

ENGINEERING PHARMACEUTICAL INNOVATION



Accelerating Advanced Infrastructure Delivery

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Accelerating Advanced Infrastructure Delivery

1. Typical Challenges
2. Importance of Team Coordination
3. Early integration of key stake holders / functional experts
4. Developing comprehensive macro / micro programming early
5. Setting realistic budget expectations
6. Setting credible schedule expectations
7. Driving execution

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Typical Challenge

- Need it yesterday
- Yikes, that much – “Cut the cost in half.”
- Maximize regulatory compliance but keep it flexible
- Mid project program changes – AGAIN
- Multiple end users all of whom think they’re Customer #1
- Where does Commissioning stop and Validation start?
- Integration and development of multiple team members
- Facility and Engineering Priorities versus Validation Priorities

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Importance of Team Coordination

1. Requires team oriented, process driven, owner project executive.
2. Team meeting logistics need to be clean, crisp, and to the point.
 - Detailed functional expert discussion should be deferred and facilitated through side bars
3. Appropriate prequalification and selection of critical consultants a **MUST.**
Owners Rep → A/E → CM → Commissioning Agent → Validation Agent
4. Team Process needs to be well defined and consistently visible
 - Meeting minutes
 - Action Items
 - Gate Keeper logs
 - Accountability
 - Critical Dates / Milestones

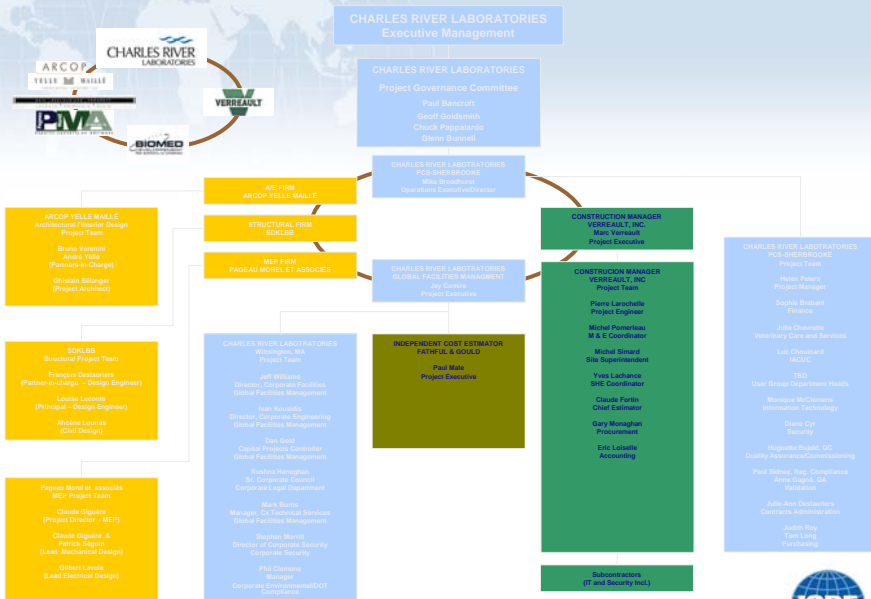
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Early Integration of Key Stake Holders / Functional Experts

