QxP

PHARMA PROJECT & GMP SERVICES PRIVATE LIMITED

+91 9979842207/+91 9979894611

info@qxpts.com

www.qxpts.com

Sobocenter, D-471 (Fourth Floor), Above Wholesale Market,
Gala Gymkhana Road, South Bopal, Bopal, Ahmedabad, Gujarat-380058.

Core Values

- Ethical, Reliable & Committed
- Integrity & Honesty
- One Stop Solution
- 20 Yrs Experience
- Achieve Goals

Our Vision

To become the world's premier brand in Consultancy to Pharmaceutical , Food, Healthcare and Personal care Industries.

Our Mission

To serve our clients achieve heights of Business with quality complies.

About us

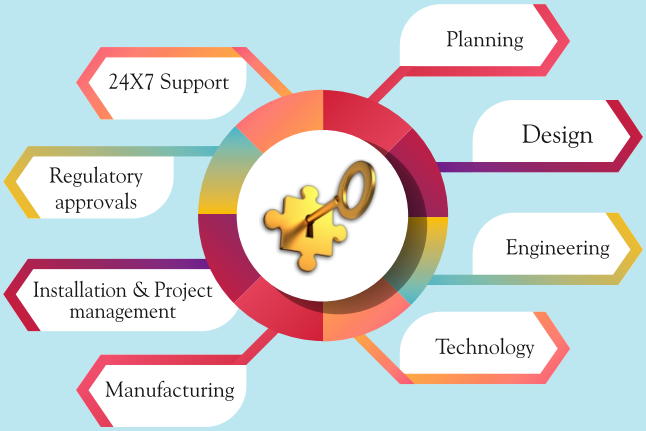
➢ Founder & Lead GMP Consultant **Mr.Pankaj Sojitra** having 20 years of Pharmaceutical industries experience start from base level working to a senior management position in Quality Assurance,Quality Control, Regulatory Affairs Technical Operation with leading pharma companies,as our founder and driving force.

➢ **QxP Technical Services Group & QxP pharma project & GMP services** established in year 2018 with the vision of providing GMP and technical services with Quality excellence to **Pharmaceutical Formulation, API, Biopharma, Medical & Surgical, Nutraceuticals industries and BA/BE Lab setup**.

➢ QxP Group is backed up with many intelligent and expert Pharma Project & Design expert, Auditors and Documentation team provide fast and cost effective Quality Services in Pharmaceuticals & Healthcare industries.

Our Expertise

- Turn key projects
- GMP Compliance and regulatory approval
- Qualification &Validation
- Sterility Assurance
- Vendor audit /Third party audit
- Computer system validation (CSV)
- Data integrity
- GxP & Total training
- Strategic sourcing
- New product development
- Regulatory services
- Plant Modifications
- HVAC Project
- Electrical Project
- Epoxy/ PU Flooring



GMP Compliance Regulatory Approval

Provide All GMP Related Technical Services Following Market,

- USFDA
- UK-MHRA
- EU-GMP
- WHO – Geneva
- PIC's
- ICH
- TGA – Australia
- MCC (SAHPRA)
- ANVISA
- ROW MARKET (Kenya (PPB),Uganda (NDA),Tanzania (TFDA),
- Ghana (FDA), Nigeria (NEFDAC),Turkish (TDA)
- India / WHO - GMP

Turn Key Projects.....

Pharma formulation

- **Parenteral**
  (Injectable, Eye, Eardrops, Nasal)
- **Oral Solids Dosage**
  (Tablets/Capsule/Liqud/Softgel)
- **Topicals**
- **MDI/DPI**

BA/BE Lab set up

Hospitals

API

- Sterile
- Non sterile

FMCG

- Nutraceuticals
- Food & cosmetics

Bio Pharmaceuticals

- Bulk (Cell-culture / Fermentation)
- Finished product (Injectable)
- Vaccines and Bio similars
- Monoclonal Antibiotics

Turn Key Project includes

- Plant layout designing
- Feasibility study report of project
- Pharma Turnkey Projects
- Project Management Consultancy
- Detailed Engineering Design & Designing of Piping Work
- HVAC System
- Detailed Electrical designing
- Plant safety & environmental Engineering
- Quality Control Lab Set up
- BA/BE Lab set up

