GXPZONE
Pharma Solutions Pvt.Ltd

WELCOME TO

GXPZONE Pharma Solutions Pvt Ltd.

We’ ve built a long standing relationship based on trust

GXPZONE is 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.

We are committed to provide best in class and affordable services in Pharmaceutical field

GXPZONE
Pharma Solutions Pvt.Ltd

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 specialists are capable of making your planned investment a sure success.

GXPZONE
Pharma Solutions Pvt.Ltd

OUR GLOBAL REACH

GXPZONE has worked with a number of companies in the UK and around the world on various projects ranging from technology transfer to gap analysis and training. GXPZONE'S global activities can be viewed to learn more about our global reach. We are continuously exploring new markets and welcome enquiries from organisations in new and emerging markets.

Most of GXPZONE'S projects are coordinated at the headquarters in the UK, while the international offices support local activities in numerous countries depending on the requirements of the venture. GXPZONE'S consultants are based in various parts of world including Europe, Asia and North America and this provides the local knowledge needed to carry out overseas projects effectively.

Introduction

GXP Audits

GxP is an umbrella term not only for Good Manufacturing Practice, but also for various other surveillance domains. Qualified persons hit resource bottlenecks due to increasing GxP audit obligations. Staff-intensive, time-consuming and costly audits, which are usually associated with enormous travel requirements, can hardly be efficiently managed by the in-house staff.

GXPZONE Pharma Solutions. Can help – as your external, accredited, independent 3rd party auditor! The abbreviation **GxP** combines guidelines for "good working practices" pertaining to various branches of the pharmaceutical industry. Manufacture of medicinal products is at the very core of **GxP.** It is governed by the fundamental principles of Good Manufacturing Practice (GMP) which serve to ensure quality, efficacy and safety of medicinal products. Based upon our exceptional experience, knowledge and understanding we exceed customer expectations.

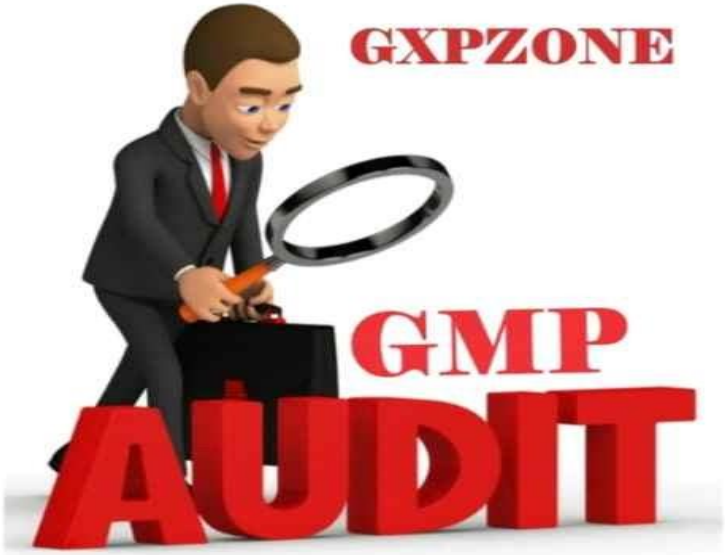
GXPZONE
Pharma Solutions Pvt.Ltd

Introduction

.

Our GXP Service Range

- GMP of APIs
- GMP of Excipients
- GMP of Finished dosage forms
- GMP of packaging materials
- GDP - Good Documentation Practices
- GWP- Good Warehouse Practices
- GEP - Good Engineering Practices
- GLP - Good Laboratory Practices



GXPZONE
Pharma Solutions Pvt.Ltd

Introduction

.

Why Quality Management System Audits?

