



Regulatory & Business Affairs Registration & Pharmacovigilance Consultation Services

DUE
DILIGENCE

STRATEGY
& PLAN

IMPLEMEN
TATION



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KNOWLEDGE

Updated with the latest regulations and other related information originated by market dynamics to provide solid opinion and regulatory intelligence.



CROSS-SECTOR EXPERIENCE

Providing acumen advice in alliance with the authority expectations utilizing past practical experience in the Gov sector and the industry.



QUALIFIED STAFF

Licensed pharmacists and academics enjoying a continuous training program.



CREDIBILITY

Trusted by pharma and biotech companies. A partner of global leading consulting firms.



AUTHENTICITY



QUALITY



CONTINUITY

Business Continuity Measures



PRIVACY

Data Privacy / Protected Servers



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OUR SERVICES



COMPANY REGISTRATION

Licensing of international MAH and legal company setup in Saudi



DRUG REGISTRATION

Gap analysis, consulting, compiling, then submission and follow up till approval



MEDICAL DEVICES

Company and product files due diligence, then submission and follow up till approval



MANUFACTURER LICENSING

Local / international manufacturer licensing
SFDA and GHC GMP



RESEARCH & ACCESS

Market research and access studies.
Price adjustments



PHARMACOVIGILANCE

Outsourced QPPV and PV System



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OUR SERVICES



REGULATORY STRATEGY

We design and implement innovative & visionary regulatory strategies to support your business decisions.



CONSULTATION

Empower your decision making by utilizing insightful opinion, market research, and intelligence reports.



COMMERCIALIZATION

Since commercial and marketing modules vary in the Saudi market with a direct impact on profit margins, we support the new access for international companies with insights on all available trade pathways.



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OUR PV SERVICES

Pharmacovigilance System Development and QPPV



OUR PHARMACOVIGILANCE SYSTEM

Developed to maintain and streamline safety services in accordance with ICH, VICH, and SFDA regulations



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OUR SERVICES

Example List of Services

Consultation

- New Market Entry Consultation
- Regulatory Due Diligence
- MNC Legal Setup
- GCC and MENA Centralized Regulatory Support
- Commercialization Support and Consultation / Private Label Manufacturing
- Marketing Routes, Distribution, and Supply Consultation
- Labelling and safety information
- Import/Clearance Support
- Pricing and Pharmacoeconomics
- ISO Auditing and Certification 13485 / 9001, GMP Pre-Auditing
- Authorized Representation AR
- Pharmacovigilance (QPPV/Systems)
- Logistic Services Support



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OUR SERVICES

Example List of Services

Registration

- New Drugs (NCEs, Biological, Biosimilars, Radiopharmaceuticals)
- Generic Drug Registration
- Health and Herbal Drugs Registration
- Food Supplements Registration
- Medical Device Registration
- Cosmetic Product / Manufacturer Notification
- Medical Supplies and Equipment's Registration
- Veterinary Drugs Registration
- Products Classification
- Manufacturer Licensing / GMP
- Fodder and Pesticides Registration
- Warehouse Licensing / Quality Systems
- Preparation of PMS Plan, PMCF Plan, and CER



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HOW WE OPERATE?

High-level description of our operation

**DUE
DILIGENCE**

**STRATEGY
& PLAN**

**IMPLEMEN
TATION**



REGULATORY STRATEGY

We guide, advise, and build strategies and action plans with an innovative and visionary input to meet the company's objective in compliance with the Saudi market guidelines.



DUE DILIGENCE AND GAP ANALYSIS

We are inventors of our own DD and gap analysis structures to ensure coverage of all requirements reaching beyond check lists and counting missing files. We believe that an accurate and thorough DD is one of the success pillars of any regulatory project.



IMPLEMENTATION

This is a process that we take into consideration from the first meeting with our client. We determine all factors that supports a smooth and expedited approvals. Foresight of the future dynamic requirements is the key of successful implementation.



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DAILY OPERATION

Solid daily operation is a key to our success.



End to End Full Regulatory Support Services

Bonding knowledge and experience with professional daily operation



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