Quality Control Lab Set up

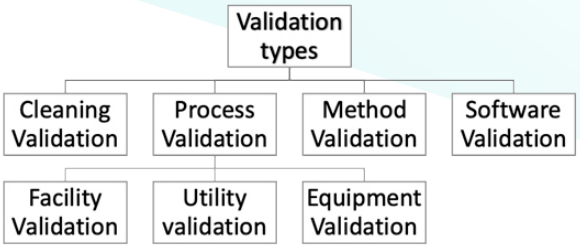
- Setting Up New/Existing Laboratory Facilities of Quality control
- Calibration of Lab instruments
- Sample management system
- Retain / Control sample management
- Stability Programme
- Analytical method validation and transfer Lab instruments maintenance programme
- Working Standard / Reference standard management
- Column management
- Data integrity / Audit Trail of Software system review

Microbiology Laboratory Set up

- ✓ Total Quality Management of Microbiology Laboratory
- ✓ Setting Up New/Existing Laboratory
- ✓ Facilities Evaluation of laboratory practices and design
- ✓ Equipment/Instrument Qualification
- ✓ Microbial Risk Assessment
- ✓ Designing Efficient Workflow Systems for Laboratory and Testing
- ✓ Microbiological Contamination Control Programs
- ✓ Plant Sanitization Problem Solving Selection and Qualification/
- ✓ Validation of Disinfectants
- ✓ Environmental Monitoring Program
- ✓ Sample location selection Risk assessment

Manufacturing Control System....

- Hold time study
- Process Validation:
- Life cycle approach with continuous process verification
- Cleaning Validation:
- PDE / ADE approach (Permeable daily Exposure approach)

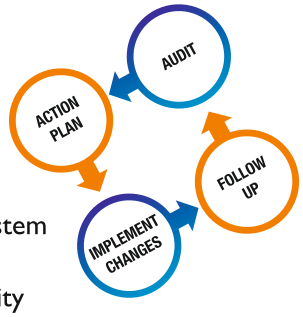


Vendor Audit :

- Our consultants will visit your facility and carry out an inspection in the style of the relevant regulatory body (USFDA, MHRA, EMEA, PICS, TGA, Local FDA etc.
- API
- RM (Raw material)
- PM (packing material)
- Contractual laboratory

Complete Solution

- ✓ System Audit
- ✓ Quality system
- ✓ Facility & Equipments
- ✓ Material System
- ✓ Production System
- ✓ Packaging & Labeling System
- ✓ Laboratory Control
- ✓ Data integrity & Reliability
- ✓ Computer system validation
- ✓ Engineering
- ✓ Water System
- ✓ Raw material suppliers
- ✓ A range of other vendor and supplier services



Total Quality Management System : (QMS)

- Site Master File
- Quality Manual / Quality Policy
- Laboratory information file Incident / Laboratory incident report

Documentation of Quality:

- » Process related Documents Engineering
- » Utility department
- » Validation & Qualification
- » Research & Development
- » Method Development department

GAP Analysis of existing facility/system/documentation for regulatory approvals QMS system includes:

- Change control
- Deviation
- Out of specification (OOS)
- Out of trend (OOT)
- Out of calibration (OOC)
- Market complaint Product recall

Risk management system of:

- Facility
- Product
- Equipment/Instrument
- Any Other System Related Documents

Qualification / Validation

Validation /Qualification

» Validation Master Plan

Preparation of Documents of all departments :

- » Standard operating system (SOP),
- » Protocols , Formats, Reports etc of all the departments
- » Water system Validation, Area qualification / Facility Qualification

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Qualification :

- ★ Risk assessment
- ★ User Requirement Specification (URS)
- ★ Design Qualification (Setup & Good Laboratory Practices (GLP)
- ★ Regulatory documentation
- ★ Vendor Evaluation
- ★ Vendor Development

Equipment's / instrument's...

- ➢ Design qualification (DQ)
- ➢ Instrument Qualification (IQ)
- ➢ Operational Qualification (OQ)
- ➢ Performance Qualification (PQ)
- ➢ Re Qualification (RQ)
- ➢ HVAC System (AHU)

Qualification along with ...