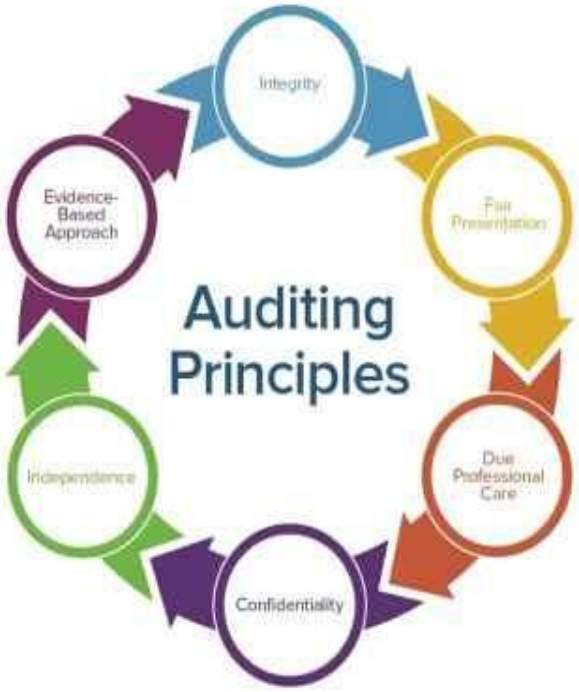
- You want to substantiate your quality level to outside parties?
- You want to continuously improve your processes beyond simple self- inspections?
- You would like to prepare for regulatory inspections?
- You want to convince potential customers and supply proof of your production quality?
- You want to exhibit full control of audit results?
- We have developed a tailor-made solution for these needs.

Our Methodology and Benefits…

Our GMP system audits focus on the implementation of the company & quality system. Key SOPs and key documents are evaluated and assessed in detail. The audit is then completed with product-based examples of their GMP system. Remote or the Virtual audits methodology is also adopted based on preliminary risk assessment and situation.

GXPZONE
Pharma Solutions Pvt.Ltd

Introduction



Your benefits are :

◄ Sharing of audit report will enhance trust and customer relationship

◄ Standardised, transparent audit procedure

◄ Full confidentiality and an audit by an independent, professional auditing company

◄ Experienced, qualified auditors with a correct understanding of auditing principles and globally accepted standards.

QM system audit offers the auditee the perfect opportunity to:

Verify the internal quality level against that of external partners.

◄ Implement continuous improvement measures beyond self-inspections;

◄ Prepare for inspections conducted by the authorities;

◄ Win clients by independent proofs of quality.

GXPZONE
Pharma Solutions Pvt.Ltd

Introduction

Now a team of total 15+ experts with highly diverse and scientific background

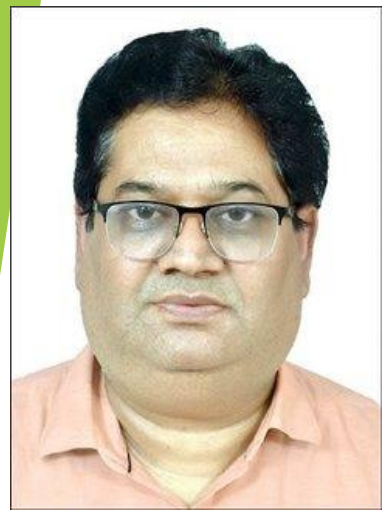
Our experts from different domains like Regulatory, Medical Affairs, Clinical Trials, PK studies, API, Formulations, Manufacturing, Marketing enrich our service offering with their comprehensive experience.

Mission : To be of best quality and most trusted Pharmaceuticals Support Service company globally.

Vision : To create a platform where all possible solutions are available for Pharmaceutical Research and development.

OUR STRENGTH & EXPERTISE

GXPZONE'S strength is their rich technical experience of both the directors in the field of Pharmaceutical industry. Further a team of 15 SME's adds to it's strength.



Mr. Sanjay Sharma has more than 30 years' experience & specialization in GMP compliance for Formulation, Biotech, Oncology, Injectable, API, Bulk Drug & Food Industries.

With more than 200 facilities inspected which are also qualified and approved by USFDA,WHO GMP,EMEA,EU, ANVISA, MHRA, PICs & all International Regulatory Standards.

Audit successfully faced:
MHRA / Eu GMP, ANVISA, INVIMA, WHO GMP
He is expert on GMP and delivered seminars in various cities in India on cGMP.

