Rutgers iJOBS: Successful Management of Life Science Projects

November 18, 2020
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Chair, PMINJ Life Sciences LCI
Agenda

• Introductions

• Project Lifecycle Integration – Processes and Knowledge Areas with Life Science Requirements

• Project Charter Case Study Exercise – Breakouts

• Wrap-Up
Project Management Institute (PMI)®
www.pmi.org

• World-wide advocate for PM profession and best practices
• Global Standards = Common framework
• 8 Credentials
  • Credential maintenance via Continuing Education

PMI New Jersey Chapter (PMINJ)
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• 3rd largest chapter in the world
• Serves all NJ, > 5500 members
PMINJ Life Sciences LCI*
Mission Statement

To create a forum for project management (PM) professionals with an interest in the Life Sciences (LS) industry** to:

- **Network, collaborate,** and **share** experiences from managing and/or working on LS project teams
- **Discuss** and **learn** about topics and activities specific to LS projects, such as validated projects, quality assurance issues, and project execution within a highly regulated environment
- **Educate** and **share** knowledge about the LS industry with the larger project management community.
- **Act** as champions in support of required project activities related to compliance with FDA or other healthcare-related regulations
- **Mentor, develop,** and **foster** growth of the next generation of LS project managers
- **Leverage** best practices, tools & techniques from other industries, such as Agile

**Pharmaceutical, medical device, biotechnology, and healthcare/medical organizations**

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*Local Community of Interest*
“Life is one big project. The trick is managing it.”
Dr. Harvey Maylor

## Definitions

<table>
<thead>
<tr>
<th>Project*</th>
<th>Project Management*</th>
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<tbody>
<tr>
<td>• Temporary endeavor undertaken to create a unique product, service or result</td>
<td>• Application of knowledge, skills, tools &amp; techniques to project activities to meet project requirements</td>
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</table>
Why Project Management

Provides structure to deliver an outcome (benefit) meeting objectives & stakeholder expectations
Life Science Projects Create:
Regulated Industries

• Ensure safety & efficacy to benefit people (patient, user)
  • And safety for property / environment

• Quality Management System (QMS), localized Regulations and harmonized Standards & Guidances apply
Project Lifecycle & PM Processes
Grounded in PM Knowledge Areas

10 Knowledge Areas

Initiate → Plan → Execute + Monitor & Control → Close
Knowledge Areas Interactions

Integration - Brings it all together!

<table>
<thead>
<tr>
<th>Integration - Brings it all together!</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
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<tr>
<td>Requirements &amp; work: project &amp; outcome</td>
</tr>
<tr>
<td><strong>Schedule</strong></td>
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<tr>
<td>Time</td>
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<tr>
<td><strong>Cost</strong></td>
</tr>
<tr>
<td>Budget</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
</tr>
<tr>
<td>People, equipment, materials, etc.</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
</tr>
<tr>
<td>KSFs, meeting stakeholder expectations</td>
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<tr>
<td><strong>Risk</strong></td>
</tr>
<tr>
<td>Impacts – negative &amp; positive – to project, and outcome’s safety &amp; risks</td>
</tr>
<tr>
<td><strong>Communications</strong></td>
</tr>
<tr>
<td>Information</td>
</tr>
<tr>
<td><strong>Stakeholders</strong></td>
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<tr>
<td>Engage for decisions &amp; roles</td>
</tr>
<tr>
<td><strong>Procurement</strong></td>
</tr>
<tr>
<td>Purchasing needs, including supplier quality</td>
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</tbody>
</table>

“Triple Constraints”

Scope  
Requirements & work: project & outcome

Schedule  
Time

Cost  
Budget

Resources  
People, equipment, materials, etc.

Quality  
KSFs, meeting stakeholder expectations

Risk  
Impacts – negative & positive – to project, and outcome’s safety & risks

Communications  
Information

Stakeholders  
Engage for decisions & roles

Procurement  
Purchasing needs, including supplier quality

Integration

Integration - Brings it all together!