- ★ EMS / BMS Transport Validation
- ★ Process Validation & continuous process verification
- ★ Cleaning validation
- ★ Hold time validation
- ★ Analytical Method validation (For QC chemical/Microbiology)

Sterility Assurance & Data Integrity

Sterility Assurance:

- ✓ Aseptic Assurance/Sterility Assurance
- ✓ Contamination Control Strategy
- ✓ Contamination Source Identification
- ✓ EM Program viable / non-Viable
- ✓ Risk Assessment for EM locations
- ✓ Gowning Qualification
- ✓ Audit Preparedness
- ✓ Sterility Assurance Services Includes:
- ✓ Quality Management System
- ✓ Media Fill

Data Integrity:

- ✓ Data Integrity Policy
- ✓ Data Integrity Historical Verification
- ✓ ALCOA Assessment
- ✓ Data Integrity Remediation Plan
- ✓ Continuous Monitoring Procedure for Data Integrity
- ✓ Audit trail Review Methodologies
- ✓ Data Integrity Risk Assessment

Audit and Compliances....

➢ Assist clients to prepare for an imminent regulatory inspection by carrying out one or more mock regulatory audits in advance of the real thing. Our consultants will visit your facility and carry out an inspection in the style of the relevant regulatory body (USFDA, MHRA, EMEA, PICS, TGA, Local FDA etc.

For Compliances……

➢ Impartial and professional assessment of their current state of compliance prioritized action plan for the rectification of areas of noncompliance. Staff coaching in the sorts of questions which are likely to be asked during the inspection and how best to answer them.

Computer System Validation (CSV)

➢ Computer System Validation (CSV) is a regulatory requirement for all computerized systems used in regulated environments in the Pharmaceutical, Biotech, Nutraceutical, and Medical Device industries. CSV ensures that computerized systems are performing properly according to customer intended uses and regulatory requirements, such as….

✓ FDA 21 CFR Part 11
✓ FDA 21 CFR Part 210/211
✓ Eudralex and PIC/S Annex 11

Total Project Management Strategies

➢ The capacity to provide complete and integrated engineering services and perform targeted actions and efficient programming, monitoring and control, ensures for the project.

- ➢ Flexibility andComprehensiveness
- ➢ Environment Protection
- ➢ Safety by design
- ➢ Cost Effectiveness
- ➢ Customized Engineering

New Product Development System

New product development, regulatory submission support Preparation of DMF/ANDA Regulatory Updates/ Guideline Updation..

Products includes……

- APIs
- Solids
- Semi-solid
- Liquids
- Sterile products
- Onco products
- Inhalers

Training:

Training on…

Onsite Training…..
and
Classroom Training…

- GMP
- cGMP
- GDP
- Data integrity
- Process and system related SOP training - QC/QA/Manufacturing /Maintenance

Regulatory / Dossiers Services

DMF/Dossier Preparation

- Dossier compilation in Common Technical Dossier (CTD) format for :
- Common wealth of Independent States (CIS) Guidelines.
- South East / West Europe Guidelines.
- Dossier compilation as per :
- Asian Common Technical Dossier (ACTD) Guidelines.
- South Africa (MCC-MRF-1) Guidelines.
- Brazil ANVISA Guidelines.
- Dossiers compilation for submissions in :
- Asia
- Africa
- Central America
- South America
- North America

Drug master file (DMF) compilation for open and closed parts Drafts data for

- BMR, MFR
- Process Validation,
- Stability Study reports,
- Dissolution profile,
- Certificate of analysis and related reports

Reports on...

- Clinical Trials studies
- Bioavailability / Bioequivalence Studies
- Justification for fixed dose combination
- Prepare Periodic Safety Update report (PSUR)
- Preclinical studies like Toxicity, Carcinogenicity, Teratology & Reproduction toxicity

One Team...
Infinite Solution...

Connect with our team...

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MEP Consultancy Services

M/s. QxP Pharma Projects & GMP Service is Ahmedabad based consulting firm which provides services related to design and execution of HVAC system, Electrical, clean- Black utility piping, PU/Epoxy flooring Consultancy Services. The Firm Provides Wide range of Consultancy services in the orbit of Industrial and Commercial. We make changes in the technology and process to meet constantly changing requirements of clients. Our sophisticated consulting ability comprises of extremely, highly developed, skilled and knowledgeable employees

AREAS OF ENGINEERING / TECHNICAL SERVICES WE OFFERED

- Development of Basic Engineering & Extended Basic Engineering
- Detailed Engineering
  - Mechanical
  - Piping
  - Electrical
  - HVAC
- Development of Pilot Plant
- Adopting Technology to Indian/Local Conditions
- Planning & Implementation of New Manufacturing Facility
- Planning & Implementation of Expansion Projects including De-bottlenecking
- Up-gradation of Manufacturing Facility
- Procurement Services
- Inspection & Expediting Services
- Utility Audit - Steam / Water Management
- Fire Protection & Safety.

