



ONAPE Project Managers

Our Role in the Animal Drug Approval Process

Project Management Branch
Office of New Animal Product Evaluation
Center for Veterinary Medicine

For more information, please contact us at
AskONAPEPM@fda.hhs.gov



PM Role

- Project managers (PMs) manage the animal drug approval process for the Office of New Animal Product Evaluation (ONAPE) using our expertise in the regulatory process
- PMs establish and maintain relationships between ONAPE and sponsors



Serve as Central Point of Contact

- Each new pioneer sponsor is assigned a PM, who serves as their central point of contact
 - Expert in the regulatory process
 - Understand the sponsor's priorities and challenges
- Most PM interactions don't require formal meetings



Establish Development Plan

- Typically done through a presubmission conference
- Ensure all technical sections are addressed – create shared expectations
- Confirm project scope and technical section requirements
- Determine the optimal regulatory approach

Monitor Progress Toward Approval

- Communicate regularly about planned submissions
- Identify any changes in scope and confirm whether there are resulting changes to requirements
- Facilitate resolution of issues



Coordinate End Game

- Confirm submissions are on track to meet requirements
- Facilitate any final coordination needed before approval



Facilitate Lessons Learned Meetings

- Review specific projects
- Discuss what worked well and what to do differently in the future

PM Role



Sponsor



FDA/CVM



Establish INAD



Approval

PM



PM Role