Dr. Subhas Phande : Technical Director and Principal advisor with GXPZONE Pharma Solutions
About 29 years of experience in Pharmaceutical Industry.
R&D, Manufacturing Quality Assurance and Quality Control functions of sterile, Oral Solids, dosage forms, Sterile API, Animal health care products Lyophilized Injections, DPIs, MDIs, Nasal sprays, Bio similar, vaccine and Pre-Filled Syringe products.
USFDA Inspections – Oral Solids, Sterile and Non Sterile APIs , Semi Solids (Ointment and Creams)
Audit successfully faced:
MHRA / Eu GMP – Dry Powder Injectable, Oral Solids, Semi Solids
ANVISA – Dry Powder Injectable, Oral Solids; Inhaler's; Biologics Semi Solids
INVIMA – Oral Solids; Biologics
WHO GMP – Oral Solid, semi Solids , Injections , Lyophilization process.

GXPZONE
Pharma Solutions Pvt.Ltd

OUR STRENGTH & EXPERTISE

Dr. Tarun Chugh is a Pharmaceutical professional with around 30+ years of rich experience in Microbiology Quality Control and Quality Assurance Department. Presently associated with M/S GXPZONE Pharma Solutions Pvt. Ltd. as GMP Auditor. Expertise in performing the gap analysis of Formulation, API, Excipients & Packaging Material manufacturing units with respect to the various regulatory standards like USFDA, MHRA, EU, PICs, TGA, ANVISA, WHO etc.

He is expert in various Microbiology techniques, Clean Room Validation, Aseptic Validations, Process validation, Water system Validation, HVAC Validation, QMS Handling, ALCOA+, Data integrity and troubleshooting with Risk Assessment.

Vivek is a Pharmaceutical professional with around 28 years of rich experience in Quality Control and Quality assurance Department. Presently associated with M/S GXPZONE Pharma Solutions Pvt. Ltd. as GMP Auditor.

Expertise in performing the gap analysis of Formulation, API, Excipients & Packaging Material manufacturing units with respect to the various regulatory standards like USFDA, MHRA, EU, PICS, TGA, ANVISA, WHO etc.

He is expert in various analytical techniques, analytical method transfer, analytical method validation, process validation, Water system Validation, HVAC Validation and QMS Handling

GXPZONE
Pharma Solutions Pvt.Ltd

OUR STRENGTH & EXPERTISE

For Project Management

Mr. Kishor Mahadeshwar – Technical director facility designer & project management

❑ Demonstrated excellence by designing (taking the responsibility for facility build from grass root, conceptual , basic, detailed & construction engineering,) various pharmaceutical facilities, implementation & maintenance, overall business administration, team building, capacity building and performance improvement across industrial machinery, associated pharmaceutical operations & work flows (making facility functional and its compliance with respect to aimed statutory approvals by arranging all production factors).

❑ Seasoned & versatile professional with excellent governance, leadership & management skills, offering incredible experience acquired more than two decades in delivering optimal results and business value in high-growth environments in the areas of business excellence & operations, project management, technical, supply chain management, quality assurance, resource management & workforce planning

Having hands on experience on designing following pharmaceutical facilities

- **API facilities**
- **Formulation facilities**
- **Vaccines / biotech facilities**
- **Lab facilities**
- **Utility facilities**

GXPZONE
Pharma Solutions Pvt.Ltd

OUR STRENGTH & EXPERTISE

For Computer System Validation

Anubha Mukherjee

Anubha is a CSV expert with GXPZONE Pharma , India. With over twenty years of experience in Consulting, she has extensive experience in design, development, implementation and management of information technology solutions for a wide range of industries and technologies.

Her present area of focus is IT Compliance & Computer Systems Validation for the Life Sciences industry.

Computer Systems Validation of Enterprise Systems :

TrackWise Systems, **Laboratory** applications, **SCADA** Systems, MES and ERP Implementations.

o GxP Assessments and 21 CFR Part 11 Compliance.

o 21 CFR Part 11 GAP Assessments of GxP Systems

o Computer Systems Validation of Chromatography Management Systems.

o Computer Systems Validation of Document Management Systems

o Infrastructure Qualification for GxP applications

GXPZONE SERVICES

The Backbone of our Company

- Regulatory Affairs
- Quality and Compliance
- Product Development
- Analytical Method development
- Project Management
- Procurement services
- Orientation Programme
- GMP Auditing Services

