Coalition for PET Drug Approval

Current Topics in FDA Applications and Inspections for PET Drug Manufacturers

Organizer:  
Steve Zigler, PhD  

Moderators:  
Sally Schwarz, MS, RPh, BCNP  
Henry VanBrocklin, PhD  

June 9, 2014  
St. Louis, MO
Agenda

12:30 PM - 12:45 PM  Summary of Survey of PET Drug Manufacturers
  Sally Schwarz

12:45 PM - 1:00 PM    Update on the Coalition for PET Drug Approval
  Henry VanBrocklin

1:00 PM - 1:20 PM     Acceptable Commitments for Approval of a PET
  Bob Wolfangel
  NDA or ANDA

1:20 PM - 2:10 PM     Acceptable Practices for Compliance with PET
  Steve Ehrhardt
  GMP Regulations

2:10 PM - 3:00 PM     Primer on Promotional Activities and Reporting
  Michael Nazerias
  Requirements

3:00 PM - 3:30 PM     Panel Discussion and Q&A
Educational Objectives

Upon completion of this session, the participant will be able to:

1. Discuss the educational efforts under way by the PET community and the FDA to standardize inspection requirements.
2. List the key elements for a successful PET drug NDA or ANDA approval.
3. Describe the required procedures to maintain compliance with PET GMP regulations.
4. Outline post-approval obligations of NDA and ANDA holders and implement them in manufacturing practices.