GXP SOLUTION |INDIA

www.gxpsolutions.com

TAILORED MADE SOLUTION FOR

SKID-TANK-VESSEL

Expert With Validation Qualification & GEP Compliance

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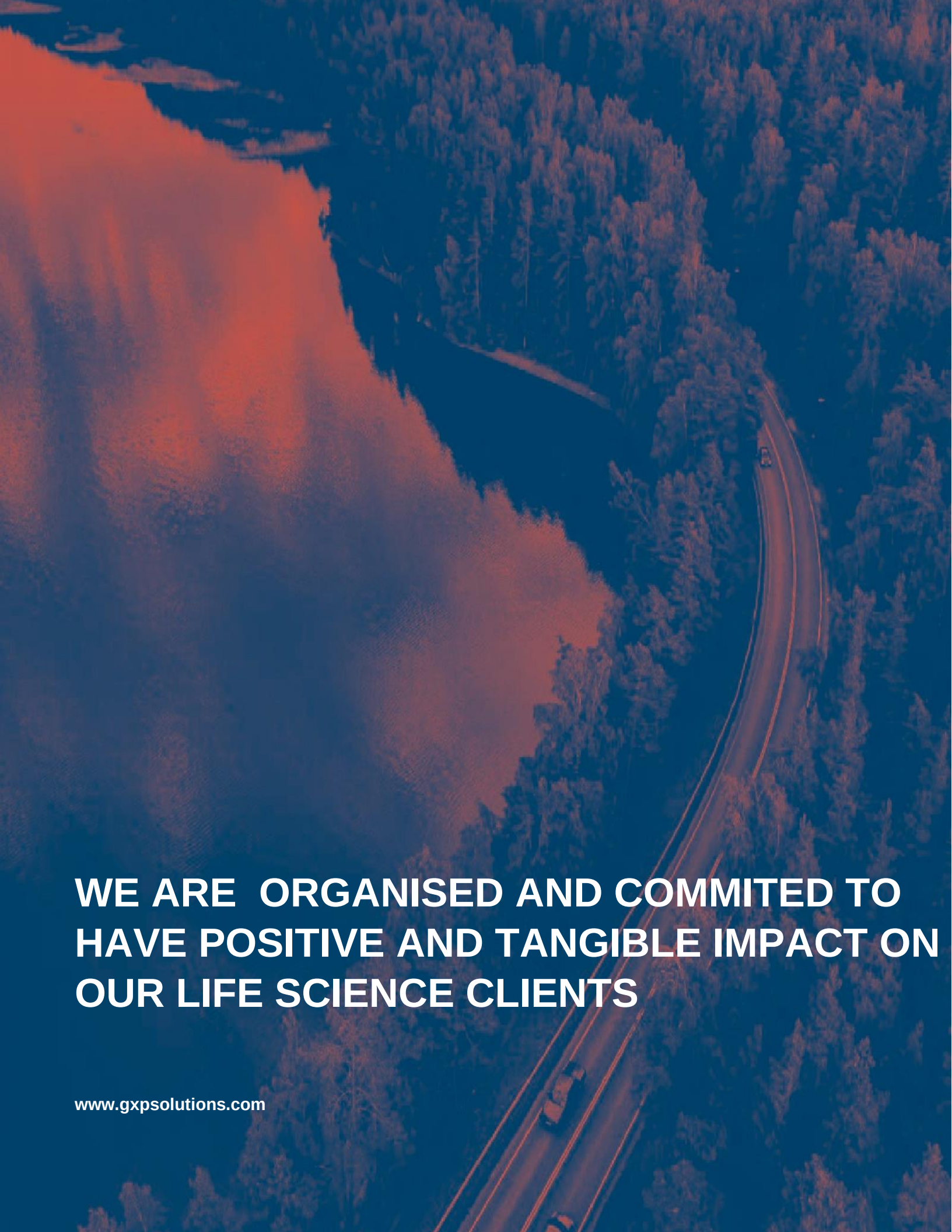

WE ARE ORGANISED AND COMMITED TO HAVE POSITIVE AND TANGIBLE IMPACT ON OUR LIFE SCIENCE CLIENTS

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WHO WE ARE

GXP Solution is a global GEP Manufacturing firm dedicated to helping life Science organizations manage regulatory compliance, mitigate risk and resolve any regulatory compliance issues or to manage any greenfield, brownfield projects across globe.

