Rutgers iJOBS: Successful Management of Life Science Projects

October 23, 2019 - PMI-New Jersey Life Sciences LCI: Claudia Campbell-Matland, PMP
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Agenda

• Introductions
• Review case study exercises
• Module 1: Project Integration & Planning - Lifecycle, Processes, Knowledge Areas
  • Exercise 1: Project Charter
• Module 2: Stakeholders – Engagement & Communications
  • Exercise 2: Stakeholder Analysis
• Module 3: Risk Management
  • Exercise 3: Risk Analysis
• Wrap-Up
Case Study Exercises

• Attendees break up into groups of 5 or 6
• Work through the high-level case study exercises and present & discuss
• Each group given 1 of these case studies
  • Develop a next-generation point of care testing device
  • Develop a new medical imaging center
• Work on exercises using templates to:
  • Develop brief list of inputs for project charter
  • Determine stakeholder categorizations
  • Develop brief list of a few key areas needing risk analysis

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Project Management Institute (PMI)®
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- World-wide advocate for PM profession and best practices
- Global Standards = Common framework
- 8 Credentials
  - Credential maintenance via Continuing Education

PMI New Jersey Chapter www.pminj.org

- 2nd largest chapter in the world
- Serves all NJ, > 5500 members
PMINJ Life Sciences LCI (Local Community of Interest)

Mission Statement

To create a forum for 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

* The LS industry is intended to include pharmaceutical, medical device, biotechnology, and healthcare/medical organizations
Module 1
Project Integration & Planning: Lifecycle, Processes, Knowledge Areas
“Life is one big project. The trick is managing it.”

Dr. Harvey Maylor

## Definitions

<table>
<thead>
<tr>
<th>Project*</th>
<th>Project Management*</th>
</tr>
</thead>
<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>
</tr>
</tbody>
</table>
Why Project Management

Provides structure to deliver an outcome meeting objectives & stakeholder expectations
Life Science Projects Create:

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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**

- **Starting the Project**
- **Organizing & Preparing**
- **Carrying out the Work**
- **Ending the Project**

**Initiate → Plan → Execute → Monitor & Control → Close**

Integration – **Scope – Schedule – Cost – Resources – Risk – Quality**
Stakeholders – Communications – Procurement

Adapted from PMBOK 6th Ed. Figure 1.5

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## PM “Knowledge Areas”

### Project Integration

<table>
<thead>
<tr>
<th>Area/Objective</th>
<th>Managing …</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>Required work – project &amp; outcome</td>
</tr>
<tr>
<td><strong>Schedule</strong></td>
<td>Project time</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>Project budget</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
<td>People (and materials, equipment, services)</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>Success factors, metrics – project &amp; outcome</td>
</tr>
<tr>
<td><strong>Risk</strong></td>
<td>Impacts to objectives – project &amp; outcome</td>
</tr>
<tr>
<td><strong>Communications</strong></td>
<td>Project information</td>
</tr>
<tr>
<td><strong>Stakeholders</strong></td>
<td>Engagement for project execution &amp; decisions</td>
</tr>
<tr>
<td><strong>Procurement</strong></td>
<td>Project’s purchasing needs</td>
</tr>
</tbody>
</table>

**Red** = 6 Project Objectives / “Knowledge Areas”  
**Blue** = 3 additional “Knowledge Areas”  
10th Knowledge Area is Integration  
*Note: Full definitions at end of this presentation*
Scope

Triple Constraints

Scope

Time

Cost

Quality

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Project Objectives

- **Scope**
  - Includes outcome scope

- **Risk**
  - Includes outcome’s risk, safety, regulatory as applicable

- **Schedule**

- **Quality**
  - Includes outcome’s & supplier quality

- **Budget**

- **Resources**

- **Stakeholders**

- **Communications**

- **Procurement**

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Initiating the Project

• Authorize project, PM, team, objectives, with project justification

• Best practice: Project “Charter”
  • Authorization document with approvals
### Project Plan

<table>
<thead>
<tr>
<th>Area/Objective</th>
<th>Planning Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>SOW (Scope of Work)</td>
</tr>
<tr>
<td><strong>Schedule</strong></td>
<td>Schedule (e.g., Gantt chart)</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>Financial Analysis</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
<td>Resource Analysis</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>Success Factors, Metrics list</td>
</tr>
<tr>
<td><strong>Risk</strong></td>
<td>Risk Analysis</td>
</tr>
<tr>
<td><strong>Communications</strong></td>
<td>Communications matrix</td>
</tr>
<tr>
<td><strong>Stakeholders</strong></td>
<td>Stakeholder (RACI) Matrix</td>
</tr>
<tr>
<td><strong>Procurement</strong></td>
<td>Supplier Analysis / Plan</td>
</tr>
</tbody>
</table>
Breadth of Planning & Integration for LS Projects

