



## Managing a Project with a CMO

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Susan Dexter, Principal Consultant  
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%**

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## **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**

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## 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

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## 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

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## New Paradigm for Project Management

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>• <i>Traditional Project Management</i></li> <li>• Identifies critical paths</li> <li>• Manages deliverables across linear timeline and to budget</li> <li>• Controlling function</li> <li>• Master of Gantt Charts</li> <li>• Author of project minutes</li> <li>• Minimizes chaos</li> <li>• Manages communications and presentations around milestones</li> </ul> | <ul style="list-style-type: none"> <li>• <i>Contemporary Project Management</i></li> <li>• Identifies critical points</li> <li>• Collaborates with partners to deliver to non-linear timeline and budget</li> <li>• Motivating function</li> <li>• Interpreter of Gantt Charts; White Board Cartoonist</li> <li>• Keeper of Decision Trees</li> <li>• Embraces chaos; removes obstacles</li> <li>• CEO</li> </ul> |
|---|---|

**MANAGES EXPECTATIONS**  
especially around decision points

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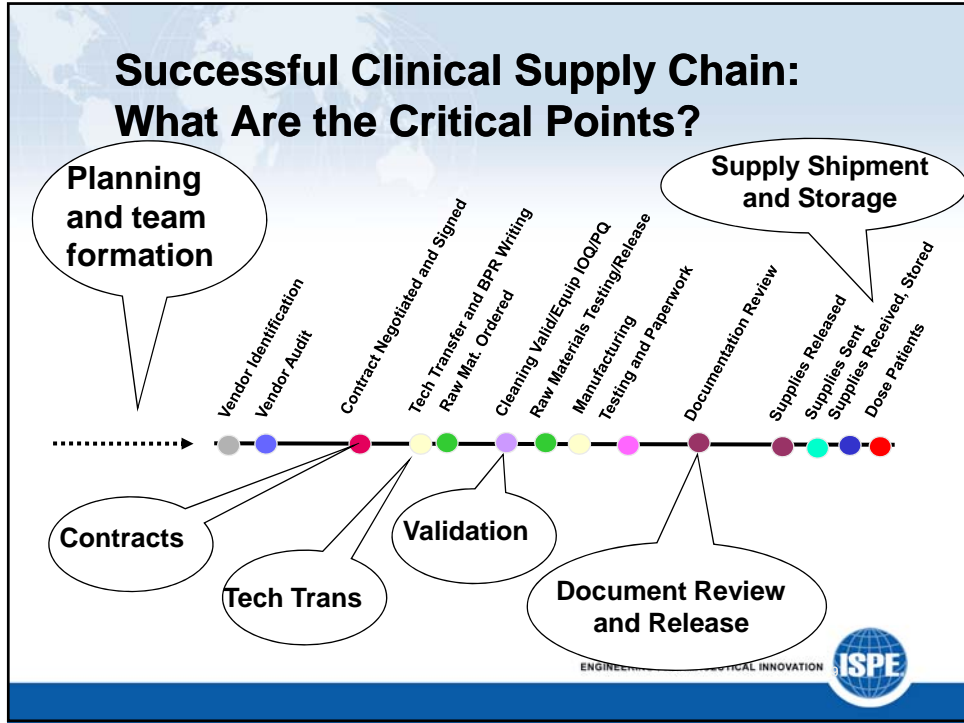
## Clinical Supply Chain: Complex Transfers and Handoffs



**11 Different Functions**  
**12 Hand-offs**

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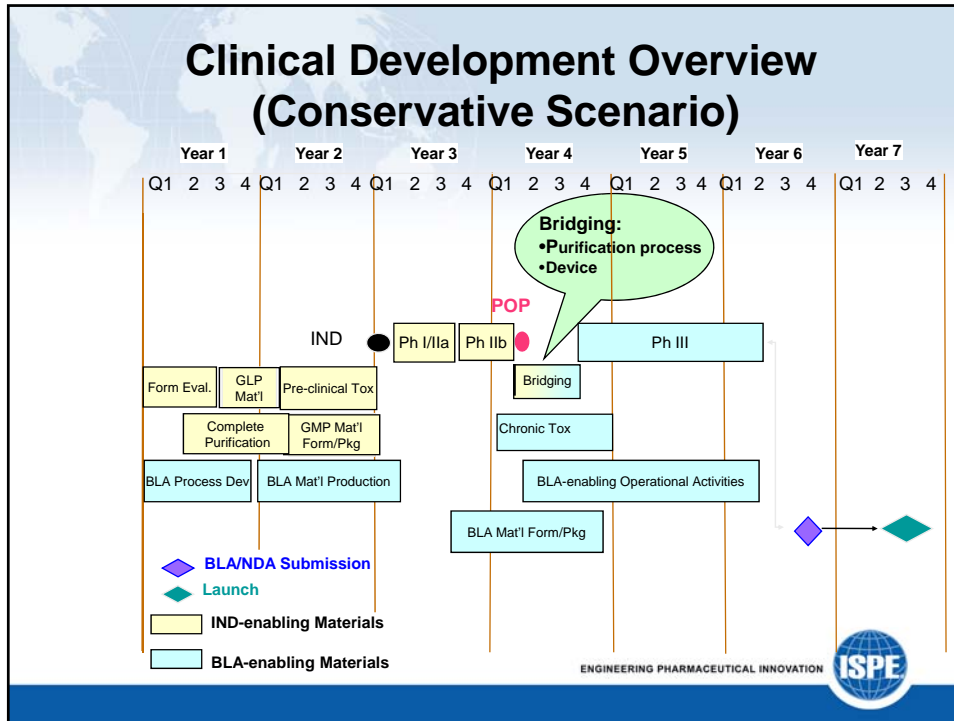




