest updated guidelines
- Preparation and submission for the replies to SFDA and GCC inquiries
- Preparation and submission for all variations related the registered product (Shelf Life extension, Adding a manufacturing site, Changing the Marketing Authorization Holder or the Agent, …etc.)
- Renewal file preparation and submission
- Import permissions and clearance for unregistered products for tenders and direct purchasing

MANUFACTURING SITES AND BIOEQUIVALENCE CENTERS SERVICES

- Manufacturing sites and Bioequivalence Centers registration and renewal of registration in SFDA and GCC
- Coordination with the manufacturing sites for the preparation of the registration or renewal file and corrective action plans related to the authority's inspection audit visits

HERBAL AND HEALTH PRODUCTS WORKING EXPERIENCES

- Although these products represent a challenge for the companies due to its registration requirements that are almost similar to the drug products, solutions can be provided to overcome easily this challenge
- Complete regulatory pre-registration study for the new products
- Complete preparation of the CTD registration file, formatting, and submission as per SFDA and other GCC authorities' guidelines
- Revision of the CTD file to ensure fast registration approval process
- Preparation and submission for the replies to SFDA inquiries
- Preparation and submission for all variations related the registered product (Shelf Life extension, Adding a manufacturing site, Changing the Marketing Authorization Holder or the Agent, …etc.)
- Renewal file preparation and submission

FOODS AND SPECIAL FOODS WORKING EXPERIENCES

- Complete report for the regulatory requirements, fees and artwork data modification for the fastest registration approval
- Registration approval for borderline products between SFDA Drug and Food Sectors

- Fast registration of special foods with medical claims
- Products compliance with SFDA, GSO and SASO guidelines

COSMETICS WORKING EXPERIENCES

- Complete report for the regulatory requirements and fees for product registration approval
- Registration of the manufacturing site in SFDA eCosma system
- Registration of the product in SFDA eCosma system
- Products label compliance with GSO Cosmetics Standards for the guarantee of GSO cosmetics conformity certificate

LOCAL SAUDI COMPANIES SERVICES

- Opening accounts in all SFDA related departments (DENR, GHAD, eCosma, FRCS, …etc.)
- Warehouse license from all SFDA sectors (Drug, Food, Medical Devices Sectors)
- Local manufacturing sites license from SFDA
- SOP's for different activities as per SFDA requirements (Storage, Handling, Transportation, Traceability,…etc.)

BUSINESS DEVELOPMENT WORKING EXPERIENCES

- Contract manufacturing or Private label services based on the selected formula or product medical category
- Providing different formulations for fast registration and fast penetration of the market
- Providing different solutions for registration by accelerating the registration process and minimize the registration costs
- List of registered manufacturing sites in SFDA
- Legal preparation and revision of the contracts to reserve the related party rights in the brand, being the Marketing Authorization Holder and maintain a secure business in the region
- Offering the manufacturing companies with different customers for contract manufacturing and/or distribution purposes

ACQUIRED SKILLS

- Project organization
- Time management skills
- Problem analysis and resolution
- Relationship development
- Team building and Team management
- Reports generation and analysis
- Basic & Advanced Selling Skills
- Negotiation, Communication Skills & Assertive Communication Skills.
- IT Related Skills: MS-office, Internet Applications.