OUR ELECTRICAL SERVICES

- Project Estimate and BOQ
- Transformer sizing according to load details
- D.G.set sizing according to Load Power details
- Selection of H.T / L.T Cables Size / Make
- Selection of Light fixtures according to site conditions (Height, Classified areas)
- Panel Designing
- Lighting / Power Distribution
- Low Voltage System Estimate
- Telephone /EPADX System
- LAN / WIFI System Design

DRAWINGS

- Electrical, Plumbing and HVAC Coordinate drawings.
- Electrical Power Distribution Scheme
- 11 KV Sub-station layout
- Panel SLD with Cable sizing
- Internal Lighting layout
- External Lighting layout
- Cable tray layout
- Earthing layout
- Low voltage system layout
- HVAC equipment location and Point of power supply
- Clean and black utility piping layout

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SOLUTION PROVIDER FOR HVAC PROJECTS CONSULTANCY

We provide Our competitive and comprehensive consulting services for design and engineering for below mentioned products : Heat Load Calculation and Area Base On Classification

1. HVAC System Design
2. Room Data Sheet
3. AHU Summary Sheet
4. Technical BOQ of HVAC Project
5. Zoning Layout
6. Ducting Layout

CLEAN UTILITY AND PROCESS PIPING FOR PHARMACEUTICAL AND FOOD MANUFACTURING

Besides piping for water for pharmaceutical, we also offer piping for the clean utilities like Pure Steam, Air and Gas which comes in direct contact with the final product and also offers process piping to carry raw materials, intermediate products as well as final products.

WE OFFER PROCESS AND CLEAN UTILITIES PIPING

- In Stainless Steel 316L and as per followed protocols like GMP, FDA and others.
- All piping system will be design with minimum or no dead leg.
- Stainless Steel 316 L Tubes, fittings used will be electropolished internally to 0.4 RA and externally polished to 180 grid.
- All Stainless Steel electropolished tubes will be welded using Orbital welding machine. With proper documentation for all orbital welding.
- Boroscopic examination of welded joint.
- Where Boroscopic examination is not possible radiography examination can be offered.
- Valves, fittings, automation and other accessories to complete the piping system

We also offer piping for back utilities like compressed air, gas, raw water and steam which will not come in direct contact with the final products. MOC offered are SS 304, uPVC, PPCH, PPRC. We also offer PTFE lined pipes and fittings.

FIRE PROTECTION AND SAFETY

- Building Code Consulting /Fire Code Analysis
- Clean Agent Suppression Systems
- Automatic Sprinkler Systems
- Fire Pump Design
- Aqueous Film Forming Foam (AFFF] and Deluge Suppression
- Systems for Tank Farm (vessel] Protection

PROCESS DEVELOPMENT SERVICE

- Scale-Up
- Process Development with objective of yield improvements, energy efficiency, use of alternate equipments/systems etc.
- Technology Transfer
- Adopting Process Technology to Indian Environment

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Our Clients.....

International

SQUARE PHARMACEUTICALS LTD. BANGLADESH
KriGen Pharmaceuticals PRIVATE LIMITED empowering innovation
ONCOWELL
BSMIT ALHYAIT On behalf of the office of Faez Kamel Hachem for food supplements
Dolopharma HEALTHCARE
CiplaQCi
RHODODENDRON BIO-TECH PVT. LTD.
ZISKA PHARMA
MOBEN Laboratoire Pharmaceutique
YASHFEEN PHARMA

Domestic

Emcure
amneal
UNISON
innoxel LIFESCIENCES Excellence Delivered
CUREFOX HEALTHCARE PVT LTD
Alembic Touching Lives over 100 years
Bharat Parenterals Limited Thinnesing Science for Life
PRIHET Pharmaceutical Pvt.Ltd.
HETVI'S
vovantis LABORATORIES
Meteoric Biopharmaceuticals
memphis passionate to Healthcare
Nutra Healthcare Pvt. Ltd. A Manufacturer & Exporter of huge range of Nutraceutical Products.
TACTUS Nutrasciences LLP.
NUTRALIKE HEALTHCARE
AVANCE HEALTHCARE PVT LTD
WOMANORA INC
Bills Biotech
Das SUPERFOODS PVT. LTD.
INFUZE WELL PRIVATE LIMITED

Continue.....

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Our Clients.....

Domestic