LARIOX PHARMA

"Your Partner in Pharmaceutical Excellence"

LARIOX PHARMA: YOUR TRUSTED REGULATORY AND PHARMACOVIGILANCE PARTNER IN MENA REGION

ABOUT US

A LEGACY OF EXCELLENCE

Lariox Pharma is a dynamic and forward-thinking Pharmaceutical consultancy firm specializing in regulatory affairs and pharmacovigilance. Founded in Egypt, since 2019 we are a proud member of a distinguished business family with a rich history spanning over six decades. Our deep-rooted experience in the pharmaceutical industry, coupled with our extensive network of commercial pharmacies and manufacturing facilities, positions us as a trusted partner for organizations seeking expert guidance in navigating complex regulatory landscapes.

OUR LEADERSHIP

DR. ESSAM ABDEL MAKSOUD: A VISIONARY LEADER

CHIEF EXECUTIVE OFFICER

Dr. Essam Abdel Maksoud brings over five decades of invaluable experience to his role as Chief Executive Officer of Lariox Pharma. Renowned for his expertise in managing a network of highly reputable commercial pharmacies, Dr. Abdel Maksoud possesses a deep understanding of the Egyptian market, including its intricacies and challenges.

With his extensive network of key stakeholders and distributors, Dr. Abdel Maksoud offers unparalleled insights into product selection, pricing strategies, and distribution logistics. His ability to identify market gaps and provide tailored solutions has been instrumental in Lariox Pharma's success.

Under Dr. Abdel Maksoud's leadership, Lariox Pharma has experienced significant growth and achieved numerous milestones. His unwavering commitment to innovation and patient safety drives the company's mission to provide exceptional regulatory and pharmacovigilance services.

DR. MARWA IBRAHIM: A REGULATORY AFFAIRS PIONEER

BOARD MEMBER

AND HEAD OF REGULATORY AFFAIRS

Dr. Marwa Ibrahim is a dynamic and visionary leader who heads the Regulatory Affairs department at Lariox Pharma. With over than 20 years of experience in the regulatory affairs field, Dr. Ibrahim has established herself as a respected expert in navigating complex regulatory landscapes.

Dr. Ibrahim holds an MBA and a Bachelor of Science in Pharmacy, demonstrating her strong academic foundation and commitment to professional development. Her ability to seamlessly blend traditional regulatory approaches with modern innovations positions her as a valuable asset to the company.

Leading two highly skilled Regulatory Affairs teams, Dr. Ibrahim inspires and empowers her team members to deliver exceptional results. Her expertise and dedication are instrumental in ensuring Lariox Pharma's compliance with regulatory standards and achieving successful market authorization.

DR. NADEEN ESSAM

BOARD MEMBER

HEAD OF PHARMACOVIGILANCE DEPARTMENT AND BUSINESS DEVELOPMENT

Dr. Nadeen Essam brings over than 20 years of extensive experience to her role as Head of Pharmacovigilance and Business Development. Her academic background, coupled with her practical experience, positions her as a valuable asset to the company.

Prior to joining our team, Dr. Essam served as an academic teacher at the 6th of October College of Pharmacy.
Following her academic career, Dr. Essam joined Unique Organization Vacsera as CEO Assistant for Technical Projects.

Dr. Essam's expertise extends to pharmacovigilance, where she is dedicated to ensuring patient safety and monitoring drug efficacy. she plays a pivotal role in business development. As our representative for foreign projects.

