ONADE Project Managers

Our Role in the Animal Drug Approval Process

Aila Albrecht, PMP
Leader, Project Management Team
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

PM Areas of Focus

- Expert in the regulatory process
- Focus on time to approval

Assigned to Sponsor Portfolio

Regulatory Expert	Time to Approval
Central point of contact	Understand sponsor priorities and challenges

Lead Presubmission Conference to Discuss the Development Plan

Regulatory Expert	Time to Approval
Ensure all technical sections are discussed – create shared expectations	Timely scheduling of meeting – discussion and resulting memorandum of conference used to establish project scope and timeline

Create Project Timeline, Monitor Progress

Regulatory Expert	Time to Approval
Document requirements discussed in the presubmission conference	Establish target approval date (baseline)
Compare projections to established requirements	Forecast upcoming submissions
Identify changes in project scope and work with project team to confirm any changes in requirements	Monitor progress toward approval - verify project scope and status, identify and resolve issues

Coordinate End Game

Regulatory Expert	Time to Approval
Confirm submissions are on track to meet requirements	Resolve any issues identified

Lessons Learned Meetings

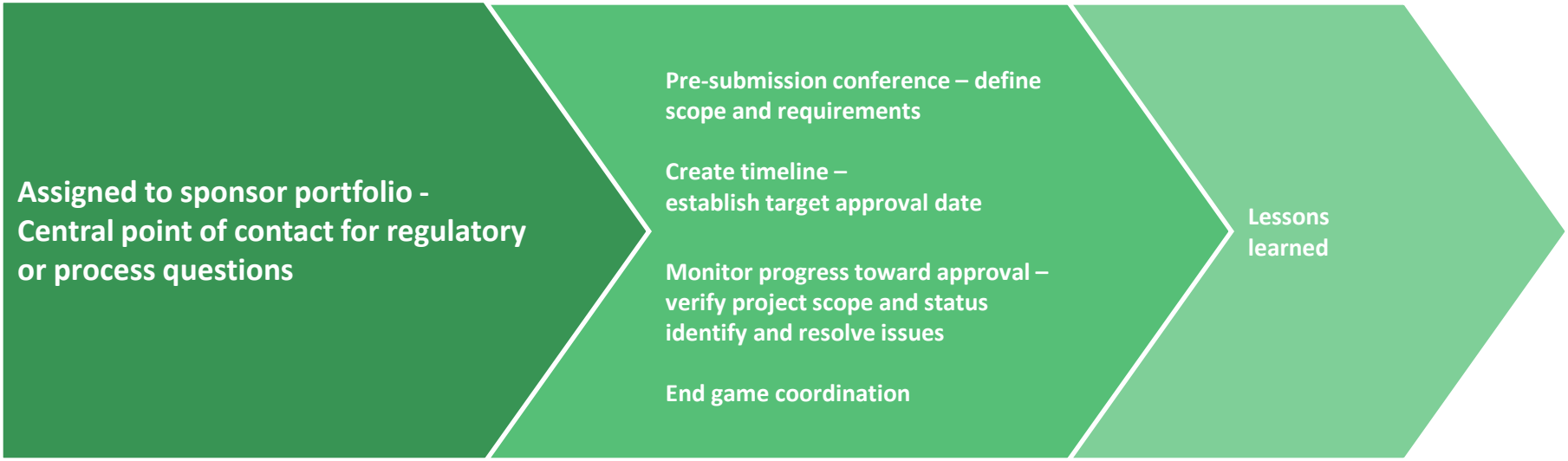
Regulatory Expert, Time to Approval
Review specific projects and discuss what worked well and what to do differently in the future

PM Role

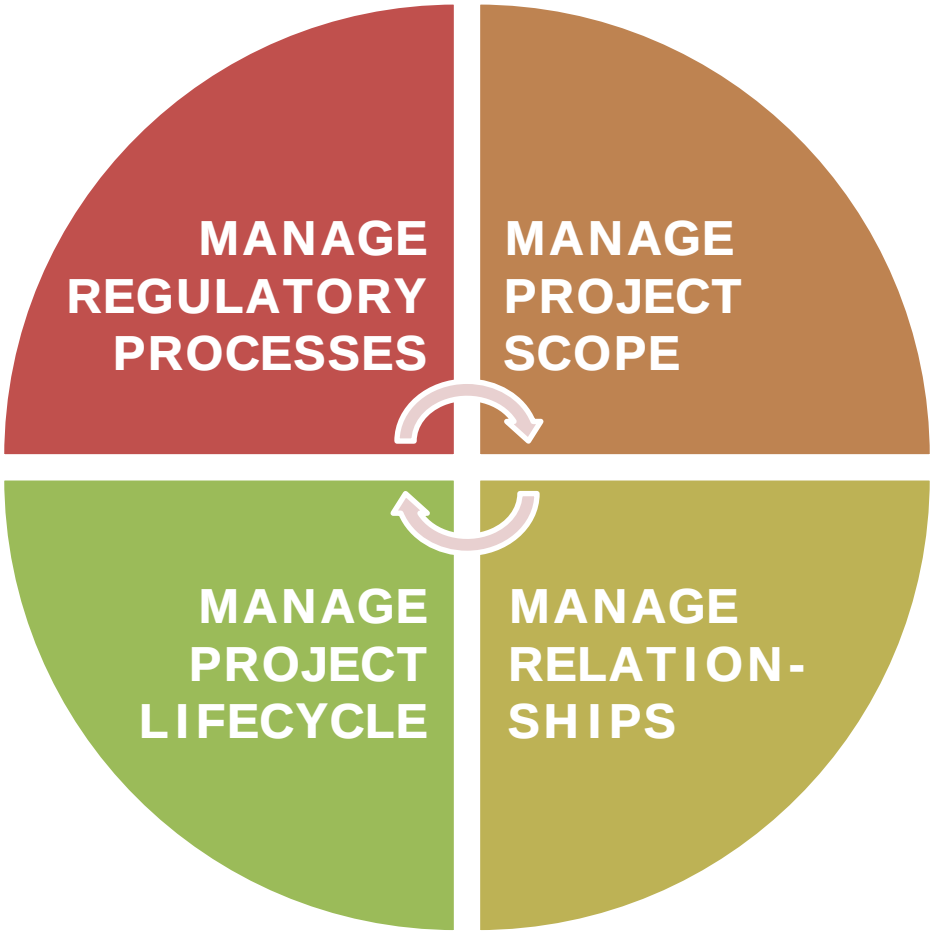
SPONSOR

FDA/CVM

PM



PM Role



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