# Spanning **Worldwide**

PHES

Prakhar Healthcare &
Engineering Services

## Regulatory Affairs Technologist

PHES
Prakhar Healthcare & Engineering Services

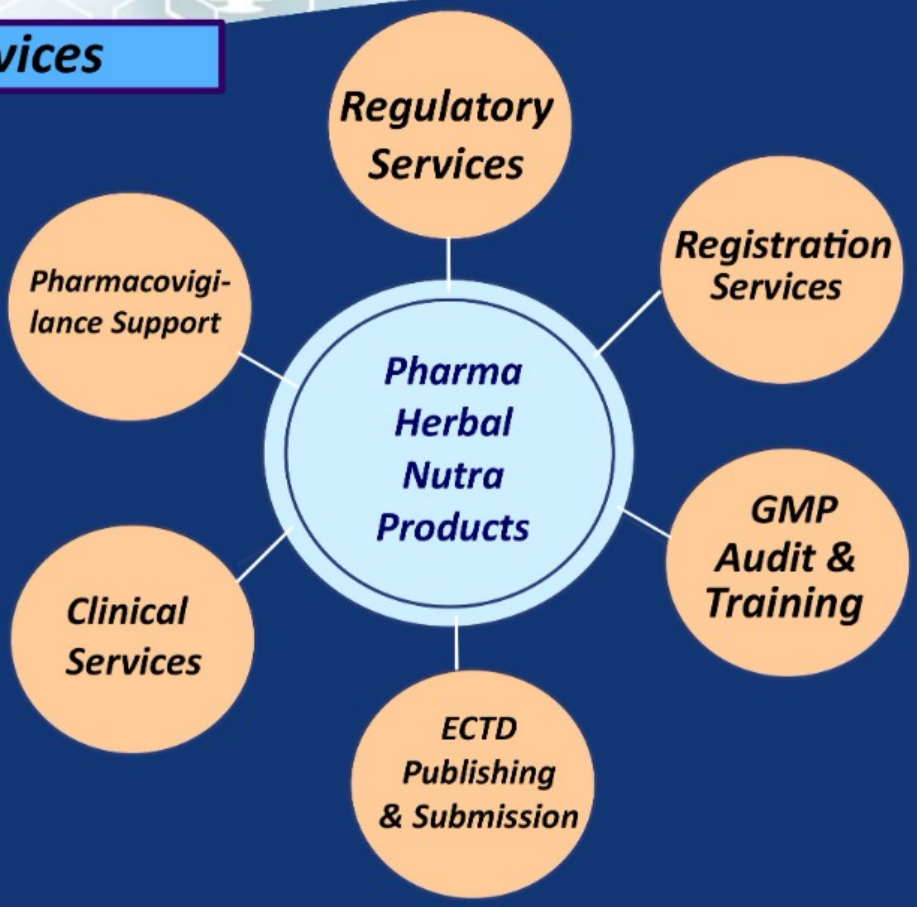
## About US

*Prakar Healthcare is dedicated to growth of client, boost agility and widen the chances of regulatory approval for the pharmaceutical companies*

## Aim

*We help our clients by transforming their goal of obtaining regulatory approvals into reality by providing guidance to manage complex regulatory procedures in a well organized way.*

## Our Services



# 1. Regulatory services

PHES
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**Regulatory Affairs Specialist :**
**Where you can trust for your Regulatory related needs for Drugs/Herbal/ Nutritional Supplements/OTC**
**PHES will help you sail through complex requirements with ease.**

**We can help with following Regulatory Activities:**

**1. Dossier preparations and New Product Development:**

- Review of documents
- ECTD/CTD/ACTD/Regional : Dossier preparation and compilation
- Assistance in Administrative documents
- Post submission Support/Handling of Queries

**2. Active Substances: DMF/ASMF/CEP:**

PHES provides proficient solutions to make accurate submissions using available data and Documents, with well-organized technical writing and submission of DMF/ASMF for our clients globally.
We offer customized service for advice and complete project management for filing of:
Applicants (Open) Part DMF & Restricted (Closed) Part DMF
CEP: EDMF/ASMF (Applicants and Restricted Part) for EU

CHINA DMF -CFDA DMF Registration of DMF in China fda for all type of EXCIPIENTS, API, pharmaceutical packing material

Certificate of Suitability- CEP Filing of CEP APPLICATION with EDQM in eCTD format.

Query reply. Renewal.

Plant Gap audit.Medical Device -USFDA

510k application for medical device with USFDA

Establishment registration

US agent service

US DRUG MASTER FILE (US DMF)- API - EXCIPIENT

Drafting and writing of DMF Open part Closed part ,CTD .

US DMF TYPE II FOR API , Drug intermediate,

EXCIPIENTS USDMF - PRIMARY PACKAGING MATERIAL

Consultancy services for USDMF TYPE III FOR PRIMARY PACKAGING MATERIAL.

DRY SYRUP BOTTLE,TABLE CONTAINER,HDPE/ PP PLASTIC...More

Vendor AuditThird Party Vendor Audit for Pharmaceutical and Allied industry.

Audit is done by industry experts and X FDA Auditors.

WHO GMP AUDITWHO GMP Plant Mock Audit - Gap Analysis - GMP Consultant for USFDA - EU GMP - and WHO

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## 2. Registration Services

We provide registration services for various categories of products:
Drugs/OTC/Herbal/Food supplements/Medical Device:

- India
- Malaysia
- Philippines
- Uzbekistan
- Vietnam
- USA
- Myanmar
- Canada

We will help you to get the safe and secure registration of products.
We hand over the registration immediately to you as soon as it received without any commercial interest.

## 3. GMP Audit and Training

We will help you to analyze your present circumstances accurately and help you navigate the regulatory hurdles.

We offer:
Consultation for strategic consulting on GMP compliance.
To recommend on continuous upgrading of manufacturing process.
Provide Training on Regulatory and QMS.

## 4. Pharmacovigilance Support

We support in Safety Monitoring and its assessment by providing support in :

Pharmacovigilance system
PSUR and RMP
QMS Pharmacovigilance
SmPC/PIL/Insert Writing