## What does “Value-Added” Mean in the Clinical Supply Chain World?

- 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?**

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## 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.**

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## 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)*

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## 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*

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## 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

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## 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)

JS EB PM CD KS

Audits contractor	A	R	R	I	I
Negotiates contract	C	I	I	A	R
Approves contract	I	I	I	R/A	C





## 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

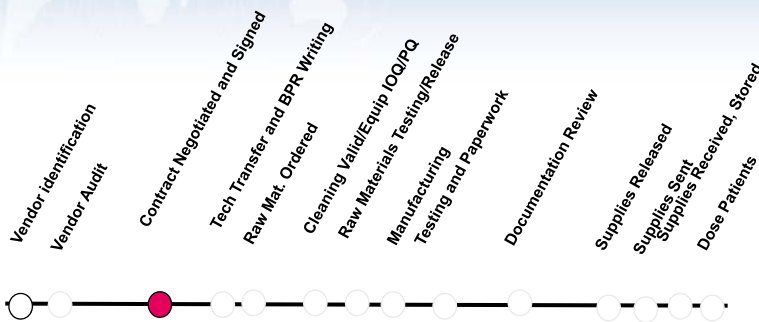


**One rack of vials broken during fill; may need second fill to cover clinical needs (TBD 4/10/XX.) Clinical contacted.**

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## Contract Negotiations Can Be Lengthy

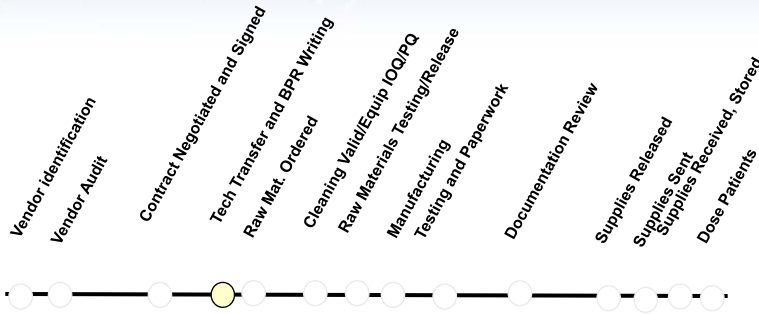


- Decision makers balk at costs
- Too many decision makers
- User requirements are fuzzy
- Terms not defined (your supplies will be available by XX)
- Project priority in question

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# Technology Transfer Hurdles

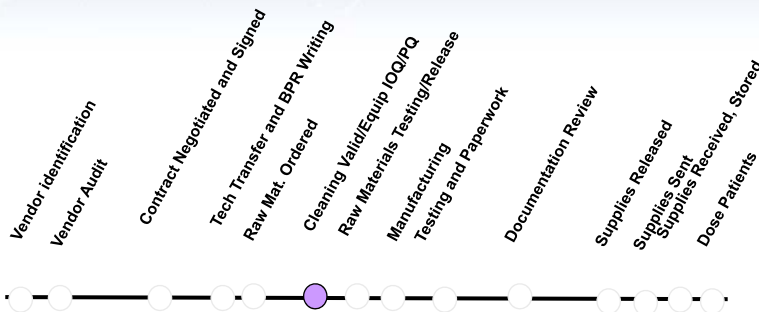


- Process? What process?
- Unclear requirements
- Misalignment with clinical strategy

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# Cleaning/Equipment/Assay Validation

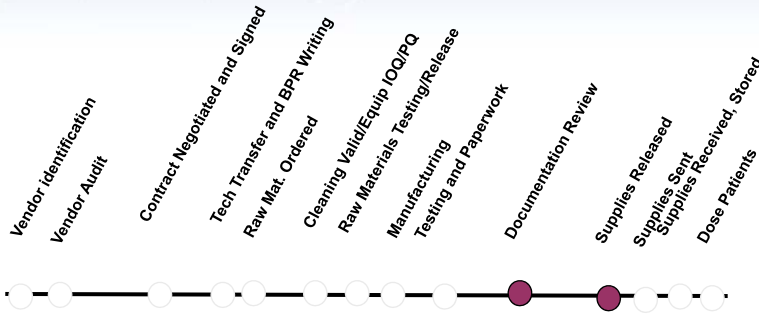


- Validation takes too long
- Unclear user requirements
- What needs to be validated?
- Sponsor input and approval

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## Documentation Review and Release



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

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## 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.