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KSFs, meeting stakeholder expectations

Risk
Impacts – negative & positive – to project, and outcome’s safety & risks

Communications
Information

Stakeholders
Engage for decisions & roles

Procurement
Purchasing needs, including supplier quality
Integration of project lifecycle, PM processes and knowledge areas is important because:

- A: It provides breadth of project activities to manage and stakeholders to engage
- B: My instructor said so
- C: It provides structure for project progress
- D: A & C
# PM’s Roles throughout Project Lifecycle

<table>
<thead>
<tr>
<th>General</th>
<th>Initiate</th>
<th>Execute (Getting Work Done)</th>
<th>Monitor &amp; Control (Project Performance)</th>
<th>Close</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrates &amp; manages project activities &amp; knowledge areas</td>
<td>Leads team &amp; works with stakeholders to justify project</td>
<td>Manages team and work to meet key objectives and deliverables</td>
<td>Measures performance vs. key objectives</td>
<td>Ensures all deliverables are complete and meet requirements</td>
</tr>
<tr>
<td>Communicates; conducts reviews &amp; reports status</td>
<td><strong>Plan</strong> (Project’s Work)</td>
<td>Track progress &amp; removes obstacles</td>
<td>Monitors risk; works with team to implement mitigations, contingencies</td>
<td>Conducts closing review; ensures stakeholders alignment</td>
</tr>
<tr>
<td>Engages stakeholders</td>
<td>Leads team &amp; works with stakeholders to plan project</td>
<td></td>
<td>Controls work and manages changes</td>
<td></td>
</tr>
<tr>
<td>Work with team to updates plans, inputs and outputs</td>
<td></td>
<td></td>
<td>Ensures outputs meets inputs</td>
<td></td>
</tr>
<tr>
<td>Conducts “lessons learned”</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Initiate**: General - Integrates & manages project activities & knowledge areas; Communicates; conducts reviews & reports status; Engages stakeholders; Work with team to updates plans, inputs and outputs; Conducts “lessons learned”
- **Plan**: Plan (Project’s Work)
- **Execute**: Execute (Getting Work Done)
- **Monitor & Control**: Monitor & Control (Project Performance)
- **Close**: Close
PMI – Key PM Competencies

Life Science Industry Expectations:
PM will also have subject matter expertise and be knowledgeable in applicable Regulations & Standards
Initiating the Project

• Project “Vision”

• Authorizes project, PM, team, objectives
  • Initial plans & justifications

Best Practices

• Kick-off meeting
  o Align on roles before!

• Project Charter (approvals)
Breadth of Planning & Integration for Life Science Projects

- R&D
- Clinical
- Quality
- IP
- Regulatory
- Supply Chain
- Manufacturing
- Technical/Customer Support
- Marketing: Voice of the Customer

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Project Plan:

PM Knowledge Areas - Integrate with Compliance Requirements

Plan Mgt. of:

Scope
- Define, Validate & Approve Scope
- Work Breakdown Structure (WBS)
- Must include regulatory, clinical & quality requirements

Sequence Activities
- Develop Schedule
- Estimate Activity Resources
- Estimate Durations, Resources
- Must include time to execute regulatory & quality scope/work

Resources
- People skills & training must be documented

Scope of Work/SOW

Gantt Chart

Resource Analysis
Project Plan: PM Knowledge Areas - Integrate with Compliance Requirements

- Plan Mgt. of:
  - Stakeholder Analysis (RACI Matrix)
  - Communications
  - Procurement

Stakeholders include: users, patients, regulatory bodies, suppliers, strategic partners, more!

- Cost
- Quality
- Risk
- Stakeholders
- Communications
- Procurement

- Estimate Costs
- Determine Budget
- Identify
- Analyze
- Plan Responses
- Supplier Analysis/Plan

Financial Analysis
Risk Analysis
Must manage product risks per applicable Regulations & Standards
Must include supplier quality requirements including audits
Pharma Drug Development Process

- Discovery & Target Validation
- Preclinical; Initial Mfg.
- IND Application
- Clinical Studies: Phase 1, Phase 2 Phase 3
- Manufacturing / Market Release
- FDA Decision
- NDA Application, PDUFA
- Phase 4 Postmarket Clinicals