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

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Plan Mgt. of:

- Scope
  - Define Scope
    - Work Breakdown Structure (WBS)
  - Sequence Activities
    - Estimate Durations, Resources
      - Develop Schedule
- Resources
  - Estimate Activity Resources

Requirements
Plan Mgt. of:

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

Project Planning

Estimate Costs

Determine Budget

Identify

Analyze

Plan Responses
Pharma Drug Development Process

Discovery & Target Validation → Preclinical; Initial Mfg. → IND Application → Clinical Studies: Phase 1, Phase 2, Phase 3

Phase 4 Clinical, Postmarket → Manufacturing / Market Release → FDA Decision → NDA Application, PDUFA

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 Device Development Process

Charter

Authorization

Phase 0

Concept, Feasibility, Requirements

Phase 1

Develop, Preclinical, Verify

Phase 2

Manufacture, Validate (Clinicals)

Phase 3

Premarket Application, MDUFA

FDA Decision

Phase 4

Market Release

Initial Plans

Design Control, Risk Management

Updated Plans

Initiate

Plan

Execute

Monitor & Control

Close

Integration – Scope – Schedule – Cost – Resources – Risk – Quality

Stakeholders – Communications – Procurement

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Phase Gates Examples

**Phase 0: Product Concept**
- **Initiate:** Program Plan, Financial Assessment, Opportunity Assessment, IP Assessment
- **Specifications:** Product Concept Document
- **Risk Management:** Risk Management File, Risk Assessments
- **V&V:** Critical Phase 1 Reqs
- **Product:** Functional Prototype

**Phase 1: Feasibility**
- **Initiate:** Program Plan, Financial Assessment, Opportunity Assessment, IP Assessment
- **Initiate:** R&D Plan, Regulatory Plan, Marketing Plan, Manufacturing Plan, Quality Plan, SW Development Plan
- **Verify:** Critical Phase 1 Reqs
- **Specifications:** Product Requirements, Form and Fit Prototype

**Phase 2: Development and Verification**
- **Initiate:** Master V&V Plan, Clinical Strategy Plan, Customer Care Plan, Service Plan, Launch Plan
- **Update:** Program Plan, Financial Assessment, R&D Plan, Regulatory Plan, Marketing Plan, Manufacturing Plan, SW Development Plan, Opportunity Assessment, IP Assessment
- **Update or Initiate:** Product Specifications, Trace Matrix
- **Verify:** Critical Phase 1 Reqs

**Phase 3: Validation**
- **Complete Verification:** Product Requirements, Clinical Studies, Manufacturing Methods
- **Verification:** Product Requirements
- **Complete Validation:** Clinical Studies, Manufacturing Methods
- **Product Requirements:** Manufacturing Methods
- **Routine Production:** Production Equivalent

**Phase 4: Release and Stabilization**
- **Update:** Program Plan, Financial Assessment, R&D Plan, Regulatory Plan, Marketing Plan, SW Development Plan, Opportunity Assessment, Master V&V Plan, Customer Care Plan, Launch Plan
- **Update:** Master V&V Plan, Clinical Strategy Plan, Customer Care Plan, Service Plan, Launch Plan
- **Update or Initiate:** Product Specifications, Trace Matrix
- **Update:** Program Plan, Financial Assessment, R&D Plan, Regulatory Plan, Marketing Plan, Manufacturing Plan, SW Development Plan, Opportunity Assessment, IP Assessment
- **Update:** Program Plan, Financial Assessment, R&D Plan, Regulatory Plan, Marketing Plan, SW Development Plan, Opportunity Assessment, Master V&V Plan, Customer Care Plan, Launch Plan
Developing Plans
Case Study Exercise #1
Inputs for the Project Charter
No one can whistle a symphony. It takes a whole orchestra.”

Dr. H. Luccock
PMI – Key PM Competencies

- Strategic, Business Mgt.
- Technical PM
- Leadership

Adapted from PMBOK 6th Ed. and PMI Talent Triangle®

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PM Duties

• Leads cross-functional team & coordinates project activities
  • Accountable & responsible - with team - for achieving objectives & deliverables
    • Works to balance objectives
  • Conducts reviews with Leadership, Project Sponsor, Client, etc.

