PharmaKnowl Consulting

Company Profile

2024

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Company Background

We are a regulatory consulting office established in 2014 in Riyadh, Saudi Arabia. We provide SFDA regulatory consulting services for the Biotechnology, Pharmaceutical, and MedTech Industries.

المعرفة الدوائية
PHARMA KNOWLEDGE

2014

PharmaKnowl Consulting

2020

About

Leading Provider of Regulatory Consulting Services in Saudi Arabia

- Experts in Laws & Regulations of
  - Pharmaceuticals / Biotechnology
  - MedTech / Medical Devices
  - Other life Sciences industries
- Comprehensive Regulatory and CRO Solutions
- Accelerated Market Access
- Former SFDA Consultants

Our team offers comprehensive solutions and tailored strategies to help you navigate complex regulations and accelerate market access in Saudi Arabia. With our specialized expertise, you can focus on innovation while we ensure your regulatory compliance.

About

Licenses

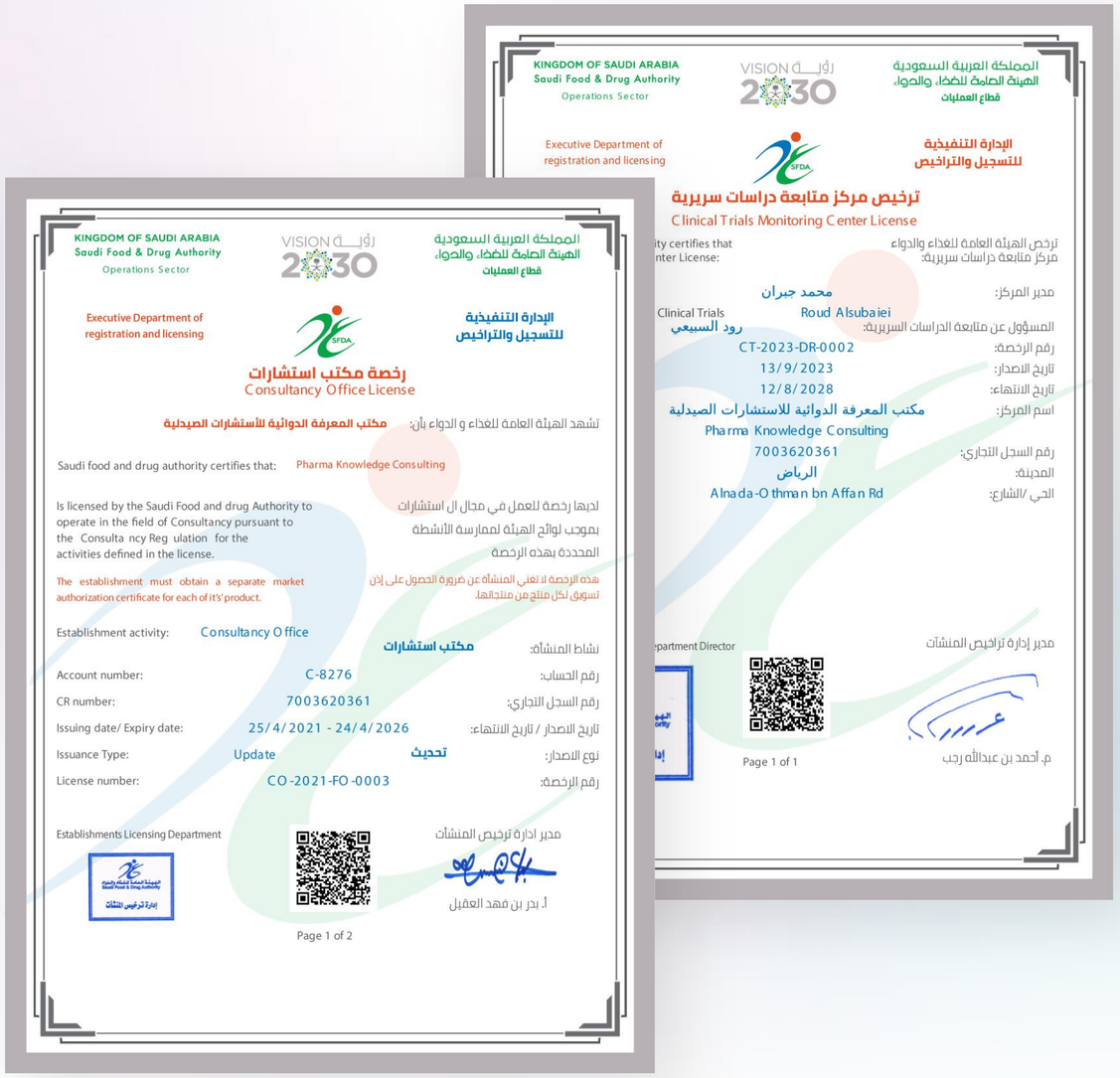
- Regulatory Consulting (SFDA)
- Pharmacovigilance (SFDA)
- Authorized Representative (SFDA)
- Clinical Research Organization – CRO (SFDA)

Certifications

- ISO 9001:2015
- ISO 13485:2016

Location

Alnada Center (Office No 13)
7164 Othman bn Affan Rd. Riyadh, 13317
Saudi Arabia



Mohammed Jobran

Pharmacy BSc, Biomedical Informatics MSc.

