Biopharm Project Solutions Inc.

Process • Engineering • Compliance

"Committed to providing reliable and expert solutions to Biologics and Pharmaceutical Projects"

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1. About Biopharm Project Solutions

Biopharm Project Solutions (BPS) was incorporated in 1997 to provide the highest level of professional, skilled and customer orientated process and engineering services to pharmaceutical and biopharmaceutical companies.

BPS staff has expertise in the design support, automation, construction, start-up, commissioning and validation of typical pharmaceutical and biopharmaceutical equipment and processes. This includes fermentors, bioreactors, chromatography columns and chromatography skids, filtration skids, tanks, CIP systems and SIP engineering, HVAC, clean steam systems, purified water systems and other clean and non-clean utilities.

BPS has process expertise in operations such as washer/sterilizers, buffer preparation, fermentation, cell culture, harvest, purification, bulk filling and production of GMP lots.

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2. Services

Process Engineering
Specification/Design Reviews, Procurement & start-up (PFDs, P&IDs, FAT, SAT, IQ/OQ/PQ & SOPs)

Automation and Controls
Development of URS/FRS/DDS. FAT protocols and test execution. Start-up, troubleshooting and commissioning. Validation execution support. Water batches and engineering batches. On-going factory floor support for routine production and change control.

Start-Up & Commissioning
Master Commissioning Plan and protocol development and execution. Troubleshooting, punch list development and follow-through.

Validation and Compliance
Master Plans (Validation, QA, System Test and Configuration Management) Computer/Process/Cleaning Validation Execution and cGMP Documentation.

Project Management
The BPS Project Manager acts as the primary interface between the client, contractors and client technical staff during construction, start-up and commissioning and validation.

Staffing
Project Staffing, Project Management & Consulting

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3. Consulting/Design Services

- Targeted design review
- Capital procurement support
- Biologics R&D
- Conceptual Design
- Basis of Design Documentation
- Process Flow Diagrams
- Equipment Layout
- P&ID reviews
- Automation and Controls - Project-wide & Skid Based
- DCS & PLC Systems
- FRS, DS, Coding & Testing
- CIP/COP/Parts Washer design and Troubleshooting
- SIP design and Operational Troubleshooting
- Autoclave design and Operational Troubleshooting
- Equipment sizing and selection
- Utilities sizing and selection

4. Key Equipment Packages

BPS has expertise in the following key equipment and system packages:

Key Process Equipment

- Fermentors and bioreactor skids
- Filter skids (TFF, hollow fiber, plate & frame and depth)
- Fixed and portable vessels and containers
- Chromatography skids
- Chromatography columns
- High pressure homogenizers
- Pumps, valves, hoses and fittings
- Mixers, agitators and mixing
- Fill/Finish equipment
- Autoclaves, Parts Washers and Dry Heat Ovens
- Bioprocess containers, connectors and tubing assemblies

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Automation and Controls Platforms

- PLC Based Skids and Systems
- DeltaV ® Based Skids and Systems
- SCADA Systems
- Fisher-ProVox®

Utilities and Utility Systems

CIP
CIP skids (fixed or portable), design reviews (mechanical, automation and piping). Equipment design for CIP, cleaning agent selection, passivation requirements and design for continuing validation.

SIP
SIP design engineering and design reviews (automation and piping integration).

Clean Utilities

- WFI generation and distribution
- USP grade water generation and distribution
- Clean Steam systems
- Clean Gases

Commissioned Systems

- Instrument Air
- RO Water
- Glycol Chillers
- Bio-waste system decontamination and neutralization

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5. Manufacturing Operations Support

BPS can support the following bioprocess operations at various stages of the demonstration process:

- Fermentation and Cell Culture Processes
- Harvest Processes (filtration and centrifugation)
- Homogenization
- Fill/Finish/Filter Sterilization/Terminal Sterilization Operations
- Clinical manufacturing support (SOPs, on-floor support, Process Validation,
- CIP Validation, SIP Validation)
- Process development
- Sterile formulation (equipment and piping integration)
- Batch Records (development, review, approval process, change control

6. Validation and Compliance

BPS staff has validated all types of systems from critical utilities to automated processing equipment.

