Managing a Project with a CMO

ISPE: April 21, 2009
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BioPharm Services, Inc.

Outline

• The Team
• The Process
• The Devil
• The CEO of the Team
• The Measurable Success
Top Rated Critical Importance Factors

• Data Reports from Surveys
  • Establishing a Good Working Relationship: 52.8%
  • Production Capabilities Relevant to Product: 50%
  • Stick to the Schedule: 47.2%
  • Demonstrated Track Record & with Similar Products: 47.2%

Planning and Team Definition:
Five Deliverables on Which All Subsequent Activities Can Be Based

1. Ensure alignment
2. Bring transparency to risks and benefits
3. Allow fluidity as new information arises
4. Describe only minimum boundary conditions
5. Manage expectations by keeping stakeholder informed
True Team Work- Inside and Out (of the CMO Relationship)

- Getting successful working teams is top on the list
  - Building Mutual Trust in team members
  - Team Fit – Covering all the bases
  - Clear Ground Rules/boundaries- interactions to retain Trust
  - Emotional Intelligence of team members- sum of the parts.  4+4>8
  - Integrity

Getting Started

- The kick-off and the “goal statement”

- Define critical milestones (pointing the way to achieving the goal)

- Milestones: points of intermediate focus

- Project Scope: Size, Budget, Time Line
New Paradigm for Project Management

- **Traditional Project Management**
  - Identifies critical paths
  - Manages deliverables across linear timeline and to budget
  - Controlling function
  - Master of Gantt Charts
  - Author of project minutes
  - Minimizes chaos
  - Manages communications and presentations around milestones

- **Contemporary Project Management**
  - Identifies critical points
  - Collaborates with partners to deliver to non-linear timeline and budget
  - Motivating function
  - Interpreter of Gantt Charts; White Board Cartoonist
  - Keeper of Decision Trees
  - Embraces chaos; removes obstacles
  - CEO

MANAGES EXPECTATIONS especially around decision points

Clinical Supply Chain: Complex Transfers and Handoffs

11 Different Functions
12 Hand-offs
Successful Clinical Supply Chain: What Are the Critical Points?

Planning and team formation

Supply Shipment and Storage

Contracts

Tech Trans

Validation

Document Review and Release

What does “Value-Added” Mean in the Clinical Supply Chain World?

- **Value-Added**:
  - Speeding an innovative new drug through development, production, packaging, and clinical testing in a cost-effective manner; interpretive problem solving; productive and transparent interpersonal relationships and communication with partners.
  
  - How many vendor/contractor’s HOME phone numbers do you have in your rolodex?
Clinical Development Overview (Conservative Scenario)

Year 7
Year 6
Year 1
Year 2
Year 3
Year 4
Year 5
Year 6
Year 7

Q1 2 3 4 Q1 2 3 4 Q1 2 3 4 Q1 2 3 4 Q1 2 3 4 Q1 2 3 4

Bridging:
- Purification process
- Device

Form Eval.
GLP Mat'l
Complete Purification
GMP Mat'l Form/Pkg
BLA Process Dev.
BLA Mat'l Production

IND
Ph I/IIa
Ph Iib
Ph III

Manufacturing Process Profile

- **Goal:** Create a defined and reproducible process that is easily transferred

  **vs.**

- **Reality:** PROCESS? What PROCESS?

  A process in development is a moving target that will undergo multiple changes.
Essential Components of a Manufacturing Process Profile

- Intended point(s) of use (US? Europe?)
- Schematic diagram of all process steps
- Sampling strategy/handling
- Which assays are performed when
- Which steps or operations are critical
- Definition of hold steps
- Definition of release criteria
- Description of stability-indicating assays and criteria
- Consideration of options/alternatives for special needs of project (limiting amounts of recombinant protein product)

Clinical Supplies: Early Attention to Product Stability is Key!

- Types of Stability Information
  - Hold and bulk stage
  - Intended conditions of use
  - Intended f.c. storage conditions
  - Shipment conditions (explore stress conditions!!!!!!!!)
  - Stability of highest and lowest concentrations you could ever imagine using
Profile of Value-Added Teams

- Consider forming team around working/learning preferences (Myers-Briggs/Belbin) rather than solely around subject matter expertise
- Include the contractor!
- Keep it small; 6-7 members
- Establish RACIs, reporting and escalation procedures to make risks transparent

RACI Tool for Leading Value-Added Teams

- A RACI matrix describes the roles and responsibilities of the team members, and can be used to manage expectations.
  - R = Responsible (does the work)
  - A = Accountable (has veto power; decision maker)
  - C = Consulting (input must be sought and considered; concerns must be addressed)
  - I = Informed (must know about activity or decision taken)

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<th>JS</th>
<th>EB</th>
<th>PM</th>
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<th>KS</th>
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<tbody>
<tr>
<td>Audits contractor</td>
<td>A</td>
<td>R</td>
<td>R</td>
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<td>Negotiates contract</td>
<td>C</td>
<td>I</td>
<td>I</td>
<td>A</td>
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<td>Approves contract</td>
<td>I</td>
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<td>R/A</td>
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Reporting/Escalation Tool

- Use traffic light approach for making risks visible and instantly understood
- Status: Week of 8 April 200X
- Project: Widget Clinical Supply
- Last Week  This Week  Next Week
- Comments
  One rack of vials broken during fill; may need second fill to cover clinical needs (TBD 4/10/XX.) Clinical contacted.