GXPZONE
Pharma Solutions Pvt.Ltd

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 assessment and mitigation
•Life cycle management
a) Post approval changes (including site change)
b) Re-registration/Annual updates
c) Change Control Management
d) Labelling updates
e) Regulatory risk assessment
f) Post approval regulatory commitment

GXPZONE
Pharma Solutions Pvt.Ltd

Quality & Compliance (GXP and GMP Consultancy)

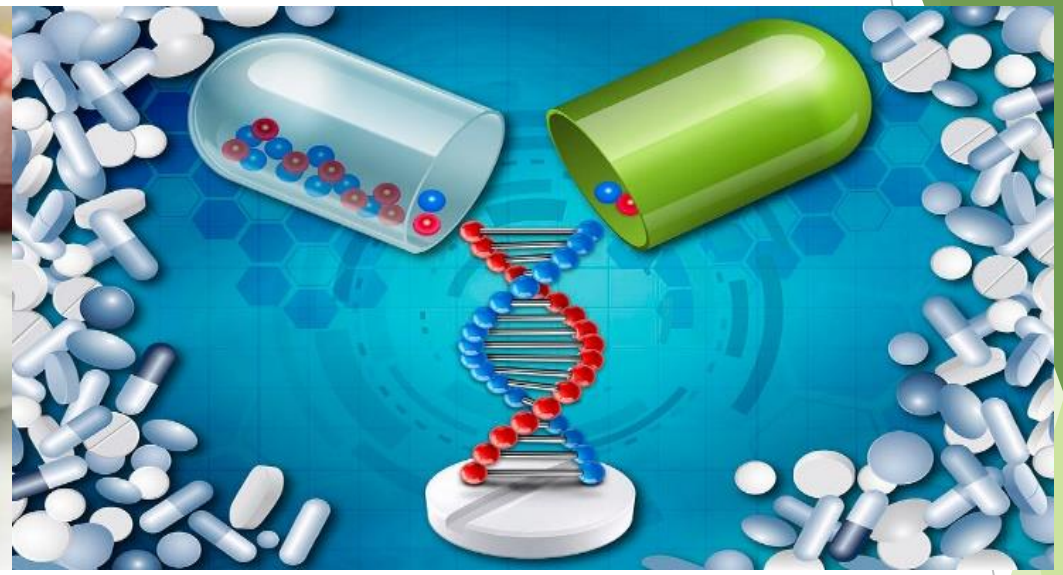
We offer services to maintain acceptable status of GMP as per prevailing regulations worldwide in below area.

- 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
- Performing vendor audits of API, Intermediates, Excepients, Packaging material
- Impart GMP trainings on various topics to

1.Workmen
2.Officers
3.Advance training modules For Manager and Above.