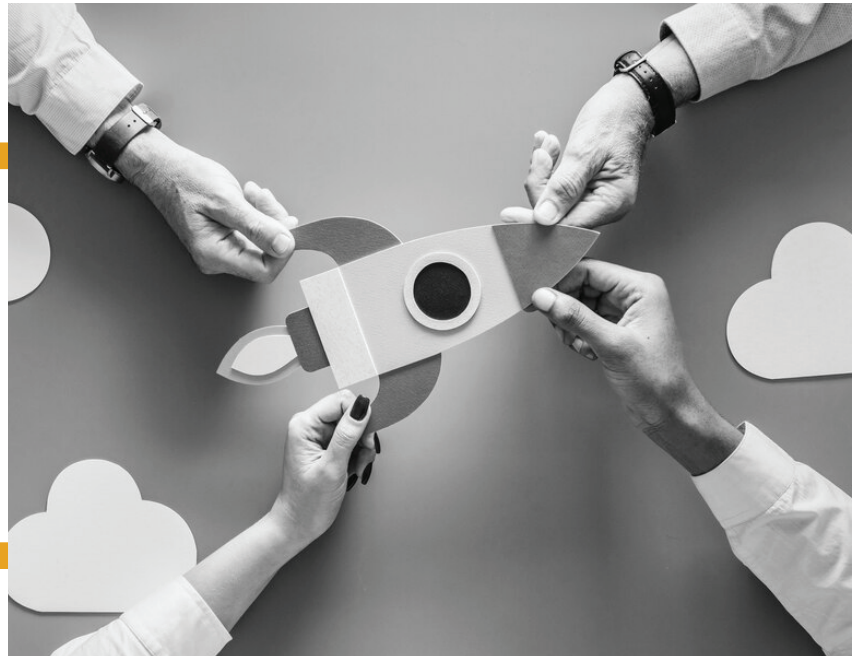
OUR MISSION AND VISION

MISSION

To empower pharmaceutical companies to achieve regulatory excellence and ensure patient safety through our comprehensive consultancy services.

VISION

To be the premier regulatory and pharmacovigilance partner in the MENA region, renowned for our expertise, innovation, and commitment to delivering exceptional results.



I - REGULATORY AFFAIRS CONSULTATION & REGISTRATION

OUR REGULATORY AFFAIRS SERVICES ENCOMPASS A WIDE RANGE OF ACTIVITIES, INCLUDING:

01

REGULATORY STRATEGY DEVELOPMENT:

Navigate the complex regulatory landscape with our expert guidance. Our comprehensive regulatory services ensure seamless compliance and timely market access for your pharmaceutical products.

02

CMC REVIEW

Regulatory Strategy Development: We work closely with you to develop comprehensive regulatory strategies that align with your business objectives and ensure compliance with Egyptian regulatory requirements

03

REGULATORY SUBMISSIONS:

Our team of experts prepares and submits high-quality regulatory dossiers to the Egyptian Drug Authority (EDA), ensuring timely and efficient approval processes.

04

REGULATORY COMPLIANCE

We provide ongoing support to maintain regulatory compliance throughout the product lifecycle, including label updates, safety reporting, and periodic submissions

05

REGULATORY AFFAIRS CONSULTING:

We provide ongoing support to maintain regulatory compliance throughout the product lifecycle, including label updates, safety reporting, and periodic submissions

WE PROVIDE THESE SERVICES TO A WIDE RANGE OF INDUSTRIES:

PHARMACEUTICALS

COSMETICS

HERBAL MEDICINE

MEDICAL DEVICES

BIOLOGICAL & BIOSIMILARS

ANTISEPTICS

FOOD SUPPLEMENT

II - PHARMACOVIGILANCE SERVICES

CORE PHARMACOVIGILANCE SERVICES

1

LOCAL PSMF & SOPS:

We have a developed and implemented Pharmacovigilance System in place, (PSMF) /(PSSFs)and Standard Operating Procedures (SOPs) that comply with local and international regulations.

2

QPPV & BACK-UP AVAILABILITY:

We provide 24/7 availability of Qualified Persons for Pharmacovigilance (QPPVs) and back-up personnel to ensure uninterrupted pharmacovigilance oversight.

3

SDEA REVISION & PREPARATION:

Our experts assist with the revision and preparation of Safety Data Exchange Agreements (SDEAs) to facilitate the exchange of safety data between parties.

4

QUALITY SYSTEM & ARCHIVING:

We establish robust quality systems and maintain secure archiving of both soft and hard copies of pharmacovigilance documents.

5

BACKUP PROCEDURES & BUSINESS CONTINUITY:

We implement backup procedures and business continuity plans to ensure uninterrupted pharmacovigilance activities in the event of disruptions.

6

LITERATURE SCREENING:

We conduct comprehensive literature screening to identify potential safety signals and assess the risk-benefit profile of your products.

7

ICSR PROCESSING & ASSESSMENT:

We efficiently process and assess Individual Case Safety Reports (ICSRs) for local products, ensuring timely and accurate evaluation of adverse events.

8

DATA MANAGEMENT:

We utilize advanced data management techniques, including Excel sheets, to effectively manage and analyze pharmacovigilance data.

9

MedDRA CODING:

We employ MedDRA coding to standardize the classification of adverse events for local marketed products.

