

PROJECT INITIATION

- Create Internal Project Core Team
- Develop Business Rationale and Justification with benchmarks
 - * Identify/Ratify Business drivers
 - * Project Phases and Milestones
 - * Personnel and Budget

FEASIBILITY STUDY (per AACE Class 5 and Class 4)

- * Declare Assumptions / Risks from prior works
- * Personnel: Create 3-year Hiring Plan, Salary + fringe
- * Block Flow Diagrams
- * Process Flow Diagrams: Limited mass balance work
- * Facility Layouts: Flow Drawings (2D)
- * Operational Areas: Per Programmatic Requirements
- * Facility layout: General HVAC Classification drawings
- * Quality Control: QC Micro, QC Chem, QA Doc
- * Site: Overall Requirements, Limitations, Tenants
- * High Level Schedule (36 month)
- * Materials: Define bill of materials (BOM), Storage, Warehouse, and Shipping
- * Electric Power: Cost per month
- * Redundancy: Power, Water, Steam
- * Equipment List: Major equipment only
- * Estimate per AACE Class 4 or 5

CONCEPTUAL DESIGN

- Collection of information from Feasibility Study with modifications
- PFDs with material balances
- Process Model Scenarios
- Facility Layouts and General Arrangements
- Facility Flow Diagrams / Transitioning & Zoning for Personnel, Product, Waste, Air
- Equipment List
- HVAC Design Criteria
- HVAC Classification Drawings
- Structural Assessment
- Evaluate Options: Modular, Podular, stick-built, or combination
- Generate Preliminary Site Design
- Code Review
- Establish Order of Magnitude Estimate
- Generate Preliminary Schedule
- Project Execution Plan and Risks
- Resource Plan and Schedule
- P&ID Framework / 40% Complete

BASIC DESIGN

- Approved Process and Facility Bases of Design
- PFDs (including material balances)
- 80% P+IDs
- Process Model
- Facility Layouts and General Arrangements
- Facility Flow Diagrams
- Utility Studies
- HVAC Design Criteria
- HVAC Classification Drawings
- Utility Study and Equipment Sizing
- Equipment List
- Utility use points and piping mains
- Automation Strategy
- Project Risk Assessment
- Structural Design
- Long lead construction documents (specs)
- Early equipment procurement
- Site Design - may be needed for new loading docks
- Establish Control Budget (20%)
- Establish Project Schedule
- Finalize Project Execution Plan
- Finalize Resource Plan and Schedule
- Permit Plan / Demo Plan / Constructability Plan
- Develop Scope for Phase DD
- Generate Scope for detailed design/construction

DETAILED DESIGN, PROCUREMENT, CONSTRUCTION

- Drawings and Specs (IFP & IFC)
- Automation Contract (process and BMS)
- Procurement Packages
- Equipment Procurement/reviews/FATs/Delivery/SAT's
- C&Q plans and protocols
- Installation Verification (I.V.)
- Construction Packages
- I.V. Punchlist Generation and Closure
- Establish Mech. Completion dates for each system
- Construction Management
- Safety Management
- Construction Administration and Field Support
- ETOP Review and Punchlist
- As-built drawings

COMMISSIONING / QUALIFICATION

- Development of C&Q plans and protocols
- Plans and Protocols should be completed
- Delivery and SAT Execution
- Validation Protocols Executed / Reports Generated
- New Operator Training
- Transition to GMP (checklist)/ QA Mock Audit
- SOP, Batch Records
- Process Validation Protocol Review
- Master BOM review / SAP
- Plant Economics: COG's and Working Cap
- Engineering Runs

AACE ESTIMATE TABLE: CLASS 1 – CLASS 5

AACE Class	ANSI Classification	Typical Use	Project Definition	Expected Range of Accuracy	
				Low Expected Actual Cost	High Expected Actual Cost
Class 5	Order-of-Magnitude	Strategic Planning; Concept Screening	0% to 2%	-50% to -20%	+30% to +100%
Class 4		Feasibility Study	1% to 15%	-30% to -15%	+20% to +50%
Class 3	Budgetary	Budgeting	10% to 40%	-20% to -10%	+10% to +30%
Class 2	Definitive	Bidding; Project Controls; Change Management	30% to 75%	-15% to -5%	+5% to +20%
Class 1		Bidding; Project Controls; Change Management	65% to 100%	-10% to -3%	+3% to +15%



© 2011-2025
BIOTECH RESOURCES GROUP, LLC

GMP FACILITY PROJECT PHASES

Robert Valdes Consultant/SME

bobv@cgmp.global 202.738.3386 (USA)