GXPZONE
Pharma Solutions Pvt.Ltd

Product Development

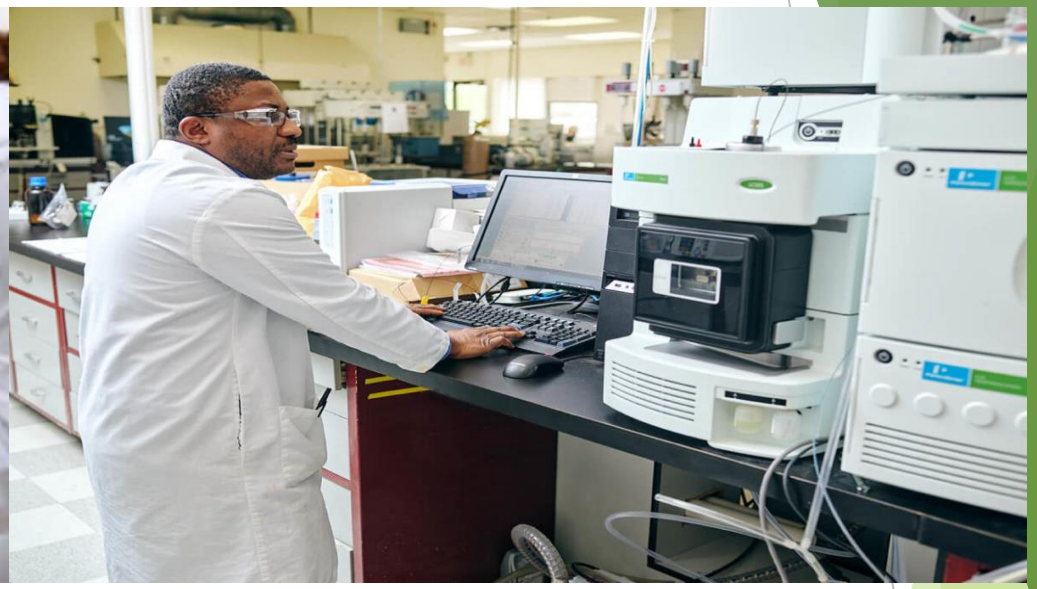


We offer product development and scale up services as per QbD.

- 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

GXPZONE
Pharma Solutions Pvt.Ltd

Analytical Development



We support manufacturer or contract laboratories for complete analytical solution as per 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

GXPZONE
Pharma Solutions Pvt.Ltd

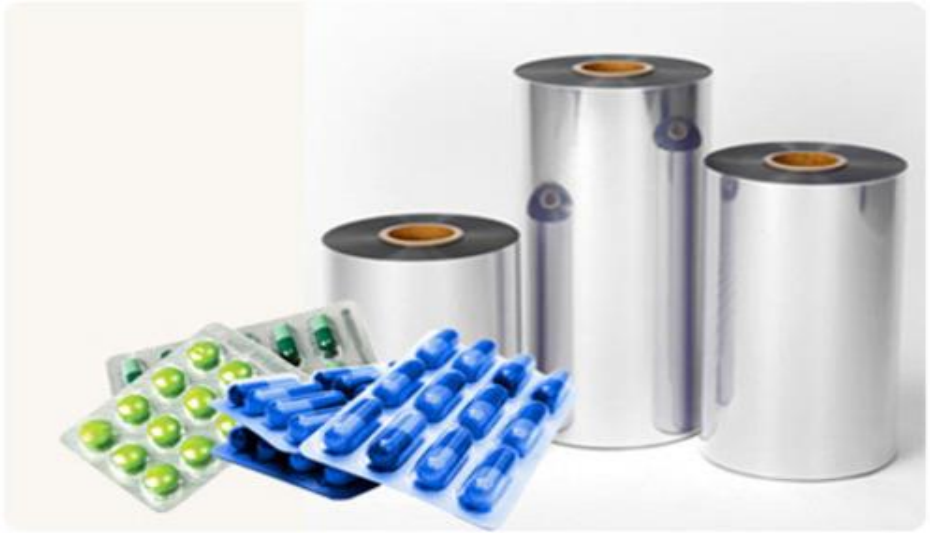
Project Management

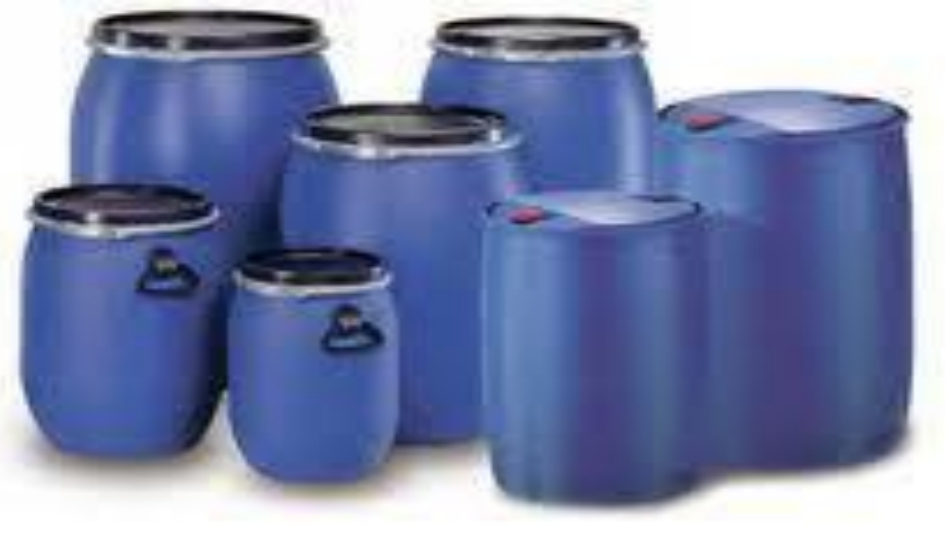
•Project Execution with support of cross functional team (Business Development, Research and development, Quality, Manufacturing, Regulatory etc) within stipulated timeline. This include developing the agenda, schedule and facilitate meetings, share minutes of meeting and follow-ups till Project completion.

