Technical Operations
Overview of Services

FSA provides a comprehensive suite of consulting services in Technical Operations, including product/process development, manufacturing management, project management, and SOP generation. Support functions such as purchasing / sourcing and vendor management are also in our portfolio.

Chemistry, Manufacturing, & Controls (CMC)

CMC (Chemistry, Manufacturing, and Controls) encompasses the activities and regulatory requirements needed to ensure that a biologic or pharmaceutical product is consistently produced with the required quality, safety, and efficacy. FSA's CMC consultants have an average tenure of more than 30 years in the field and were involved in the first wave of approved biologics in the US and development of current generation of biopharmaceuticals.

CMC services include guidance in the following areas:

Chemistry (Drug Substance Development)

- Process Optimization
  - Process Review
  - Technology Assessment
  - Analytics

Manufacturing (Drug Product Development & Production)

- Manufacturing Process Guidance & Oversight: Biologics & Small Molecule
  Establishment of Good Manufacturing Practices (GMP) to ensure batch consistency.
- Facility Design
- Build vs Buy Analysis
- COGS Analysis

Controls (Regulatory & Quality Assurance)

- Development of specifications and quality control measures.
- Stability testing to determine shelf life and storage conditions.
- Compliance with global regulatory guidelines (FDA, EMA, ICH, etc.).
  We collaborate with best-in-class firms in regulatory affairs.

Process Development

FSA can guide **Process development** in biologics, assisting in the design, optimization, and scaling of manufacturing processes, ensuring they are efficient, reproducible, and compliant with regulatory requirements.

Services include

- Selection and optimization of production methods (e.g., cell culture, fermentation, purification).
- Process development and scale-up
  - Upstream process development
  - Downstream process development
  - Formulation development
- Analytical Development
- Scale-Up / Tech Transfer

Support Services

Project Management

Project management in biotech and medical devices involves the planning, execution, and oversight of complex projects related to drug/product development, manufacturing, regulatory approval, through commercialization. By the PMBOK®, these are discreet projects with a beginning and an end. It is the combination of these projects that create a process with a defined objective such as scale-up to 500-liters or 510(k) clearance.

Led by a PMP with over 30 years in biopharma, FSA can cover the range of activity in biologic and small molecule development project management, from setting up effective PM architecture to actively managing development and manufacturing programs.

Project Management services include:

- Project Planning and Strategy
  - Defining project scope, objectives, and deliverables.
  - Developing timelines and milestones aligned with regulatory and business goals.
  - Allocating resources, including personnel, budget, and technology
- Cross-Functional Team Coordination
  - Managing interdisciplinary teams, including R&D, CMC, clinical, and regulatory.
  - Facilitating communication and collaboration among scientists, engineers, QA/QC, and regulatory affairs teams.
  - Ensuring alignment between scientific progress and corporate strategy.
- Regulatory and Compliance Management
  - Navigating regulatory requirements from FDA, EMA, and ICH, and other authorities.
  - Managing documentation, submissions, and interactions with regulatory bodies.
  - Ensuring adherence to Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP).

- Risk Management
  - Risk Analysis. Identifying potential risks in R&D, manufacturing, or clinical trials**.
  - Implementing mitigation strategies to address scientific, operational, or regulatory challenges.
  - Maintaining contingency plans to keep projects on track.
- Budget and Resource Management
  - Monitoring project costs and ensuring financial efficiency.
  - Securing funding and managing relationships with investors or grant agencies.
  - Adjusting resource allocation to optimize productivity and minimize delays.
- Clinical and Commercial Readiness
  - Overseeing preclinical and clinical trial progress.
  - Coordinating manufacturing scale-up for commercial production.
  - Supporting market access strategies.

** FSA is highly skilled in managing clinical development programs; ClinOps PM is a specialized CRO-associated skill for which we would provide recommendations of qualified firms.

Purchasing

FSA can assist with setting up purchasing systems and act as a resource for procurement of materials, equipment, and services for technical operations. We have expertise in budget management and integration of the purchasing systems with the financial systems.

Purchasing services include:

- Supplier Selection and Vendor Management
- Procurement of Raw Materials and Consumables
- Capital Equipment Acquisition
- Regulatory and Compliance
- Cost Management and Budget Control
- Inventory and Supply Chain Optimization

Materials Management / Supply Chain

For small – medium size life sciences companies, this role may be incorporated in the purchasing function. In its full scope, materials management and supply chain encompasses the procurement, storage, distribution, and tracking of raw materials, components, and finished products to support research, development, and commercial production.

FSA assists in building the systems that address the requirements of materials management/supply chain in biologic development and medical devices; supplier evaluation and management, lead-times for critical materials, regulatory, cost, and risk.

Materials Management & Supply Chain includes:

- Procurement & Supplier Management
- Inventory Management & Storage
- Logistics & Distribution
- Regulatory Compliance & Quality Assurance
- Supply Chain Optimization & Risk Management