



Design & Construction

BIO
PHARMAX

Biopharmax is committed to maintaining the highest engineering standards to achieve cGMP as required by the various authorities (FDA, EMA, local), to execute the project precisely so that schedule and quality are met without compromising on performance.



Tailor Made Turnkey Solutions
Biotechnology & Pharmaceutical Facilities
40 Years over 100 projects

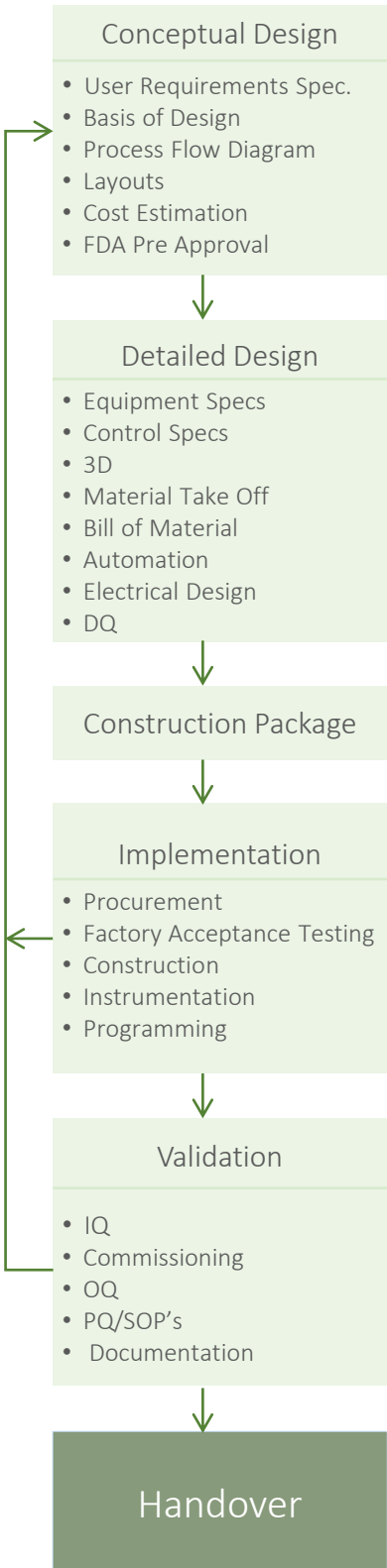
About Us

Biopharmax is a global design and construction provider of manufacturing facilities and systems for Biotechnology, Pharmaceutical and synthesis API manufacturers.

For over 40 years Biopharmax has catered to industry leaders around the world and has gained unique capabilities in process engineering and technology transfer related projects.

Biopharmax undertakes projects from the URS/pre-concept stage through the implementation stage all the way to successful validation. Biopharmax process design expertise combined with Turnkey execution assures our clients a cutting edge production facility completed on time, within budget and with full compliance to the required regulatory standards.





All In-House Capabilities

- Process*
- Architectural*
- Clean Utilities/ Plant Utilities*
- HVAC & Clean rooms*
- Laboratories*
- Control & Automation*
- Validation*
- Mechanical Engineering*
- Electrical Engineering*
- Procurement & Contracting*

Areas of Execution

- Bio-Technology*
- Pharmaceutical*
- Chemical*
- Nanotechnology*
- Medical Devices*

Applications

- Engineering Scale-up*
- Bacterial Cells (Insulin and other)*
- Gene Therapy*
- Mammalian Cells (mAbs, and other)*
- Viral vector*
- Gene Therapy*
- Stem Cells*
- Plant Cells*
- Cell Culture*
- Blood/Plasma Fractionation*
- Vaccines*
- Sterile/Aseptic Process & Filling*
- Synthesis API processes*
- Medical Devices*



Process Design

Process design is Biopharmax's core specialty, focusing our design to provide efficiency, flexibility and reliability into the process. Delivering innovative, integrated and complete pharmaceutical solutions. Striving for engineering excellence, and process optimization.



Biopharmax specializes in:

- Engineering Scale up
 - Fermentation
 - Synthesis
- Upstream Process
 - Plant
 - Bacterial
 - Mammalian
 - Fed batch & per fusion processes
- Downstream Process
 - Chromatography
 - Sterile/Closed process
 - Nano-filtration
 - Hallow fiber
 - UF skids
- Sterile & Aseptic Filling
 - Injectables

Engineering Scale-up

Scaling up a production process is a very complex engineering challenge. The task is complicated by changes in material behavior such as decrease of separation performance and loss of material during the process. Sizing equipment for optimal performance and maintaining parameters for larger production quantities are not straight forward processes. Careful attention must be given to the material characteristics, process requirements and overall production throughput.