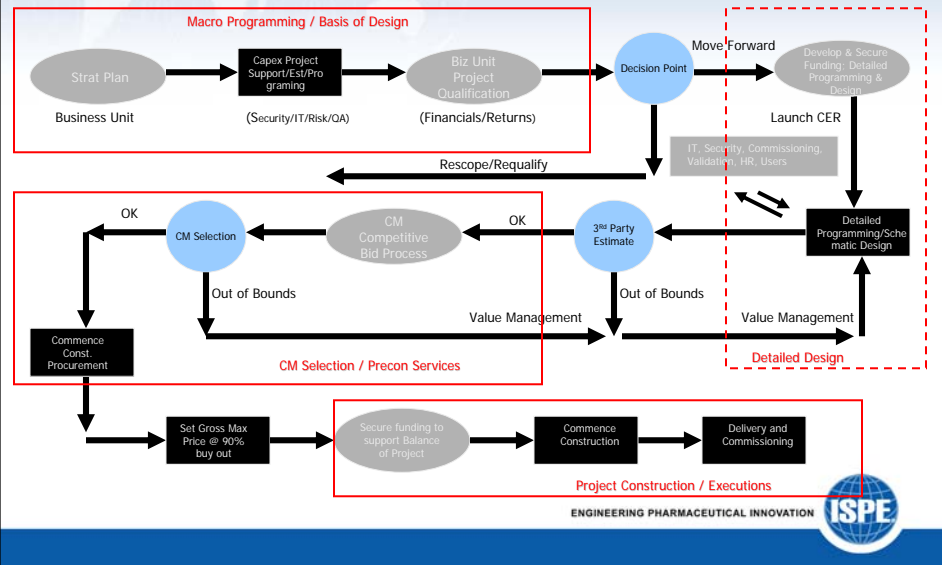
1. Basis of Design (BOD) – Macro Programming
2. Internal Support
 - Requires a team member commitment
 - Quality, Validation, Engineering, OPS, Facilities, IT, Security, R&D, Procurement, Real Estate
3. Full integration of stakeholders and functional experts in Macro Programming will maximize scope capture and provide for an “ALL IN” Basis of Design.
4. The initial BOD will provide the basis for realistic scheduling and budget estimates.

PCS Sherbrooke Organizational Chart – 03.12.2008



Developing Comprehensive Macro/Micro Programming Early

Strategic Planning – Capital Projects *Planning and Implementation w/ CFMS*



Setting Realistic Budget Expectations

- Get approval of Concept/Strategy First
 1. Fund Diligence / Programming only
 2. Develop Conceptual Budget 10,000 ft levels
 3. Budget should be wide range
 4. Return Measurements (ROI, NPV, PayBack) should be wide range as well.
- Post Program / BOD Completion
 1. Develop next level budget
 - * Use 3rd Party estimation at this phase
 2. Revise financial returns based on next level assumptions built around "real program"
 - * Qualify in accordance with Program
 3. Use Program / BOD and substance for RFP – A/E
 4. Request next level funding for A/E only

2 %
PC

Setting Realistic Budget Expectations Cont. Post A/E Completion – 80-100% Design Detail

- Use A/E 80-100% Design Set / BOD and Performance Specification as basis for CM RFP

12 %
PC

- > Include required coordination of
 1. IT
 2. Security
 3. FFE
 4. Define Ownership
 - *"Anything that does not fall out of facility when tipped over should stay in CM contract."*
 5. Core Construction
 6. Green Initiatives
- Fringe Initiative/Out of the Norm Costs:
 - A. LEEDS Certification costs
 - B. Risk based vs. traditional validation of critical systems
- Develop Final Estimate from:
 - A. CM Competitive Bid
 - B. Revised 3rd Estimate
 - C. Detailed Equipment Matrix
 - D. Integrated Budgets for IT, Validation, FFE, etc.
- Final Estimate – Budget now based on "real" program, design and multiple estimates with comprehensive input.
- Re-run Financials / Returns

GO → NO GO

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Setting Credible Schedule Expectations

1. Ensure full integration of all support team schedules in Master Schedule held by CM.
 - Micro Schedules: IT, Security, Equipment, Construction, Commissioning, Validation.
2. CM Schedule should include man loading logic
 - Hours worked to work output.
3. Revise update monthly and use two week look aheads.
4. Constant communication on changes – Use FTP site.

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Driving Execution

1. Mandate strong leadership
 - Interview CM Super/PM's extensively
 - Ensure appropriate experience
 - Consider personalities and chemistry
2. Enforce Accountability
 - Penalize low performance
 - Identify weakness
 - Make changes early
 - Ensure team attendance
3. Define Total Project KPI
 - Schedule adherence
 - Budget adherence
 - Coordination / Integration

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Thank You
Questions?

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