19 Years of Regulatory Experience:

Chief Regulatory Pharmacist

Saudi Food and Drug Authority (SFDA) – 9 Years

Regulatory and Scientific Office Manager

Multinational Company - 6 Years

Regulatory Principal Consultant

PharmaKnowl Consulting - 5 Years

Why PharmaKnowl

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 (SFDA) and the industry.

Qualified Staff

Licensed pharmacists and biotechnologists enjoying a continuous training program.

Credibility

Trusted by top 10 pharma and biotech companies. A local partner of global leading consulting firms.

Authenticity
SFDA, MOH, MOC Licensed

Quality
ISO 9001:2015 Certified

Continuity
Business Continuity Measures

Privacy
Data Privacy / Protected Servers

Why PharmaKnowl

√ Unique Regulatory Solutions

√ Advanced Authority Communication

√ Professional Team of Consultants

√ Full outsource / Plug-In Teams

√ High Tech Regulatory Solution

Our Clients


Orphalan


COVIS
PHARMA


mundi pharma


Chiesi
global rare diseases


FRESENIUS


AstraZeneca


AMRYT
PHARMA


Pharmex


septodont


Immedica
pharma


ATNAHS


Abbott


Lundbeck


Exeltis
Rethinking healthcare


Luye
Pharma


Pharmanovia


AMGEN


SAMSUNG
BIOLOGICS


Emmaus
Life Sciences, Inc.


DAEWOONG
PHARMACEUTICAL CO.,LTD.

Our Clients


PDI


MEGAGEN


VIDA
PHARMA


ZOLL


seca


EUFOTON
medical lasers


PHCbi


Quanta System


CENDRES+
MÉTAUX


MEDICALZ®


MICROAIRE
For Surgery. For Life.™


Dr.
Schumacher


itena
CLINICAL


Snibe
Diagnostic


MBST®


innate
A TRUSTED COMPANY


BIOTECH DENTAL


Armstrong
Medical


schwarzer
cardiotek


ESSILOR

Services

Clinical Research

Comprehensive clinical research services, including trial design, management, and regulatory compliance.

Pharmacovigilance

Outsourced PV function, QPPV and PV System. Assign our professional QPPVs for your pharmaceutical products.

Quality & GMP

We audit and develop quality systems compliant with GMP and ISO standards. Providing auditors and SFDA former inspectors to fine tune all compliance aspects.

Regulatory Affairs

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

Consultation

Regulatory strategy development, due diligence, and support for mega projects such as tech transfer, MA transfer, and licensing.

Representation

Local agent/authorized representative to work as an applicant on behalf of the marketing company to maintain compliance.

Regulatory Projects & Operations

- Products Registration
- Life Cycle Management
- Manufacturer GMP/ISO audit

- MA Transfer / LM Change
- Tech Transfers / Local Manufacturing
- Licensing Agreements

- Dossier & Technical File Development
- Due Diligence / Gap Analysis

- Distributor Add/Change
- MAH Registration

Regulatory Intelligence

- ✓ Intel information about the market.
- ✓ Regulatory updates including analysis of expected impact, timelines, and recommendations

Regulatory Consultation

Pharma Consultation

- Scientific Office / Distributors
- Drug Pricing
- SFDA Meeting & Appeals

MedTech Consulting

- MD Technical File
- CER/PMCF
- Biocompatibility/Stability Tests

Strategy Development

- Regulatory impact analysis
- Manage possible risks
- Reduction of cost and timelines

Local Representation

- ✓ Local Agent / Applicant
- ✓ Authorised Representative (AR)
- ✓ Scientific Office Management

Independent & Non-Commercial

- Start without a distributor
- Accelerated Approval
- International Company Registration
- Licenses Control / Data privacy
- SFDA meetings & representation

Pharmacovigilance Services

Partner of global PV providers.

QPPV

Qualified Person for Pharmacovigilance

PSMF/PSSF

Development of PV Master File

QMS

Quality management system

Database

DB operation and XML submission

Clinical Research Services

Partner of global CRO providers.

- Licensed CRO by SFDA
- Clinical Project Management Teams
- Trial data management
- Functional Service Provider (FSP)
- Submission & approval from ECs/IRBs/CAs
- CRF, CSR, CER, PMCF generation & submission.
- Statistical analysis and management of the trial data

Example

Submission Operations

How We Operate

PharmaKnowl

SFDA

- Sectors Affairs
- Regulatory Dept
- Assessment Dept
- Clearance

Manufacturers

1
2
3
4

Meetings
Project Progress
Coordination

Due Diligence
Projects discussions
Oversight Meetings

← Gap Analysis
← Drafted Letters
← Translation/Designs
← Compiled File
← SFDA Submission

Product File ←
Suppliers' files ←
Certificates ←
Labels ←
Déclarations ←

→ Inquiries
→ SFDA Letters
→ SFDA Invoices
→ SFDA Approvals

Gap Analysis Report →
Deficiencies →
Clarified SFDA Inquiries →
Draft Responses →

Gap Analysis Report

Unique Method

A special way of product file review, developed by PharmaKnowl and continuously updated.

