- bio X



BRIAN DUFFY

Principal, Head of Strategic Bioengineering Services

978.360.7466 | bduffy@bioxeng.com

Strategic Bioengineering Services

SPECIALIZED SUPPORT FOR BIOTECH, PHARMA & NOVEL THERAPEUTICS MANUFACTURING SITES AND PROJECTS

Owner's Project Management for Capital Project Design and Execution

Leveraging years of experience on both the owner and AE firm sides to ensure clearly identified project goals and aspirations, team alignment and organization, and successful project execution in all phases:

- » Greenfield/Brownfield
- » Manufacturing Cleanroom Environments
- » Upstream, Downstream, Fill/Finish
- » Novel Therapeutics, MAbs, Vaccines
- » Design/Construction/ Start-up/CQV
- » Process Debugging
- Shutdown Planning

Project Process SME

Process Engineering support for capital project leadership, process optimization efforts, and manufacturing readiness evaluations.

Master Planning BIOTECH & PHARMA SITES

- » Assessing Production Site/Network Potential: Evaluating capabilities in line with therapeutic demands.
- » Defining Current Risks and Challenges
- » 5-Year Plan for Progress:
- Roadmap for facility expansion, technology upgrades, and risk mitigation.
- Strategy for Annual Assessment: Periodic audits and continuous improvement

ENVIRONMENTAL SUSTAINABILITY

- » Identifying Sustainable Goals: Setting objectives in carbon emissions and environmental initiatives.
- » Determining Green Technologies and Systems: Selection of eco-conscious systems and waste reduction techniques.
- Phasing Strategy and ROI: Balancing environmental goals with profitability.
- » Performing Life Cycle Assessment (LCA)
- » LEED & BREEM Support



STRATEGIC BIOENGINEERING SERVICES CONTINUED



Strategic Bioengineering Services Project Execution Process



Survey the client to identify needs:

- » Capture project goals and aspirations
- » Define initial operational requirements and process needs
- » Identify facility state and necessary first steps

2

Populate a User Requirements Brief (URB)

Develop a Project Execution Plan, including:

- Governance
- Scope
- Goals and Objectives
- Milestones & Phase Gates
- Program Organization
- Roles & Responsibilities
- Project Controls
- Communications
 Strategy
- Risk Management
- Project Close-out

4

Develop Request for Proposal for Architecture & Engineering Design, Construction Management (CM), Commissioning/ Qualification/Validation (CQV), and Automation Services

5

Manage the Design, CM, CQV, and Automation firms through on-boarding, execution, and project close-out.