The Validation Master Plan (VMP)

The VMP is a milestone in the validation project life cycle. It is an approved roadmap that is referenced and kept updated during the course of the project. It brings the whole validation project together to get a quality job done. The VMP:

- Provides a single reference document for the project and all responsible parties Clearly states the project validation philosophy, the general expectations and the nature of validation testing
- Defines the roles and responsibilities of key parties with a stake in the project
- Identifies what equipment, processes and automation/controls systems will be validated and what performance and acceptance measure will be used
- Describes how Training, Maintenance, Change Control and Validation will be handled

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Project Alignment

Validation Projects begin with an alignment and planning meeting between the owner, BPS and other parties integral to the project. This meeting establishes the roles and responsibilities of parties and defines the major goals against which project success will be measured.

Validation Project Management

BPS provides an experienced manager for every project. This helps ensure the all aspects of the projects are planned, executed and closed out per the schedule, budget, and quality requirements.

Computer Validation

Computerized hardware/software control systems used in GMP processes must be qualified. This qualification includes utility monitoring systems (eg. BAS) and information systems (eg., LIMS, Electronic Document Management and Data Historians). BPS provides the necessary planning, protocol management and execution to address the varying needs of the computer and automation component of a validation project. The computer validation can be from the relatively simple (eg. single loop controllers, on/off devices and PLCs) to sophisticated facility wide systems (e.g. SCADA, LIMS and BAS). BPS ascribes to the industry accepted System Life Cycle (SLC) methodology for the development, implementation, validation and maintenance of computerized systems. BPS follows SLC methodology to ensure a computerized system can be validated and meets the process/project requirements.

Protocol Preparation (IQ/OQ/PQ)

BPS staff is knowledgeable about all aspects of equipment and computer validation. BPS staff uses the client's documentation system (pre-approved templates or format) or can tailor a particular format to meet the client's requirements. IQ test subsections rely on equipment data forms or the data is extracted from design and engineering documents. OQ protocols are designed to verify proper equipment function based on design ranges and anticipated operational requirements. By its nature, PQ testing is equipment and process specific. BPS staff prepares PQ protocols by inserting pre-approved test subsections into a prepared client format. The specific tests are outlined in the appropriate guideline.

Protocol Execution (IQ/OQ/PQ)

BPS staff skilled in equipment qualification, SIP/CIP process and computer validation assist the client with execution of validation protocols.

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Summary Report

Once execution is complete, BPS staff generates a summary report for review and approval.

Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)

BPS supports the validation approach that aims to combines commissioning with the IQ. This can streamline the qualification process. The SAT component complements the FAT and IQ. BPS works with the client and equipment fabricator to draft suitable tests and acceptance criteria.

Standard Operating Procedures

SOPs are required for all critical operations in the manufacturing process per 21CFR 211, Subpart F-Production and Process Controls § 211. BPS staff prepare and field-test SOPs for facility systems, processing equipment, preventive maintenance and general facility operation (e.g. gowning procedures).

Training and Preventative Maintenance

Once the equipment and utilities are qualified and SOPs are substantially approved, BPS hands-on trains the client personnel in operation, cleaning, sterilization/sanitization and maintenance. Specific equipment training modules can also be developed for complex automated systems (e.g.. bioreactors and filtration skids).

7. Project Management

Every successful start-up and validation project is the result of a well-executed plan. BPS pays particular attention to crafting a plan, dissemination of the plan and then management of the execution. The BPS Project Manager acts as the primary interface between the client, contractors and client technical staff.

Construction

BPS staff is able to provide specific support during construction to initiate review of Turn-Over Packages, development/execution of FAT/SAT and SOP development.

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Start-Up and Commissioning Support

BPS supports the pre-commissioning and commissioning phases by assisting with or leading the planning, development, and implementation of key documentation packages (Construction Turnover, Start-Up and Checkout and Pre-Validation Verification) During start-up and commissioning, BPS provides installation oversight and support for process equipment/utilities start-up, shakedown and trouble shooting. BPS provides seasoned technical assistance
for the start-up effort

8. Clients

Although BPS is a young company, the following are some of projects we have supported recently:

Engineering & Bioprocessing

- **Merck & Co., Inc. – Merck Research Labs (Biologics Pilot Plant)**

  Processing suite construction oversight
  Equipment design and design review (Fermentors/bioreactors, chromatography skids, homogenizers, vessels etc.)
  Process equipment shakedown
  Laboratory equipment shakedown and start-up

- **Merck & Co., Inc. - Merck Vaccine Business**

  Manufacturing process shake-down
  Batch record development and approval
  Engineering and clinical lot manufacturing support
  PLA preparation support SOP updating and document review
  Bulk stability study protocols/project plan development
  Multi-valent bulk vaccine manufacture process/design engineering support
  Buffer projects support – development and validations lots
  Validation equivalency studies for MOC, cleaning and sterilization of sterile process equipment
  Operator training on Batch Records, SOPs and validation sampling routines
  Initiation of automation, materials tracking and change control procedures

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- **Principia Pharmaceutical Corp.**

  Fermentation and Purification PFDs
  Pilot plant production metrics
  Selection of contract bio-manufacturing facility

- **Glaxo SmithKline**

  Pilot plant bioreactor engineering study (CIP/SIP/operability & sterile transfers)

- **SONUS Pharmaceuticals**

  Detailed P&ID reviews for sterile processing equipment, CIP and SIP.