10

RISK MINIMIZATION ACTIVITIES:

We develop and implement Risk Minimization Measures (RMMs) and special pharmacovigilance activities, such as Dear Healthcare Professional (DHCP) letters, follow-up targeted questionnaires, and other initiatives, to mitigate safety risks.

11

PVGA REQUIREMENTS:

We ensure compliance with all relevant authorities and Guideline.

12

EMPLOYEE TRAINING:

We provide training to current agent company employees on how to receive and report ICSRs for marketed products.

13

NATIONAL DISPLAY RMP:

We assist with the preparation and submission of National Display Risk Management Plans (RMPs).

14

NATIONAL APPENDICES:

We prepare and submit National Appendices for imported or re-registered products.

15

RECONCILIATION:

We ensure reconciliation with involved parties to maintain accurate and consistent pharmacovigilance records.

BY PARTNERING WITH LARIOX, YOU CAN BE CONFIDENT THAT YOUR PHARMACOVIGILANCE ACTIVITIES ARE CONDUCTED WITH THE HIGHEST LEVEL OF QUALITY AND COMPLIANCE.

III - EARLY ACCESS PROGRAMS

Our early access programs provide patients with access to investigational drugs before they are approved for general use. These programs can be invaluable for patients with serious or life-threatening conditions who have limited treatment options. Our services include:

PATIENT ENROLLMENT AND MANAGEMENT:

We manage the enrollment of patients into early access programs and ensure their safety and well-being.

DATA COLLECTION AND ANALYSIS:

We collect and analyze data from early access programs to inform drug development and regulatory submissions.

REGULATORY COMPLIANCE:

We ensure that early access programs comply with all relevant regulatory requirements.

BY CHOOSING LARIOX, YOU CAN BE CONFIDENT THAT YOUR PHARMACEUTICAL PRODUCTS WILL BE BROUGHT TO MARKET EFFICIENTLY AND SAFELY.

IV - GLOBAL PRESENCE AND ALLOCATIONS

Lariox extends its regulatory affairs expertise beyond its core markets to encompass the GCC countries (Emirates, Saudi Arabia, Kuwait, Bahrain, Oman) and regions in North, South, and West Africa. While we do not maintain direct offices in all these areas, our strategic collaborations with local consultants enable us to provide comprehensive regulatory support.

LARIOX Pharma

GLOBAL PRESENCE

V - MARKET ACCESS SERVICES

offers comprehensive business development services & Market Acsses services to help you expand your reach and identify strategic partnerships.

KEY BUSINESS DEVELOPMENT SERVICES

PARTNER IDENTIFICATION:

We source and evaluate potential partners, including manufacturers, distributors, and retailers, to align with your business objectives.

AGENCY SOURCING:

We assist you in finding suitable agencies, whether you are seeking medical devices, pharmaceuticals, or cosmetic products.

MARKET APPLICANT / AUTHORIZED REPRESENTATIVE (AR) SERVICES

We provide AR services in Egypt , Saudi Arabia and the Emirates.

BY LEVERAGING OUR EXPERTISE AND GLOBAL NETWORK, LARIOX CAN HELP YOU EXPAND YOUR BUSINESS, FORGE VALUABLE PARTNERSHIPS, AND ACHIEVE SUSTAINABLE GROWTH.

STRATEGIC PARTNERSHIPS

LARIOX IS PROUD TO COLLABORATE WITH A NETWORK OF ESTEEMED STRATEGIC PARTNERS, INCLUDING:

fidia

Pharmanovia

durbin
part of the uniphar group

PharmaOverseas
مستقبل توزيع الدواء

ALRAZI الرازي
PHARMA INDUSTRICS للصناعات الدوائية

PHARMA MART
TOGETHER FOR A BETTER LIFE

ASPAmed PHARMA

Molecure

Al Andalous
MEDICAL COMPANY

2DEERS

Gravity Pharma

بيت الخبرة الدوائية
Byet Elkhabra El dwaea

Provectu Pharma®

stiphil pharma
ستيفل فارما للصناعات الدوائية

ucb

These partnerships allow us to leverage our combined expertise and resources to deliver exceptional solutions to our clients. By working closely with these industry leaders, we can offer a wider range of products and services, enhance our market reach, and ensure the highest standards of quality and compliance.

OUR SERVICES

Lariox Pharma offers a comprehensive suite of services designed to support pharmaceutical companies throughout the product lifecycle, we have earned the trust of numerous multinational companies and have been authorized to represent them in Egypt .

LARIOX
Pharma

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