Medical Device Development Process

- Concept, Feasibility, Requirements
- Develop, Preclinical, Verify
- Manufacture, Validate (Clinicals)
- Premarket Application, MDUFA
- FDA Decision
- Market Release, Postmarket Surveillance

High level processes for project planning & phases
Ex: Integrating PM Processes with Medical Device Development Process

Charter

Authorization

Concept, Feasibility, Requirements

Phase 0

Develop, Preclinical, Verify

Phase 1

Manufacture, Validate (Clinicals)

Phase 2

Premarket Application, MDUFA

Phase 3

FDA Decision

Market Release, Postmarket Surveillance

Phase 4

Authorization

Ex: Integrating PM Processes with Medical Device Development Process

Updated Project Planning + Execution, Monitoring and Controlling

Initiate → Plan → Execute + Monitor & Control → Close

10 Knowledge Areas


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Managing the Project

Project Sponsor = Leadership Project Champion
Breakout Session

• Groups of 5 or 6 into breakout “rooms”

• Your project: Develop an in vitro diagnostic (IVD) device for screening or diagnosis of a disease, condition of your choice

• Use template provided to draft your project charter

• Return to present & discuss with the entire group
Scope and Changes

• Define in-scope and out-of-scope, key success factors & deliverables
• Requirements must be written well
• Integrated Change Management:
  • Obtain justifications
  • Analyze risks
  • Adhere to change control process, avoid “scope creep”!
Schedule

- Create WBS* with your team to determine tasks and time
- Review, update & report throughout lifecycle

*WBS: Work Breakdown Structure

Define / Sequence
- Determine logical task order
- Coordinate inter-dependencies

Resources & Costs
- People / skill sets, services
- Materials, equipment, tangibles

Duration
- What can go wrong (risks), e.g., unavailable or delayed predecessors

Estimate
- Historical information
- Expertise (internal / external)
- Granularity is key!
# Gantt Chart MS Project

<table>
<thead>
<tr>
<th>Task Name</th>
<th>Duration</th>
<th>Start</th>
<th>Finish</th>
<th>Predecessors</th>
<th>Resource Name</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project 1</strong></td>
<td>50 days</td>
<td>Fri 9/6/19</td>
<td>Thu 11/14/19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop project charter</td>
<td>10 days</td>
<td>Fri 9/6/19</td>
<td>Thu 9/19/19</td>
<td></td>
<td>Claudia</td>
</tr>
<tr>
<td>Develop project plan</td>
<td>40 days</td>
<td>Fri 9/20/19</td>
<td>Thu 11/14/19</td>
<td></td>
<td>Claudia</td>
</tr>
<tr>
<td>Develop risk management plan</td>
<td>30 days</td>
<td>Fri 9/20/19</td>
<td>Thu 10/31/19</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Project 2</strong></td>
<td>51 days</td>
<td>Fri 9/6/19</td>
<td>Fri 11/15/19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Task 1</td>
<td>10 days</td>
<td>Fri 9/6/19</td>
<td>Thu 9/19/19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Task 2</td>
<td>2 days</td>
<td>Fri 9/20/19</td>
<td>Mon 9/23/19</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Task 3</td>
<td>1 day</td>
<td>Fri 11/15/19</td>
<td>Fri 11/15/19</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td><strong>Project 3</strong></td>
<td>65 days</td>
<td>Fri 9/20/19</td>
<td>Thu 12/19/19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Task 4</td>
<td>15 days</td>
<td>Fri 9/20/19</td>
<td>Thu 10/10/19</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Task 5</td>
<td>40 days</td>
<td>Fri 9/20/19</td>
<td>Thu 11/14/19</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Task 6</td>
<td>50 days</td>
<td>Fri 10/11/19</td>
<td>Thu 12/19/19</td>
<td></td>
<td>10</td>
</tr>
</tbody>
</table>
Costs

• Resources: People, Materials, Equipment, other Tangibles, Services
  • Estimate from: previous projects, internal estimates, supplier quotes

• Needs regular reviews, updates, reporting

• Prepare “cases” with risks & rationales
  • Don’t pad!

