Your turnkey
solution partner For
Biopharmaceutical Facility

bio PHARMAX
Dream. Design. Deliver

Biopharmax Group

www.**biopharmax**.com

Our Mission

Design, Build and Validate "Tailor-Made" Biopharmaceutical Manufacturing Facilities

About Us

Biopharmax is a Global Design and Construction provider of manufacturing facilities and systems for Pharmaceutical- API, Formulations, Biotechnology, Biologicals, Nutraceuticals and Medical Devices.

Biopharmax is a true one-stop-shop with over 200 expert engineers, and all the disciplines under one roof: architecture, process, facility, mechanical, piping, electrical, instrumentation and automation, HVAC, utilities, and validation, all with the same goal to accomplish a successful project.

OUR IN-HOUSE CAPABILITIES

Process & Utilities	Electrical Engineering	Laboratories
Mechanical Engineering	Clean Rooms	Validation
Instrumentation & Automation	HVAC	Procurement & Contracting

What **Biopharmax Brings to the table -**

Biopharmax provides Turnkey based solutions, allowing a full range of services required to design and execute your new manufacturing facility, resulting in a time efficient, cost effective, tailor-made, highly optimized projects.

Our Experience

Biopharmax Group has a rich experience of nearly 40 years in the design and construction of Pharmaceutical/Biotech Manufacturing Facilities.

Our Reach

Over time Biopharmax has completed projects in Northern and Central America, Western and Central Europe, China, India, other Asian countries.

Our Expertise

Production process include Small molecule synthesis (API), Bacterial/Mammalian/ Plant cell up stream/downstream, Plasma Fractionation, Stem Cell therapeutics, mAbs, Gene Therapy, Vaccines, Nutraceuticals and more.

We Deliver

Conceptual Design, Basic Design, Detailed Design, Construction and Execution, Turnkey Projects, Project Management Consultancy and Validation.

We Care

Biopharmax has strong track record for constructing facilities that have been approved by USFDA and / or EMEA, Canadian FDA, WHO, China FDA, etc.

Achievements

CLEAN UTILITIES - PW, WFI, PURE STEAM

Specialized department with extensive experience in the design, installation and commissioning of purified water (PW) and water for injection (WFI) system (USP), Biopharmax can provide complete state-of-the-art computerized systems for controlling and batch recording of the whole operation.

CIP/SIP

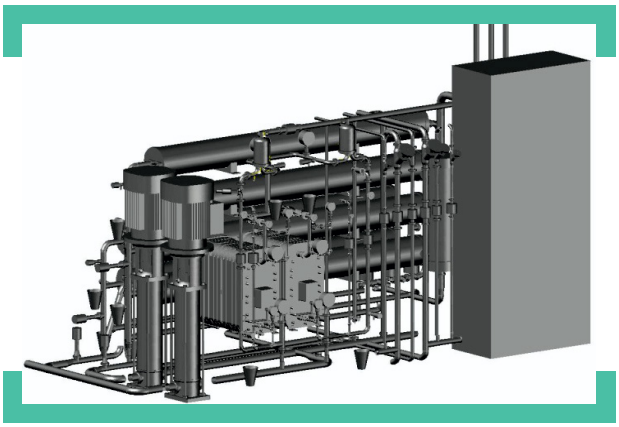
We design, develop, supply and install Mobile and Fixed CIP & SIP Units for sanitization and sterilization. The units are custom made, modular, skidded in automated or semi-automated Models as per the required time cycle for cleaning and sterilization as a part of cGMP requirements from portable to large fixed Multi-Tank system.

FEATURES:

- Sanitary Design to meet all cGMP criteria.
- Contact parts : SS 316 L, Mirror polished & EP to < 0.5 Micron finish
- Orbital Tube welding
- Automation as per MCA & USFDA 21 CFR Part 11
- Built to custom requirement
- 100% Drainability

SKID DESIGNING / FABRICATION

- 3D modelling of complete skids in Plant 3D application including – Structural, Mechanical, Piping and E&I.
- E&I engineering including junction box, component datasheets.
- Extraction of 2D General Arrangement drawing for Piping, Structural and Electrical.
- Piping Isometric Extraction.
- Piping and Structural Analysis to optimize supporting arrangement and main structural frame member's size.
- Orbital welding, Borescope, & Passivation of piping.
- FAT includes mechanical tests, automation testing, and document verification.