Specialized in delivering customized manufacturing and process system for the pharmaceutical industries
-Inhouse Automation
-Inhouse documentation
-inhouse validation

Individually, each practice is a leader in its specific field, staffed withexperts recognized for the depth of their knowledge and a track record of making an impact. Collectively, GXP Solution offers a comprehensive suite of services designed to assist clients across thebusiness cycle—from proactive risk management to the ability to respond rapidly to unexpected events and dynamic environments.

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FDA 21 CFR PART 11 COMPLIANCE

Our Philosophy:

We are committed to meeting and exceeding our customers'expectations of value by providing high quality equipment, excellent service, and complete process solutions.

We offer customised manufacturing solution like...

- Process Tank/Sterile product mixing vessels
- Media Preparation, Sterilizers,
- Holding Tanks/Aseptic processing system.
- Kill / Deactivation Tanks
- Mobile/Fixed PHT/CIP/SIP UNIT
- Parenteral manufacturing SKID
- Smart Tanks/Intelligent automation.

Portable Process Tank

Process Tank

Process Tank

A process skid is a self-contained production environment – “a system in a box,” capable of easy transportation with little effort. Multiple skids, entirely fabricated and integrated at cost-friendly offsite locations, can be shipped to the manufacturing site, where the last bit of civil site upgrades happen. Individual modules can be set up, using repeatable processes to the existing production infrastructure increasing throughput and meeting growing demand. Process skids also lend themselves to a high degree of customisation.

MOBILE SKIDS (Sterile Processing System) (Capacities: 5 to 500 ltr)

- ✓ Our Mobile skid are designed for efficient mixing and blending operations and can be moved around from one area to another.
- ✓ They are compact design skid suitable to easy mounted Bottom mounted magnetic mixers with options for low /medium/ high shear application

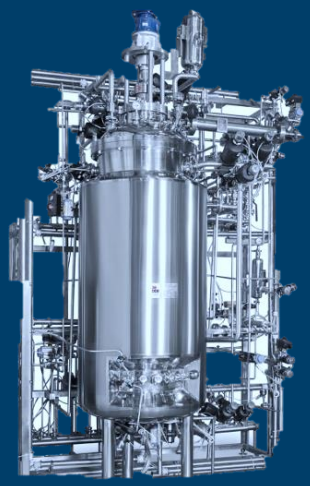
- ✓ Flush bottom outlet valve with sampling/sterilization configurations
- ✓ Contact parts : SS 316L, Mirror polished & EP to <0.5 Micron finish &Orbital Tube welding
- ✓ Load cell for weight measurement /level sensors for level measurement.
- ✓ Online pH, Temperature , conductivity , DO Sensing through sanitary part on the vessel shell.
- ✓ If Required Automation as per MCA & USFDA 21 CFR Part 11
- ✓ Built and design to custom requirement
- ✓ 100% Drain ability
- ✓ GMP documentation like DQ, FAT, IQ, OQ & PQ Protocols
- ✓ Site Installation & Commissioning
- ✓ Documented Output of cleaning & sterilization cycles

INTEGRATED SKID (CAPACITY 100 TO 15000 Ltr)

- ✓ Integrated skid is a fully integrated end to end solution seamlessly integrating to aseptic process handling application.
- ✓ It is handling medium to high capacities.
- ✓ The system designs with customized application and it is 100 % cleanability

- ✓ Bottom mounted magnetic mixers with options for low /medium/ high shear application
- ✓ Flush bottom outlet valve with sampling/sterilization configurations.
- ✓ Contact parts : SS 316L, Mirror polished & EP to <0.5 Micron finish &Orbital Tube welding
- ✓ Load cell for weight measurement /level sensors for level measurement.
- ✓ Online pH, Temperature, conductivity, DO Sensing through sanitary part on the vessel shell.