Contract Negotiations Can Be Lengthy

- Decision makers balk at costs
- Too many decision makers
- User requirements are fuzzy
- Terms not defined (your supplies will be available by XX)
- Project priority in question
## Technology Transfer Hurdles

- Process? What process?
- Unclear requirements
- Misalignment with clinical strategy

## Cleaning/Equipment/Assay Validation

- Validation takes too long
- Unclear user requirements
- What needs to be validated?
- Sponsor input and approval
Documentation Review and Release

• Paperwork reviewed post-facto
• Discrepancies take longer to investigate and resolve
• Unclear release criteria

Project Management Framework

• **Level 0 - Troubled:** Key project management practices are missing or very weak.

• **Level 1 - Functional:** Project management is instituted functionally, without adequate emphasis on project planning, control, and execution. Functional orientation hinders cross-functional coordination.

• **Level 2 - Integrated:** Project management is cross-functional with well established plans but is not optimized for proactive planning, cycle-time reduction and issue resolution.

• **Level 3 - Fully Capable:** With necessary skills, discipline, and alignment in place, project management is fully optimized for critical path management, execution, and planning.
Self-Assessment Scorecard

<table>
<thead>
<tr>
<th>Project Management &amp; Execution</th>
<th>Sub-Elements</th>
<th>Level 0 Troubled</th>
<th>Level 1 Functional</th>
<th>Level 2 Integrated</th>
<th>Level 3 Fully Capable</th>
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<tbody>
<tr>
<td>Project Definition</td>
<td>Project Scope/Charter</td>
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<td>Segmentation Strategy</td>
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<td>Product Specification</td>
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<td>Project Organization</td>
<td>Cross-Functional Team Structure</td>
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<td>Performance Assessment</td>
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<td>Project Team Meetings</td>
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<td>Roles &amp; Responsibilities</td>
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<td>Team Empowerment</td>
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<td>Team Communication</td>
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<td>Project Planning &amp; Scheduling</td>
<td>Project Scope and Timing Evaluation</td>
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<td>Short-Term Project Planning</td>
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<td>Long-Term Project Planning</td>
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<td>Cycle Time and Resource Planning</td>
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<td>Project Control</td>
<td>Project Scope Control</td>
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<td>Design Change Process</td>
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<td>Project Budget Management</td>
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<td>Product Cost Management</td>
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<tr>
<td>Risk/Critical Issue Management (Validation)</td>
<td>Deliverable Completion Management</td>
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<td>Issue Management (Post Validation)</td>
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<td>Cross-functional Decision Making</td>
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<td>Stage Gate Decision Making Efficiency</td>
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<td>Major Deliverable Peer Review</td>
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<td>Design Completion</td>
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<td>Progress Metrics</td>
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Risk/Critical Issue Management (Validation Stage)

<table>
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<tbody>
<tr>
<td>Risk Identification</td>
<td>• Critical issues are not translated into potential risks</td>
<td>• Critical issues affecting any one function are identified as risks by that function</td>
<td>• Critical issues are cross-functionally identified and translated into risks</td>
<td>• The cross-functional team agrees on the critical issues and translates them into risks using a structured methodology</td>
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<td>• No process exists for identifying risks cross-functionally</td>
<td>• No process exists for identifying risks cross-functionally</td>
<td>• Individual functions may not agree on the impact to the project</td>
<td>• Team members are comfortable identifying risks outside their functional areas</td>
</tr>
<tr>
<td>Risk Assessment</td>
<td>• Risks are not evaluated and prioritised</td>
<td>• Risks are evaluated and prioritised cross-functionally</td>
<td>• Risks are evaluated and prioritised cross-functionally and disseminated to the stakeholders that may be impacted</td>
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<tr>
<td>Risk Containment</td>
<td>• Risk containment is not considered an issue</td>
<td>• Risks are managed functionally with limited input from cross-functional resources that would be impacted</td>
<td>• Critical path alternatives are considered cross-functionally</td>
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<td>• Continuity plans are put into place to minimize the impact on projects but may be difficult to finalize</td>
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<td>Risk Monitoring and Tracking</td>
<td>• Risks are only considered after they adversely impact the project</td>
<td>• Risks affecting functional areas are monitored and tracked individually by functions</td>
<td>• Risk identification, assessment, and containment are done at project level</td>
<td>• Risks that may potentially impact other programs are communicated to the appropriate teams</td>
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<td>• A process is in place to track progress against identified risks</td>
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<td>• Metrics are in place to track risks from identification through evaluation, prioritization, and solution / containment</td>
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Conclusions

1. Makes risks and opportunities transparent
2. Illuminates Critical Decision Points
3. Links strategic and operational/tactical roadmaps in a holistic manner
4. Uncovers Value-Added activities. Provides minimum framework
5. Is an important tool for managing expectations, especially around value-driving decisions

Contact Information

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