•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.

GXPZONE
Pharma Solutions Pvt.Ltd

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 extend our expertise to collate feedback from all departments, plug the gaps and help to enhance supply thereby improving product availability to the market.

•We can provide the Quality API, Excepients, Packaging material, Reference Listed drugs and impurity standards at very competitive prices, all the vendors are well evaluated and qualified before procurements.

GXPZONE
Pharma Solutions Pvt.Ltd

Industry Orientation Programme

This programme is introduced to provide practical application of basic concepts of Pharmaceutical science to Pharmacy (3rd/4th year) and Science graduates/Post graduates for “Bridging the gap between Academia and Pharmaceutical Industry” and seeking job opportunity in Pharmaceutical industry.

Classroom training is provided with emphasis on Quality Assurance, Regulatory Affairs, Laboratory, Research and Development, Bioavailability / Bioequivalence and Documentation to bridge academic and industry gap.

GMP Consultancy

GXP and GMP Consultancy

As well as offering training courses we also provide pharmaceutical GXP and GMP consultancy and auditing services. For this we only use leading industry specialists. Specialists who not only have a great deal of experience but also have practical skills and ability to get issues sorted. Our idea is that our consultants should be able to work with you and help you, rather than create even more work for you! We can help with the following areas of the pharmaceutical industry:

Auditing service

We perform supplier audits as well as internal audits against most recognized pharmaceutical standards. We use specialist sector-specific auditors as needed, including experienced IT/ Computer System auditors.

Inspection preparation

We help get sites ready for Regulatory and Corporate inspections, including working with groups to get their own areas ready. We can also assist behind the scene during the inspection itself.

GXPZONE
Pharma Solutions Pvt.Ltd

GMP Auditing Services

- # System and Facility Audit
- # For-Cause Investigation Audit
- # Site Qualification Audit
- # Retrospective Audit
- # Feasibility Audit
- # GAP Assessment Audit
- # GCP/GLP Compliance Audit

GMP audits and inspections

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. This also supplements the internal self-inspection and expectations of the regulatory agencies of an independent audit of QA department by external agency.

The objective is also to monitor the effectiveness of GMP implementation programs. This is done by adopting a ‘partnering’ approach with the firm and placing emphasis on sound science and current regulatory requirements. All information shall be treated as confidential and the mechanics of operation shall be based on transparency and ethical principles.

This helps the firm in assuring consistent quality and adherence to GMP across the entire supply chain i.e. from procurement to distribution, complaint evaluation and product quality reviews. We also carry out audits to the assist the firms in establishing feasibility of third party manufacturers, qualifying vendors of raw and primary packaging material.

GXPZONE
Pharma Solutions Pvt.Ltd

Career Services

GXPZONE Pharma Solutions is also a talent hunt organization for providing manpower solution to clients across the pharma industry.

GXPZONE Pharma Solutions has emerged as one of the leader in providing quality manpower to Pharma Industry. Right since our inception we have believed in delivering smart and comprehensive recruitment solutions to the needs of our clients & candidates.

Candidates who wish to make career with us and our clients in pharma industry may upload their resume.

GXPZONE
Pharma Solutions Pvt.Ltd

Registered Office
222 First Floor (F2) Nitikhand I , Indirapuram Ghaziabad – 201014
Corporte Office
101, 1st Floor, Jaishree Heights, Plot No. CS-02, Gyan Khand -1, Indirapuram, Ghaziabad 201014

Branch Office
Mumbai
Ramdas Complex, Near Maruti Suzuki Show Room, Khambalpada, MIDC-1, Dombivli (East) Dombivli : 421202 Mumbai
Phone
+91-9557775676
Landline
+91 1204293426,
Email
info@gxpzone.com
Website
www.gxpzone.com

GXPZONE
Pharma Solutions Pvt.Ltd

We Value your Association

Thanks