• In smaller organizations, may have additional roles
• In life sciences, expected to be SME in additional areas
PM Skills

- Communication
- Relationship building
- Engage, Manage, Influence
- Leadership
- Conflict Management
- Decision-making, Judgement

- Techniques
- Tools
- Templates
- Schedules
- Deliverables
- Budgeting
“Of all the things I’ve done, the most vital is coordinating the talents of those who work for us and pointing them towards a certain goal.” - Walt Disney
### Leadership

Action of motivating a group of people or an organization to act towards a common goal

### Management

Process of dealing with or controlling things or people

<table>
<thead>
<tr>
<th><strong>Leader:</strong></th>
<th><strong>Manager:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vision, Mission-driven</td>
<td>Task, Deliverable-driven</td>
</tr>
<tr>
<td>Focus people on overall purpose</td>
<td>Focus people on tasks/work</td>
</tr>
<tr>
<td>Transformational, takes risks</td>
<td>Controls the work &amp; risks</td>
</tr>
<tr>
<td>Influence</td>
<td>Directs</td>
</tr>
<tr>
<td>Long-term vision</td>
<td>Shorter-term results</td>
</tr>
</tbody>
</table>

### Common Qualities:

Communicates, Motivates, Leads by Example
PM’s Role in Project Execution

• Manages implementation of plans & work to meet objectives
• Ensures everyone knows their tasks & deadlines
• Tracks progress
• Reviews and communicates regularly
• Reports status to stakeholders
PM’s Role in Monitoring & Controlling

• Monitors / measures work being executed vs. objectives / metrics
• Controls work and manages requested changes
• Monitors risk triggers, issues and works with team to implement risk reduction plans / contingencies
• Works with team to verify outputs meets inputs, e.g., vs. requirements, acceptance criteria, metrics
• Conducts “lessons learned” throughout project
Why do Projects Fail?

• Scope:
  • Inaccurate, changing, not documented / approved

• Communications
  • Lacking, ineffective

• Stakeholders
  • Not engaged / managed

• Risk
  • Not planned for, plans not used

• And more!

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Managing Teams and Engaging Stakeholders can feel at times like…

HERDING CATS
Engaging Stakeholders

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

• Opportunities to:
  • Build/cultivate interest in/support for project
  • Build your relationships

• Potential risks and how to reduce

• Project lifecycle engagement strategies
Stakeholder Identification & Analysis

RACI Matrix

<table>
<thead>
<tr>
<th>Power</th>
<th>Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

- Keep Satisfied
- Manage Closely
- Monitor
- Keep informed

Adapted from PMBOK Table 13-4

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## Analyzing Stakeholders - RACI Example

<table>
<thead>
<tr>
<th>Power</th>
<th>Interest</th>
<th>Low</th>
<th>2nd Priority (Keep Satisfied)</th>
<th>1st Priority (Manage Closely)</th>
<th>3rd Priority (Keep Informed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
<td></td>
<td>Keep Satisfied – 2nd Priority Meet Needs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Engage &amp; consult in interest area</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Try to increase support</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Aim to move to “Key Player”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td></td>
<td>Manage Closely – 1st Priority Key Player!</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Decision-making/Governance</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Engage &amp; consult regularly</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Focus most efforts here</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High</td>
<td></td>
<td>Monitor - Lowest Priority</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Inform w/ general communications</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Aim to move to “Keep Informed”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td></td>
<td>Keep Informed – 3rd Priority Show Consideration</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Involve in low-risk/interest areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Inform/consult in interest areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Cultivate support</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table adapted from Stakeholdermap.com
# Stakeholders Engagement Planning Example

```plaintext
<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Goals, Motivations, Interests</th>
<th>Influence</th>
<th>Interest</th>
<th>Priority</th>
<th>Win/Win Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>VP</td>
<td>Successful project delivery, on-time, on-budget</td>
<td>High</td>
<td>High</td>
<td>1st -Key Player</td>
<td>Approve key decisions</td>
</tr>
</tbody>
</table>
```

**RACI Matrix**

Use to Develop Engagement & Communications Plans

Table adapted from Stakeholdermap.com
Governance & Status Reviews

- Governance = Leadership
  - Build relationships
  - Enlist your manager and/or Project Sponsor for guidance/coaching in difficult situations
- Communications:
  - Report with project’s business value in mind
  - Schedule regular reviews
- Progress vs. objectives, metrics
  - Major progress, milestones achieved
  - Risk to plans & recommended risk reduction methods with rationales
- Engage your team for preparations!
Relaying Information

• Use visual, graphical tools
  • Easy to read/comprehend, e.g., dashboards, symbols
• Level of detail appropriate to audience
• Use templates for messaging consistency
Engaging Stakeholders

- Communicate & consult early & often
- Set & manage expectations
- Ensure they know what is needed from them and when
- Evaluate & plan for your stakeholders, including risk
- Make time for 360 relationship building
- Don’t underestimate the effort needed – lifecycle process
- Remember we’re all human!
Case Study Exercise #2
Stakeholder Categorizations
Risk & Quality Management for Life Science Products

• Required as part of making safe & effective products
• Customers, breadth of stakeholders include:
Device or drug will have its own Quality Plans

- Test Plans, Protocols & Reports
How do We React to “Risk”?  

