About US

APP is the trading name and the company is registered as Sikdar Consulting Ltd in the UK under Reg number 08277789

We are a team of highly experienced team based out in the UK and supporting pharmaceutical compnies since 2012 across EU, US, UK and Japan.

Address – Unit 3, Campbell Court, Bramley, Tadley, United Kingdom, RG26 5EG.

Opening hours:
Monday To Friday: 9:00 AM - 6:30 PM

APP

ALPHA PHARMA PARTNERS

T: 0203 900 0824
E: Welcome@alphapharmapartners.com

Our Services

Regulatory services:

We can offer practical advice as to the best strategies to adopt for successful applications.
1. Preparation of regulatory dossiers for the UK, Europe and other markets in the CTD format
2. Due diligence and Gap Analysis of dossiers
3. Life cycle management including all types of variations, renewals and Change of Ownership applications

Pharmacovigilance services:

At APP we provide our clients a host of Pharmacovigilance and related services
1. QPPV services maintenance of the PSMF
2. ICSR processing
3. Aggregate report writing
4. PSUR
5. DSUR
6. RMP
7. Maintenance and update of the SmPC
8. Safety Signal Management
9. Literature review
10. Supporting in Audits and Inspections

Medical information services:

Our Medical Information service provides a dedicated phone number with access to trained call handlers who can answer queries and also have access to medical professionals for more complex queries ensuring your customers get the information they need.

QP services:

Medicinal products imported into the UK and EEA from third countries have to be certified by a Qualified Person (QP) to be released into the market.
We have in house QPs to provide QP certification and a large network of associates to cover any peaks or supply demands.
We can support with the preparation and submission of MIA applications and can audit to assure compliance with GMP requirements.
We are able to support you with the QP audits or even support you with inspection findings related to GMP/MIA inspection.

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Our Services

Analytical Batch testing services

We provide these batch testing services through experienced and expert chemists/analyst and laboratory management.

Our turn around time is between 3-5 business days.
Within our contract laboratory we can support you with the
Routine quality control analysis of finish products
Routine quality control analysis of raw materials
Analytical method development

GDP and RP services:

Our team of Responsible Persons (RPs) have extensive experience in Good Distribution Practice (GDP) and can provide distribution consultancy services in the UK and EEA. We have involvement in the import and export of both licenced and unlicenced medicines including controlled drugs in both territories.

We can supply from our in-house team both contract RPs and RPi's who are available to help you build your QMS and support not only your application for your WDA but provide ongoing expertise to manage your supply chain.

Manufacturing Importation and Storage Services

Our team of Responsible Persons (RPs) have extensive experience in Good Distribution Practice (GDP) and can provide distribution consultancy services in the UK and EEA. Through our numerous clients we have involvement in the import and export of both licenced and unlicenced medicines including controlled drugs in both territories.
We can supply from our in-house team both contract RPs and RPi's who are available to help you build your QMS and support not only your application for your WDA but provide ongoing expertise to manage your supply chain.

Manufacturing Site Transfer and Product Development

In APP, we have a team with experience and expertise across most areas of product development and manufacturing together with the project management skills that are essential for a successful technical transfer project.
Every transfer is unique, and we will integrate with your team to ensure the technical objectives are met within agreed project timescales

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