Biopharmax has many years of experience in different scale up projects, and is able to quickly develop a scale-up plan based on the results of laboratory scale production. Biopharmax always offer a practical solution that deals with potential concerns and optimizes the process to ensure a successful scale up with optimized production equipment, high yields while ensuring the correct product parameters.

Process Water – PW & WFI

Biopharmax has a specialized "Water for Biopharm" department with extensive experience in the design, installation and commissioning of purified water (PW) and water for injection (WFI) systems (USP). Biopharmax designs and executes a complete solution of water system that comply with the EU and USP strict standards. With the most advanced water system technology including: non-media pretreatment, chemical free dechlorination, Hot Water Sanitization, Reverse Osmosis and Continuous Electro Deionization with the highest level of automatic control.

BIOPUREMAX

Green Technology - Biopuremax Water System

Biopuremax™ is the ultimate pure water system solution, it is an environmentally friendly, clean, simple, reliable and effective way of supplying chemical free – hardness reduced water for use as RO feed water without the need of any additional treatment.

The Electrolytical Scale Reduction (ESR™) solution replaces both ion exchange softeners and antiscalant chemicals. An electric current generates a high pH near the cathode which deposits scale in the reaction chamber and releases CO₂.

Municipal feed water is commonly treated with a sanitization agent Chlorine that damages delicate RO membranes or CEDI resin. This oxidizer is removed by the high powered ultraviolet lamp – the HOD™ unit.

The HOD™ unit is an powerful UV unit that uses no added substance. It has no moving parts, no regeneration requirement and its SS 316 smooth clean pipe construction has no media that may trap incoming contamination. All contact materials are SS 316L or quartz sleeves.

The system has no moving parts, no regeneration requirement and no media that may incubate bio-growth.

Control & Automation

Automation is a key factor for achieving a high-efficiency production floor performance. Biopharmax has an experienced team of software and control engineers with vast experience in the Biotech and Pharmaceutical Industries. The programming process is done according to SDLC (Software Development Life Cycle) starting from design stage, including:

- Hardware and software design documents
- FDS (functional Design Structure)
- Software programming according to S88
- Simulation
- Commissioning
- Validation (CSV and process validation)
- Comply with CFR Part 11
- Data Integrity

Biopharmax is experienced with creating fully automated systems such as: Process, CIP/SIP, HVAC, PW/WFI, RO, Ultra filtration systems and BMS. We strive for high level of automation to ensure:

- Batch to batch repeatability and minimize rejected batches
- Improve process control resulting in increased product yield
- Reducing the human factor to improve facility safety
- Multi product manufacturing / formulation / filling by utilizing a recipe program
- Future expansion support for complete plant integration
- Process monitoring in compliance with QA and validation requirements

CIP / SIP

The cleaning-in-place and sterilization-in-place is an essential part of the overall system requirements. The cleaning procedures must be achieved with minimal disruption to the production process and with complete assurance of its effectiveness resulting in clean system that prevents bacterial growth.

Our process engineers provide fully automated cleaning programs adapted for the equipment and suited for the specific product.

To achieve full and optimal network connectivity between the CIP system and the production floor, the skid control unit is based on a unique industrial PC using a sophisticated screen display, which is linked to the plant's process production Control system for final cleaning.

Biopharmax supplies a compact CIP skid, designed for easy installation and operation with full integration to the plant computer network.

Clean Rooms

Biopharmax specializes in clean room construction with the most advanced filtration and HVAC systems suitable to the function of the production room. All projects comply with the strictest FDA standards, GMP environment and ISO classification. Biopharmax customizes the clean room components and level of cleanliness to the client's specific needs, including a sophisticated control system to regulate and measure pressure, temperate, humidity level etc. The quality of the clean room is what distinguishes Biopharmax from its competitors, including the highest level of wall panels, ceiling, windows and doors with precise finishes to prevent any bacteria accumulation.

Laboratories

Biopharmax has proven designs and has constructed hundreds of laboratories for over 40 years of service. Laboratory types such as: QC, biological, R&D, cytotoxic, analytical, chemical, and more. We make sure to customize the laboratories to the specific needs of the client considering the changing needs of the facility and complementing the project type. Modern design using clean, easy to maintain surfaces, creating the most comfortable environment for the user. We make sure the design fits the needs of the client, for example, furniture that is unaffected by heavy loads of massive equipment and that features high durability and excellent quality. Focusing on the integration of laboratories as part of the manufacturing facility process. This is one of the benefits of Biopharmax Turnkey approach.



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