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# Self-Assessment Scorecard

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

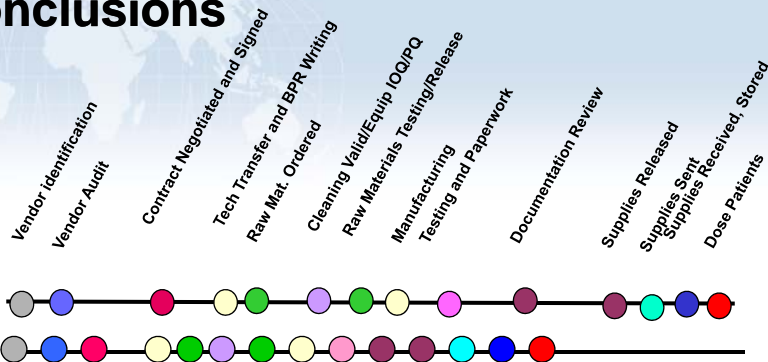


## Risk/Critical Issue Management (Validation Stage)

Elements	Level 0 Troubled	Level 1 Functional	Level 2 Integrated	Level 3 Fully Capable
<b>Risk Identification</b>	<ul style="list-style-type: none"> <li>Critical issues are not translated into potential risks</li> </ul>	<ul style="list-style-type: none"> <li>Critical issues affecting any one function are identified as risks by that function</li> <li>No process exists for identifying risks cross-functionally</li> </ul>	<ul style="list-style-type: none"> <li>Critical issues are cross-functionally identified and translated into risks</li> <li>Individual functions may not agree on the impact to the project</li> </ul>	<ul style="list-style-type: none"> <li>The cross-functional team agrees on the critical issues and translates them into risks using a structured methodology</li> <li>Team members are comfortable identifying risks outside their functional areas</li> </ul>
<b>Risk Assessment</b>	<ul style="list-style-type: none"> <li>Risks are not evaluated and prioritized</li> </ul>	<ul style="list-style-type: none"> <li>Risks are evaluated and prioritized functionally</li> </ul>	<ul style="list-style-type: none"> <li>Risks are evaluated and prioritized cross-functionally</li> <li>The impacts of each risk are understood cross-functionally and disseminated to the functional leaders that may be impacted</li> </ul>	<ul style="list-style-type: none"> <li>Risks are evaluated and prioritized cross-functionally</li> <li>Risks are categorized and given probabilities</li> <li>Risk impact on the organization is understood by all involved</li> </ul>
<b>Risk Containment</b>	<ul style="list-style-type: none"> <li>Risk containment is not considered an issue</li> </ul>	<ul style="list-style-type: none"> <li>Risks are managed functionally with limited input from cross-functional resources that would be impacted</li> </ul>	<ul style="list-style-type: none"> <li>Critical path alternatives are considered cross-functionally</li> <li>Contingency plans are put into place to minimize the impact on projects but may be difficult to finalize</li> </ul>	<ul style="list-style-type: none"> <li>Critical path alternatives consider the impact on other projects</li> <li>Containment strategies are implemented for out-of-control risks</li> <li>An interim phase review is called if necessary</li> </ul>
<b>Risk Monitoring and Tracking</b>	<ul style="list-style-type: none"> <li>Risks are only considered after they adversely impact the project</li> </ul>	<ul style="list-style-type: none"> <li>Risks affecting functional areas are monitored and tracked individually by functions</li> </ul>	<ul style="list-style-type: none"> <li>Risk identification, assessment, and containment are done at regular intervals</li> <li>A process is in place to track progress against identified risks</li> </ul>	<ul style="list-style-type: none"> <li>Metrics are in place to track risks from identification through evaluation, prioritization, and solution / containment</li> <li>Risks that may potentially impact other programs are communicated to the appropriate teams / functions</li> </ul>



## Conclusions



### Early Alignment of Strategic and Tactical/Operational Elements:

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

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## Contact Information

- Susan Dexter
- Principal Consultant
- BioPharm Services, Inc.
- [sdexter@biopharmservices.com](mailto:sdexter@biopharmservices.com)
- Direct: 401-398-2177
- Cell: 401-339-6870

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