“The first step in the risk management process is to **acknowledge the reality of risk**. Denial is a common tactic that substitutes deliberate ignorance for **thoughtful planning**.” - Charles Tremper
Risk Management: An iterative lifecycle process!

General Risk Management Framework

**Plan**
- Changes in identified risks / New risks identified
- Plan actions
- Gain approvals

**Identify**
- Evaluate, Prioritize: Impact level Likelihood to occur
- Sources Triggers

**Estimate & Analyze**
- Changes in identified risks / New risks identified
- Monitor & control identified risks and any changes.
- Add new risks / information

**Report**
- Escalation pathway & Change control process

**Respond & Verify**
- Monitor & control identified risks and any changes.
- Add new risks / information

- Sources Triggers

- Evaluate, Prioritize: Impact level Likelihood to occur

- Plan actions
- Gain approvals

- Changes in identified risks / New risks identified
- Monitor & control identified risks and any changes.
- Add new risks / information
## Analyzing Risk

<table>
<thead>
<tr>
<th>Risk identified by:</th>
<th>Risk ID</th>
<th>Positive or negative risk?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What might happen?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What could result?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How might that impact the project?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Qualitative Analysis (Must be completed)

<table>
<thead>
<tr>
<th>Risk may impact (check all that apply):</th>
<th>Impact</th>
<th>Probability</th>
<th>Detectability</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schedule?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budget?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Quantitative Analysis (Must complete for highest severity threats & largest opportunities)

<table>
<thead>
<tr>
<th>Financial impact</th>
<th>Schedule impact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Response approach</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
## Ranking Risks:
### Project Risk Chart (Example) - Threats

<table>
<thead>
<tr>
<th>Probability (of occurrence of the harm/threat)</th>
<th>Impact Risk Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negligible</td>
</tr>
<tr>
<td>High</td>
<td>Medium</td>
</tr>
<tr>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

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# Ranking Risks: Project Impact Chart (Example)

<table>
<thead>
<tr>
<th>Scale</th>
<th>Probability</th>
<th>± Impact on Project Objectives</th>
<th>Time</th>
<th>Cost</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>61 - 99%</td>
<td>&gt; 90 days</td>
<td>&gt; $200K</td>
<td>Significant impact on overall functionality</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>31 - 60%</td>
<td>25 - 89 days</td>
<td>$51K - 199K</td>
<td>Some impact on key functional areas</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>6 - 30%</td>
<td>1 - 25 days</td>
<td>$11K - $75K</td>
<td>Minor significant impact on overall functionality/secondary functions</td>
<td></td>
</tr>
<tr>
<td>Negligible</td>
<td>&lt; 5%</td>
<td>No Change</td>
<td>&lt; $10K / no change</td>
<td>No change in functionality</td>
<td></td>
</tr>
</tbody>
</table>

Modified from Fig. D11, Practice Standard for Project Risk Management, www.pminj.org
## Determining Risk Responses

<table>
<thead>
<tr>
<th>Risk Impact</th>
<th>Potential Responses based on Risk Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative (Harm)</td>
<td>Avoid, Reduce, Transfer, Accept</td>
</tr>
<tr>
<td>Positive (Benefit)</td>
<td>Exploit, Enhance, Share, Accept</td>
</tr>
</tbody>
</table>

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Consider Re-framing Risk Management as Problem Solving for Contingency Planning

A: Define problem
B: Brainstorm possible solutions
C: Evaluate solutions pros & cons
D: Develop recommendations & “why”
E: Make contingency plan & implement if / when needed
Handling Risk

• Keep it Simple - use a logical, step-by-step approach
• Schedule specific team risk meetings to maintain focus
• Uncertainty is inherent - manage expectations
• Communicate! Include risk updates in reviews
• Do not treat it like a checkbox exercise
Case Study Exercise #3
Areas Needing Risk Mgt.
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 also incredibly rewarding – enjoy the journey and challenge yourself to grow
Email Us!
LifeSciencesInfo@pminj.org

Visit:
www.pminj.org/nj_lifesci-lci.mr