Commercial-Centered Objectives

Structured to attain two main objectives:

- Fastest submission timelines.
- Minimum SFDA findings / Inquiries.

Parallel Processing

Maximizing speed by utilizing all opportunities for parallel processing of SFDA requirements between PharmaKnowl and the Manufacturer.

	A	B	C
1	Section	Requirements	PKC Comments
2	**Module 1**	**Regional Administrative Information**	
3	1.0	Cover Letter	PKC will prepare template
4	1.1	Comprehensive Table of Content	PKC will prepare
5	1.2	Application Form	PKC will prepare
6	1.3	Product Information	
7	1.3.1	SPC	Please provide document so PKC can share annotations
8	1.3.2	Labelling	Please provide document so PKC can share annotations
9	1.3.3	PIL	
10	1.3.3.1	Arabic PIL	Translation is required - to be arranged after completeing the
11	1.3.3.2	English PIL	Please provide document so PKC can share annotations
12	1.3.4	Artwork (Mock-ups)	Please provide document so PKC can share annotations
13	1.3.5	Samples	PKC will prepare template
14	1.4	Information on the Experts	
15	1.4.1	Quality	Please Provide
16	1.4.2	Non-Clinical	Please Provide
17	1.4.3	Clinical	Please Provide
18	1.5	Environmental Risk Assessment	
19	1.5.1	Non-Genetically Modified Organism (Non-GMO)	Please Provide either GMO or Non-GMO letter
20	1.5.2	GMO	
21	1.6	Pharmacovigilance	
22	1.6.1	Pharmacovigilance System	Please provide PSSF and your local QPPV cv
23	1.6.2	Risk Managements Plan	Please provide RMP and summary PSMF
24	1.7	Certificates and documents	
25	1.7.1	GMP Certificate	Please Provide
26	1.7.2	CPP or FCS	provide the document when available before legalization to review. We will try to proceed with a commitment letter to legalize

Project | Questioneer | Application Information | Details | CTD | +

PharmaKnowl Due Diligence Sheet

Our Learning Management System

SFDA Bank of Inquiries

We track and collect SFDA inquiries to build internal references work instructions to solidify our operation & gap analysis methods.

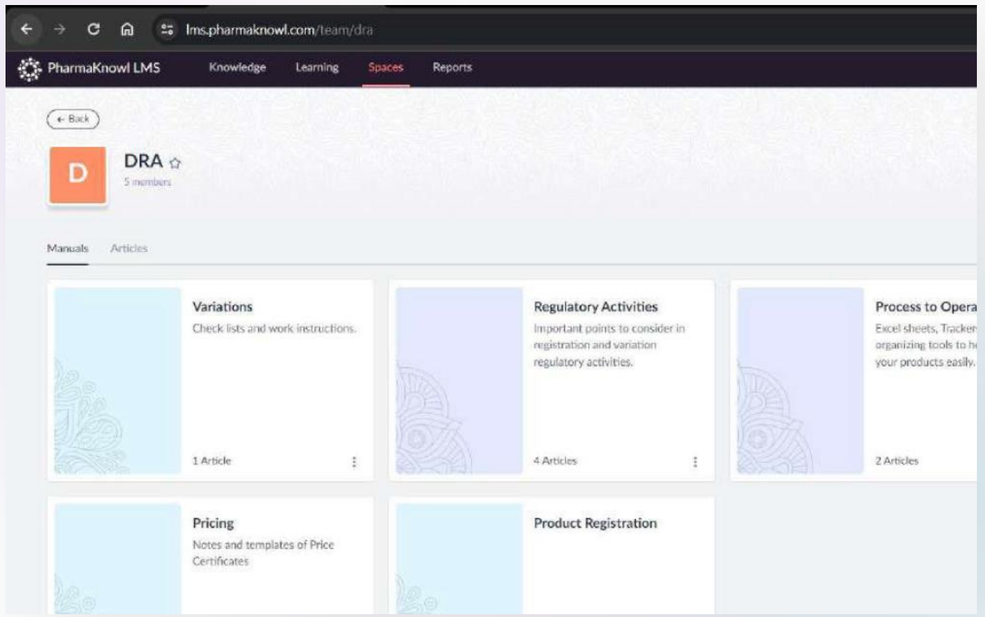
Gap Analysis Checklist

Periodically updated by all staff as a reference for new registration, variations, updates, and manufacturer registration.

Annual Training Records

Annual training in regulatory and post-marketing surveillance, including:

- QMS
- Code of Conduct
- Anti-Bribery & Anti-Corruption Policies
- Conflicts of Interest
- Interaction with healthcare stakeholders



Thank You!

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