- ✓ 21 CFR part 11 compliant, fully automated PLC Controlled touch screen IPC/HMI.
- ✓ Block valves for dead leg compliance to avoid product stagnancy
- ✓ Built and design as per customer requirement
- ✓ 100% Drianability
- ✓ GMP documentation like DQ, FAT, IQ, OQ & PQ Protocols
- ✓ Site Installation & Commissioning
- ✓ Documented Output of cleaning & sterilization cycles.



ASPTIC PROCESSING & FILLING VESSELS

Documentation and Validation

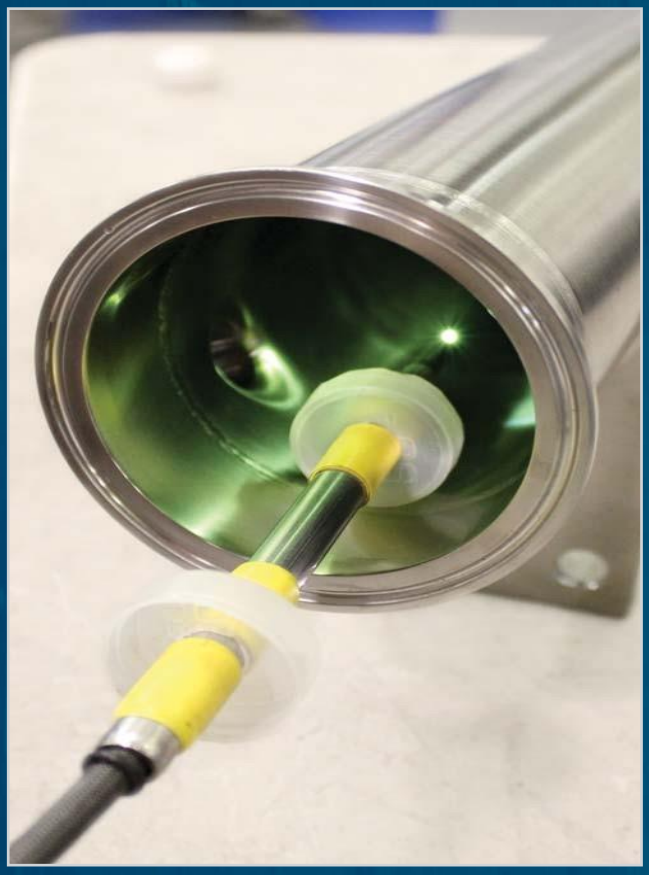
Documentation:

The documentation for your system begins before the first drawing is generated or the first welding arc is struck. Material traceability is established with the purchase and receipt inspection of materials and is systematically maintained throughout the manufacturing and assembly processes.

Process Traceability:

Many different processes take place during the fabrication of Pharm equipment. Several methods are used to document that the equipment has been designed, fabricated, assembled, and tested appropriately. These include:

- ✓ Borescope inspection and video capabilities.
- ✓ Software design specification (as required).
- ✓ Factory testing procedures.
- ✓ Master inspection traveller.
- ✓ Inspection records.
- ✓ Weld records.



Submittals:

After receipt of your order, GXP Solution will send you drawings for final approval. These documents define the mechanical scope of supply and allow procurement and fabrication of the key components to proceed so the schedule is minimized while ensuring that the proper equipment will be supplied. Subsequent submittals are provided for software and functional testing details as required. We encourage you to comment and provide feedback on these documents to ensure compliance with your project requirements.

IQ/OQ Capabilities:

GXP Solution offers installation qualification (IQ) and operational qualification (OQ) documents to support our products. Execution of these protocols can be performed by GXP Solution's service technicians at the time of start- up and commissioning.

Factory Acceptance Testing

GXP Solution factory acceptance testing starts prior to your arrival on site with your review and approval of the test documents. We also pre-test the equipment prior to your arrival. Any project specific requirements outlined in the functional specification and design specification documents will be checked and tested as needed.