LABORATORIES

- Quality control laboratories
- R&D laboratories
- Microbiology laboratories
- R&D facilities
- Small-scale production facilities for personalized medicine
- Multipurpose laboratories support multiple products



CONTAINMENT

- Find the right balance between GMP versus containment.
- Complete containment risk assessment.
- Reduce cleanroom cost through use of new production technologies (e.g. continuous manufacturing and automated dispensing).
- Plan and design high containment facilities.
- Achieve modular GMP and containment facility solutions for R&D, pilot scale to large scale production.
- Design airlocks/ mist shower which support containment safety procedures.
- In-depth knowledge of cGMP and containment.
- Relevant technology expertise within closed process and barrier/isolation technologies.

CLEAN ROOM

Our team of cleanroom consultants will advise in evaluation and recommendations for short range, medium term and long-term design objectives and improvements.

- Clean Room Design, Evaluations, Upgrades and Expansions
- HVAC Design and Upgrades of Your Existing Cleanroom
- Close-Tolerance Temperature & Humidity Control
- Negative Air Pressure Clean Laboratories
- Portable/Mobile Cleanrooms and Containment Clean Laboratories

SINGLE USE BIOPROCESS FACILITY

Single-use systems (SUS) refers to biopharmaceutical manufacturing (bioprocessing) equipment designed to be used once (or for a single manufacturing campaign) and then discarded.
Designing a facility and operations for fully disposable systems requires different considerations compared to traditional stainless-steel systems. Based on a modular engineering approach, we can quickly assess the costadvantages that single-use technology can bring you.

Benefits of single-use technology

- Reduced cleaning requirements
- Decreased plant footprint and capital investment
- Improved batch turn-around times
- Reduced risk of product cross-contamination
- Faster change over Products
- Faster facility set-up
- Modular Approach/Plug and Play

SOFTWARE & AUTOMATION

Achieve a high-quality production floor performance with our 25+ years of experience and expertise in Industrial Automation.

- Indepth OT & Instrumentation knowledge is our strength.
- We deliver complete, turn-key solutions from operation, instrumentation to design, validation, and post commission support.
- **We provide-**
  - Hardware and software design documents
  - FDS (functional Design Structure), URS
  - Software programming according to S88
  - Third Party Communication
  - Batch Management
  - Recipe Management
  - Audit Trail Reports
  - Data Integrity
  - Data Analysis
  - Simulation
  - Compliance with 21 CFR Part 11
  - IOT
- Biopharmax assures-Lower Production Cycle Times and Improved Manufacturing Efficiency

COMMISSIONING, QUALIFICATION, VALIDATION (CQV)

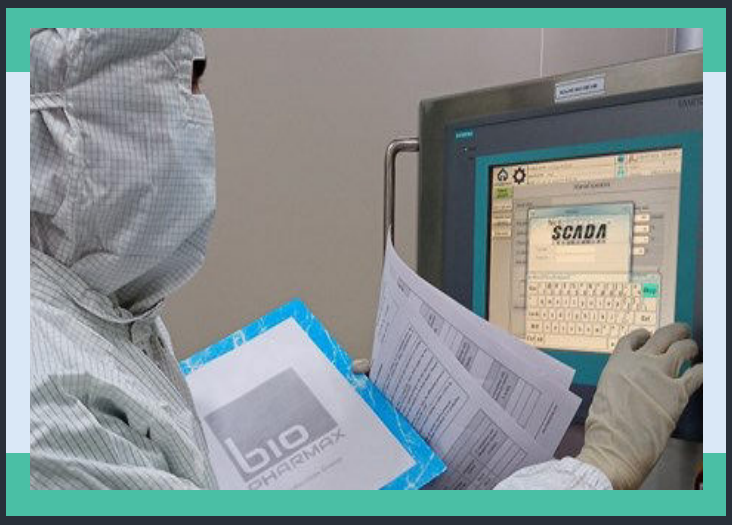
Our experience, expertise, and commitment provides quality services to meet your CQV and compliance needs. We have adopted the risk based approach to qualification, which is scientific and focused on process and product understanding and targeted on achieving suitability for intended use.

Commissioning & Qualification & Validation

- Validation / C&Q Master Plans
- Defining Systems & boundaries
- URS/ DQ/ IQ/ OQ/ PQ
- System Classification (SC) / Impact Assessment (IA)
- Risk Assessment (RA)
- FAT/ SAT
- Start-up & Commissioning
- Requirement Traceability Matrix (RTM)
- Validation Summary Report (VSR)

CSV

- CSV Master Plans
- Initial Risk Assessment (IRA)
- Gap analysis and remediation
- Validation Test Plan (VTP)
- URS/ FS/ HDS/ SDS/ IQ/ OQ
- Configuration Specification (CS)
- Functional Risk Assessment (FRA)
- Requirement Traceability Matrix (RTM)
- CSV Summary Report (VSR)



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