- **Centocor Inc. – Biologics Pilot Plant Projects**

  Process Engineering support
  Utilities and process equipment start-up
  Automation and controls (design reviews, URS/FRS/DDS generation)
  FAT, Start-up/Commissioning and validation troubleshooting of Bioreactors, Wave bioreactors, Portable CIP system, MF/UF systems and process filters, Chromatography skids, Chromatography columns,
  Start-up/Commissioning, troubleshooting and load pattern development support for Parts Washer and Autoclave
  Start-up and Commissioning of USP water system, Clean Steam Generator and distribution system
  New Facilities process engineering support (construction punch list, flex hoses, equipment design changes, PFD reviews, equipment layout proofs, SOPs, Preventative Maintenance planning, Redline of P&IDs & GAs for as-builts)

- **Amgen (Immunex RI Facility)**

  Laboratory autoclave engineering study (suitability for validation)
  Valve and filter housing SIP studies

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- **Amgen (Thousand Oaks)**

  Cleaning validation application to pilot plant facilities

- **Centocor Inc. – Manufacturing & Engineering**

  FAT, SAT, start-up/ commissioning and validation support for Autoclaves and Parts Washers
  Start-up/commissioning of Waste-water Reclamation System (Electrodialysis Reversal), and LFMs
  Development of URS/FRS/DDS for automated process chromatography skids, packing skid, and MF/UF skids
  Design review (P&ID, PFD and GA) for chromatography systems, MF/UF systems and portable vessels
  Process engineering support for new bulk drug product facilities (Review Basis of Design, Equipment Lists, Equipment Layouts, Room Layout etc.)
  Design and specification support for purification process equipment and utilities (depth filters, chromatography columns, process vessels, CIP skid etc.)
  FAT/SAT of process vessels, utility skids, process filters and chromatography columns.
  Commissioning Master Plan development, start and commissioning of process equipment and utilities (clean and non-clean)

- **ENZON Inc. – Manufacturing Facility**

  SOP and PM development for HWFI system

Validation & Compliance

- **Ganes Chemical Corp. – Active Pharmaceutical Ingredient (API) Manufacturer**

  Validation Project Management
  Utilities, CIP, Equipment and Process qualification

- **Merck & Co., Inc. – Merck manufacturing Division**

  Vaccine manufacturing facility start-up, IQ/OQ, CIP/SIP Validation

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- **Amgen (Thousand Oaks)**

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- **Wyeth Ayerst, Inc. – Pearl River**

  Air Handler validation execution (IQ/OQ/PQ)

- **Wyeth Ayerst, Inc. – Rouses Point**

  Nitrogen, Instrument Air, Potable Water, Air Handling Unit, Clean Air, and Clean Steam validation execution (IQ/OQ/PQ)

- **Merck & Co., Inc. – Merck Research Labs (Biologics Pilot Plant Project)**

  Process equipment FAT (review and execution support), IQ/OQ support
  Start-up, shake-down runs, support, SIP/CIP validation support
  CTU IQ/OQ/PQ protocol preparation, execution and final reports
  Autoclave and Dry Heat Oven IO/OQ/PQ protocol preparation, execution and final reports

- **JRH Biosciences Inc.**

  Cleaning validation on fixed tanks, Gabauer Company filling line equipment IQ/OQ. PM development and implementation

- **Abbott Labs Inc.**

  Mixing validation

- **Merck & Co., Inc. – Automation and Information Technology**

  Computer Validation for Locally Controlled Environment (LCE)
  Tunnel, Barrier, Filler and Weigh check systems
  Test protocol development and remediation
  SCADA/PLC Platforms
  SOP development and field-testing

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- **ENZON Inc. – Manufacturing Facility**

  Investigation and troubleshooting of OOS reports
  Due diligence for 3rd party manufactured fermentation products

- **Centocor Inc. – Biologics Pilot Plant Projects**

  Automation validation support and protocol execution