Validation:

As a leader in process preparation systems for the finished pharmaceutical, bulk, API, biotechnology, medical device, and medical diagnostic industries, we have extensive industry experience preparing comprehensive documentation and validation packages.

As the pharmaceutical industry has evolved, so has our approach to validation. We are qualified to provide documentation and validation compliance due to our extensive experience within the industry, our attention to regulatory changes, and our capability to adapt to each of our customers' specific needs. The optional completed installation qualification (IQ) and operational qualification (OQ) documentation and validation packages provide documented evidence that our systems are built and commissioned in accordance with user requirements specifications (URS), functional requirements specifications (FRS) and detail design specifications (DDS), as well as FDA and cGMP standards.

GXP Solution Company maintains a staff of professionals with considerable experience within the pharmaceutical industries and broad educational backgrounds in quality, engineering, chemistry, and technical services. Since our validation and quality systems are integrated within the company structure, there are substantial benefits realized from shared databases as well as our detailed understanding of the equipment.

Industry Experience:

GXP Solution has successfully provided documentation and validation assistance for large and small pharmaceutical and biotech projects including:

- **Production Tanks with SKID, holding tanks including controls and related process equipment.**
- **Process equipment for numerous buffer hold and preparation facilities consisting of as many as 40 vessels, the associated controls, electrical equipment, structure, utility & process piping.**
- **Vessels used in pharmaceutical and biotech service.**

HOW WE MAKE THE CRITICAL DIFFERENCE

critical and complex changes, risks and compliance.

Industry experience

Our industry groups are staffed with seasoned practitioners who possess many years of hands-on management and operational experience in life science industries.

Comprehensive services

Our practices, as standalone offerings and ascomprehensive solutions, address the manyinterconnected issues our clients face.

Definitive expertise

Our professionals are experts, with extensive, practical experience in applying that expertise togenerate a

Regulatory Compliance

Our regulatory compliance experts are well experienced with USFDA, EUGMP, MHRA, WHO or GAMP audit for entire life science industries

A culture that delivers

Our culture and working style reflect a bias for the tangible and a tenacity for solutions that makea meaningful difference.

A CULTURE THAT DELIVERS

Our working style and approach reflect our commitment to make a meaningful difference.

