PM Areas of Focus

• Expert in the regulatory process
• Focus on time to approval
Assigned to Sponsor Portfolio

<table>
<thead>
<tr>
<th>Regulatory Expert</th>
<th>Time to Approval</th>
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<tbody>
<tr>
<td>Central point of contact</td>
<td>Understand sponsor priorities and challenges</td>
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Lead Presubmission Conference to Discuss the Development Plan

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<tbody>
<tr>
<td>Ensure all technical sections are discussed – create shared expectations</td>
<td>Timely scheduling of meeting – discussion and resulting memorandum of conference used to establish project scope and timeline</td>
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## Create Project Timeline, Monitor Progress

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<tr>
<td>Document requirements discussed in the presubmission conference</td>
<td>Establish target approval date (baseline)</td>
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<tr>
<td>Compare projections to established requirements</td>
<td>Forecast upcoming submissions</td>
</tr>
<tr>
<td>Identify changes in project scope and work with project team to confirm any changes in requirements</td>
<td>Monitor progress toward approval - verify project scope and status, identify and resolve issues</td>
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## Coordinate End Game

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<tr>
<td>Confirm submissions are on track to meet requirements</td>
<td>Resolve any issues identified</td>
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Lessons Learned Meetings

Regulatory Expert, Time to Approval
Review specific projects and discuss what worked well and what to do differently in the future
PM Role

**SPONSOR**
- Discovery or Acquisition
- Development
- Regulatory Submission
- Support Marketing

**FDA/CVM**
- Gather Information
- INAD
- NADA

**PM**
- Assigned to sponsor portfolio - Central point of contact for regulatory or process questions
- Pre-submission conference – define scope and requirements
- Create timeline – establish target approval date
- Monitor progress toward approval – verify project scope and status
- Identify and resolve issues
- End game coordination
- Lessons learned
PM Role

MANAGE REGULATORY PROCESSES
MANAGE PROJECT SCOPE
MANAGE PROJECT LIFECYCLE
MANAGE RELATIONSHIPS

For more information, please contact me at aila.albrecht@fda.hhs.gov, or 240-402-0625