GXPZONE
Pharma Solutions Pvt.Ltd

GXPZONE PHARMA
Solutions Pvt Ltd.

An India Based Knowledge Process Outsourcing Company

About Us

We are one of the leading Pharmaceutical GMP consulting company in India. Specialist in Pharmaceutical, Biotech, Bulk Drug, Chemical Industry.
We provide latest technological advancements in compliance with the various international regulatory authorities, including Validation / Qualification / Risk Assessment / GXP confirming to international regulatory norms such as USFDA, MHRA, TGA, WHO GMP, etc.

Gxpzone- Is a complete product solution provider in the field of Pharmaceuticals. The consulting team comprises professionals having rich and extensive experience in product development, world wide Regulatory submission and Quality Assurance. We offer services in the field of Regulatory submissions, Quality and compliance, Product development and Life Cycle management for developed markets like US, Canada, Europe, Australia, New Zealand to emerging markets Asia, Africa, Middle East, Latam, CIS etc.

Vision- To be the company that best understands and provides complete "GXP Compliance and Training solution" Services for Industry as well as Academic

We focus on.....

Healthcare Industry- The focus on providing value added services exclusively to the Healthcare Industry and handling a variety of Pharmaceutical projects make us the most appropriate choice.

Technical Developments- Our continuous access to technical developments through strategic alliances/ co-operations with best consultants / experts bring you the latest concepts and know how.

Our Team- Our team of SME's are capable of making your planned investment a sure success.

GXPZONE Services (The Backbone of our Company)

- **Regulatory Affairs**
- **Project Management**
- **GMP / Vendor Auditing Services**
- **Quality and Compliance ((GXP and GMP Consultancy)**
- **Analytical Method development**
- **Product Development**
- **Procurement services**

Regulatory Affairs

We provide all kind of consulting services in Regulatory affairs for national and international markets.

- Preparation of Regulatory strategy for dossier submissions
- Dossier compilation for US, Canada, Europe, Australia, New Zealand and Emerging markets (Type: eCTD, CTD, ACTD or country specific)
- Dossier conversion to CTD/ACTD format.
- Regulatory gap and risk assessment and it's mitigation plan
- Life cycle management
  a) Post approval changes (including site change)
  b) Re-registration/Annual updates
  c) Change Control Management
  d) Post approval regulatory commitment

Project Management

- Project Execution with support of cross functional team (Business Development, Research and development, Quality, Manufacturing, Regulatory etc.) within stipulated timeline. This include developing the agenda, schedule and facilitate meetings, share minutes of meeting and follow-ups till Project completion.
- All kinds of projects like New Product development and submission, site transfer, deficiency management, New Product launches and any other specific projects that require tighter control on timelines.

GMP / Vendor Auditing Services

- We conduct GMP audits/inspections of Vendors to verify the compliance status of the manufacturer and suggest improvements. The types of audits that are covered here include gap analysis audits and mock inspections to assess the preparedness level for GMP inspections.

Quality and Compliance (GXP and GMP Consultancy)

We offer services to maintain acceptable status of GMP as per prevailing regulations worldwide in below area.

- GMP audit preparation for USFDA, MHRA, PIC/S, ANVISA, WHO-GMP etc.
- GMP gap assessment and remediation of Quality system, Manufacturing, laboratory and Engineering
- Development of document management system.
- Development of entire Quality and GMP System
- Perform Equipment, Utility and Facility Qualification.
- Perform process, analytical and cleaning validation Perform risk assessment of the system and facility

Analytical Method development

We support manufacturer or contract laboratories for complete analytical solutionasper Pharmacopoeial, ICH and national requirement.

- Analytical Method Development and Validation
- Out of Specification (OOS) and Out of Trend (OOT) Investigation
- Analytical Method Improvement
- Pharmacopoeial Compliance of Drug substance, Raw materials and Drug Product GLP Compliance

Product Development

We offer product development and scale up services as per QbD.

- New Product Development (US, EU etc.)
- Product and manufacturing process trouble shooting
- Product and process improvement to mitigate quality risks
- Support for process validation
- Product upgradation to meet Pharmacopoeial requirement

Procurement services

- We are providing services to enhance performance of Supply chain. Since Pharmaceutical product delivery is highly dependent on several internal and external factors like sourcing, quality, regulatory etc.
- We provide the Quality API, Excipient's, Packaging material, Reference Listed drugs and impurity standards at very competitive prices, all the vendors are well evaluated and qualified before procurements.

MAJOR CLIENTS LIST

Name	Location	Accreditation
Nabros Pharma	Ahmedabad	WHO GMP, PICS
Astra Life sciences	Ahmedabad	WHO GMP
Doshion	Ahmedabad	WHO GMP
Parmax Pharma	Rajkot	WHO GMP
Beacon Pharma	Bangladesh	EU, UKMHRA
Pharbacocentral Pharmaceutical co. Ltd.	Vietnam	EU GMP
Pharmasyntez - Tuymen	Russia	EU, PICS
Indorama Pharma	HP	WHO GMP

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