- ❖ PRACTICAL
- ❖ COLLOBRATIVE
- ❖ LOGICAL
- ❖ REASONABLE
- ❖ PRACTICAL

- ❖ DATA INTEGRITY
- ❖ CSV
- ❖ CQV
- ❖ GMP
- ❖ GEP

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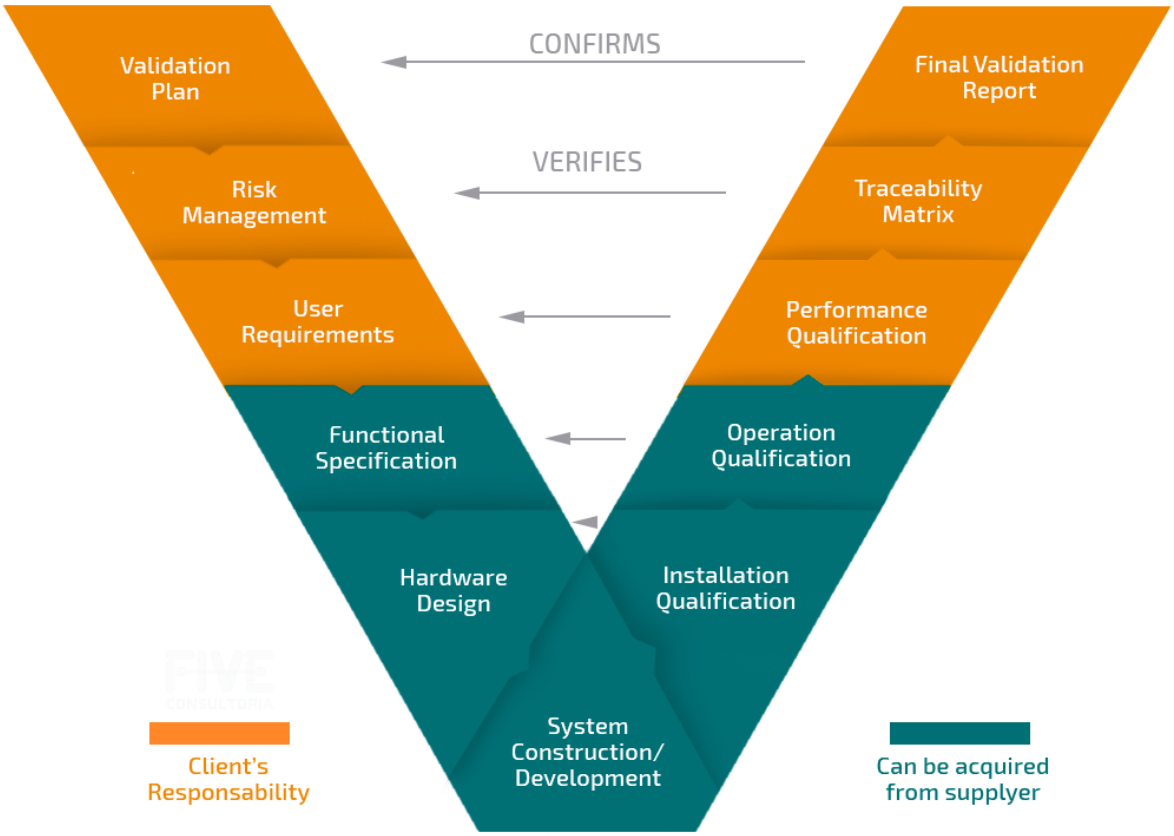

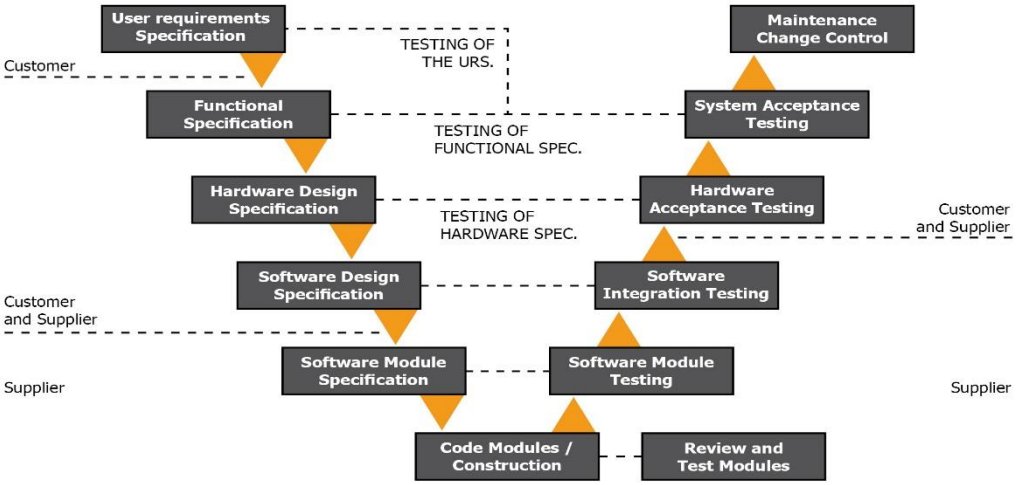

GAMP 5

COMPREHENSIVE COMPLIANCE AND GMP SERVICES

CONVERTING EVERY CHALLENGE OF RISK, COMPLIANCE AND REGULATORY IN TO

OPPORTUNITY

FOCUS AREAS

Sterile Facility

Biotech facility

GXP
SOLUTIONS

API

OSD Facility

R&D/F&D

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Computer System Validation:

We have dedicated teams for following CSV segment:

- Manufacturing Equipments with PLC+HMI+SCADA
- QC Instruments & Software
- IT infra like Networks,Servers,Clients,PCs,Network Softwares
- Cloud Validation
- Robotics system Validation
- BMS,EMS and QMS Validation
- SAP Software Validation
- ERP Software Validation
- Laboratory Equipment Software validation like HPLC, GC, LCMS-MS, UV, PH meter, FTIR and more
- Analytical Software Validation like SAS, WinNonlin, Chromeleon and more
- Pharma Serialization/Aggregation Validation software, TraceLINK, Track and Trace system, Warehouse management software and Labelling system validation.
- LIMS, Lab View & EMPOWER software validation.
- Excel sheet/Spreadsheet Development and Validation.