• Challenge assumptions
Evolves throughout project lifecycle
- Needs buy-in from functional management, Sponsor and Leadership
- What people / skills are needed?
  - When, how long? In-house?
  - What is competing for their time?
- Review, update and report on costs & strategies throughout lifecycle
Procurement

• Part of budget / costs determination
  • Determine needs (including resources) and purchasing approaches
• Ensure scope, deliverables, responsibilities, exit terms are clearly defined and approved
• Understand supplier processes
• Plan for risks & quality per regulatory requirements
• Review, update & report on throughout lifecycle
• Consider strategies throughout project
Project Quality Management: Meeting Requirements and Stakeholder Expectations

Organization Quality Mgt. System & Quality Policy

Stakeholder Expectations, Requirements

How?

- Re-verify & manage stakeholder expectations throughout lifecycle
- Ensure KSFs & metrics are defined and reviewed regularly to assess project performance
- Ensure quality efforts, including lessons learned, have adequate time in the schedule

Project Quality Attributes:

- Systematic approach
- Transparency about issues
- Authenticity in relationship
- Regular & effective communications
- Continuous improvement mindset
(These are also PM attributes!)

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Project Risk Management
Negative and Positive Impacts

Key: Use as an iterative lifecycle process!

- When: Execution
  - Includes: Monitor for new/revised risks – put into the process

- When: Project planning
  - Includes: Escalation pathway & Change control process

- When: Project planning, update in Execution
  - Includes: Risk sources & triggers

- When: Project planning – gain approvals for response plans; Update plans in Execution
  - Includes: Effectiveness verification of executed responses

- When: Project planning, update in Execution
  - Includes: Estimate impact level & likelihood to occur, then prioritize

- When: Execution
  - Includes: Effectiveness verification of executed responses

New or revised risks, information
Balancing the Triple Constraints and Fulfilling Quality

- **Time**
  - Less Time
    - Reduce Scope
    - Add Resources

- **Cost**
  - Bigger Scope
    - Add Time
    - Add Resources (and Cost)
  - Less Budget
    - Reduce Scope
    - Reduce Resources (Add Time)

- **Scope**
  - Think about Risks!
Why do Projects Fail?

• PM lifecycle processes & tools not used, or not used effectively
  • Objectives / knowledge areas management
  • Ex: Lack of change management
• Misalignment of strategic goals
• Lack of common understanding
Stakeholder Identification & Analysis

RACI Matrix

<table>
<thead>
<tr>
<th></th>
<th>High Interest</th>
<th>High Power</th>
<th>Low Power</th>
<th>Low Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep Satisfied</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Manage Closely</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Monitor</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keep informed</td>
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</tbody>
</table>

Adapted from PMBOK Table 13.4
Stakeholders beyond the Organization for Life Science Products
Engaging & Communicating with Stakeholders

• Communications: Who, when, how, frequency, for what purposes, using what tools?

• Ensure they know what is needed from them and when

• Evaluate & plan, including risks

• Build & maintain relationships

• Lifecycle 360 engagement – don’t underestimate effort

• Remember we’re all human!

Communications Matrix Example

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Type</th>
<th>Frequency</th>
<th>Topics</th>
<th>Attendees</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Kick-off</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Team Meetings</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Phase Gate Reviews</td>
<td></td>
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<tr>
<td>Project Close-out</td>
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</table>
Governance & Status Reviews

• Engage your team for preparations!
• Report progress & risks vs. objectives, metrics
• Enlist your manager and/or Project Sponsor for guidance/coaching in difficult situations
• Use visual, easy to understand tools & methods
Pop Quiz!

- Leading a project, managing your team and engaging stakeholders:
  - A: Requires hard & soft skills
  - B: Requires regular communications and different communication methods
  - C: Requires building relationships across all levels of an organization or across organizations
  - D: Can be like herding cats!
  - E: All of the above
Summary

• Project Management is art & science - requires soft & hard skills
  • Build relationships with all levels of stakeholders
  • Regular communication is key
  • Don’t operate in a silo
  • Hold team members accountable & responsible for their work, but also be ready to jump in if needed

• Being a PM can be frustrating at times, but is also incredibly rewarding – enjoy the journey and challenge yourself to grow
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