All CSV activities should be documented with the following:

- System inventory and assessment
- User requirement specifications
- Functional requirement specifications
- Validation Plan (VP) –
- Validation Risk assessments
- Validation Traceability Matrix
- Network & Infrastructure Qualification
- Installation Qualification
- Operational Qualification
- Performance Qualification
- System Release Documentation –
- Validation Report –

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Commissioning Qualification & Validation:

ISPE Baseline Guidelines® Guide Volume 5: Commissioning & Qualification & ASTM E2500: Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment.

We have dedicated teams for following CQV segment:

- Sterile Plant Equipments like
  - Autoclave
  - Depyrogenation Tunnel
  - Cop & Cip Systems, Sip Systems
  - Manufacturing tank and system
  - Vial Washer
  - Filling line
  - Lyophiliser
  - Capping machine
  - Inspection system
  - All Utilities line like compressed air & Steam
- Water System for WFI, Purified water,Pretreted water etc
- HVAC & Facility
- OSD Plant Equipments like Coater, Shifter, Multimill, Grinder & Packing Equipments
- API Plant Equipments like Reactors, Filtration ,Jet mills,Crystalization etc..

All CQV activities should be documented with the following:

- VMP
- URS
- DS & DR
- FRS
- Commissioning (FAT,SAT)
- Risk Assessments
- Change Management
- PM/Calibration Program
- Qualification IQ/OQ/PQ
- SOP Development/ Training
- GMP release
- Validation Report

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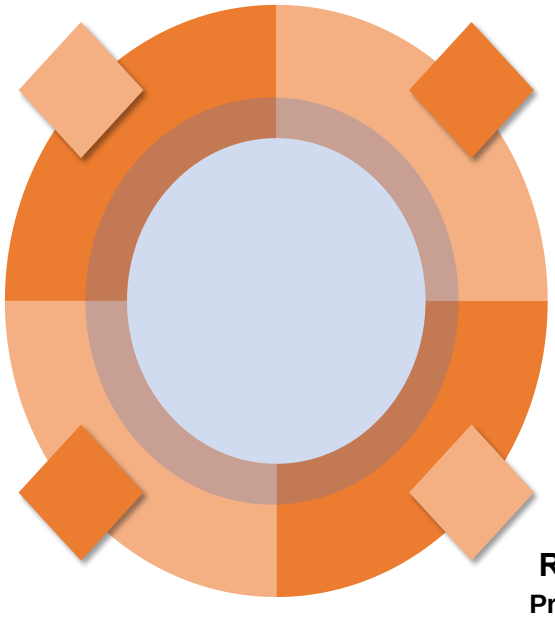
GMP & ENGINEERING

Pharma Plant Set-Up:
For complete setup of pharmaceutical manufacturing unit which includes IV fluids, Injectable, Tablet, Capsule, Liquid orals / externals, Powders, Bulk drugs, Ointment / Cream manufacturing plants.
Handling of Green /Brown Field Projects.

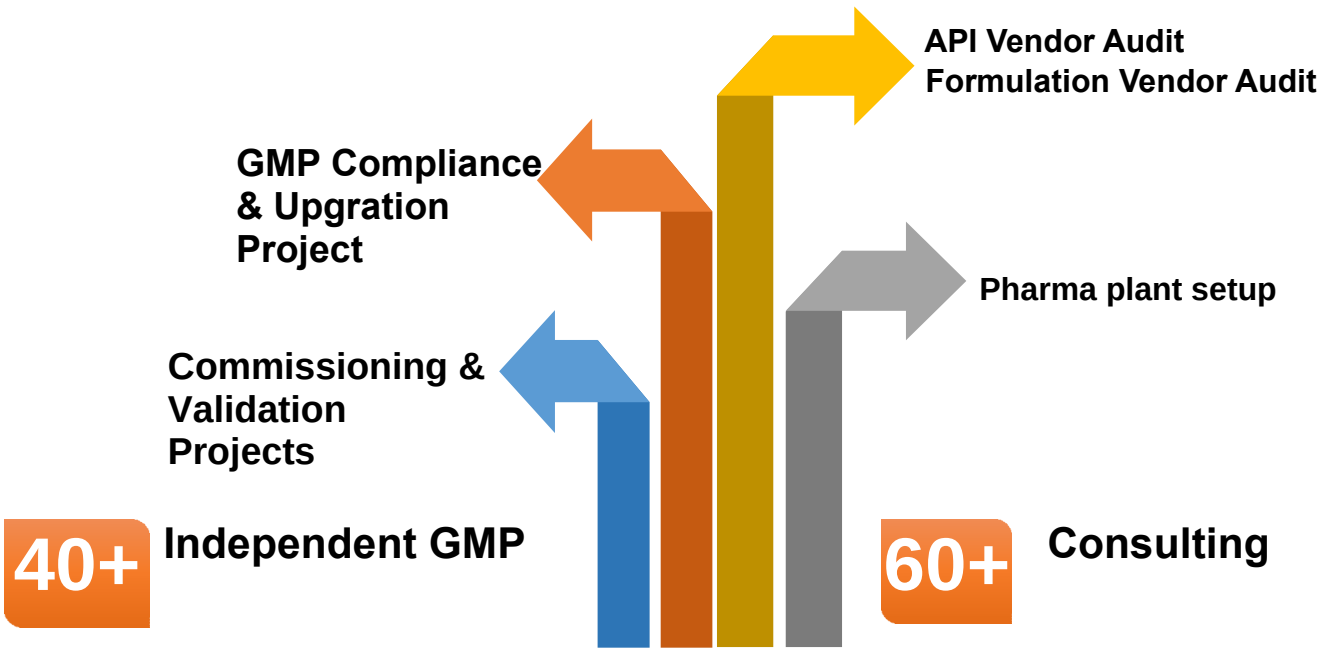
QP SERVICES:
Product Release
QP Audit & Certification
Documentation Evaluation
QMS Review
Risk Management



Sourcing Procurement
of best\quality of Raw Materials, Packing Materials & Finished Goods at competitive price from established manufacturers /trading houses across the globe

Regulatory Services:
Provide CTD/eCTD Dossier compilation & submission
Pre and Post submission Testing & Medical writing

GMP EXPERIENCE



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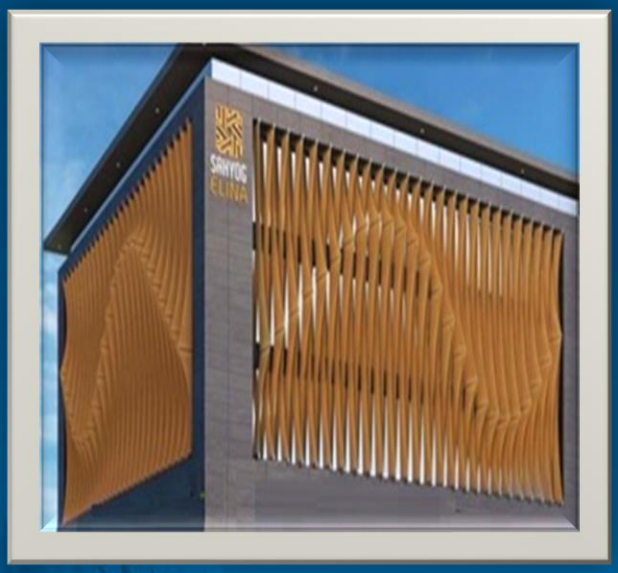

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