PET Drug Manufacturing

At a Small Entity

Steve Mattmuller, RPh, BCNP
Kettering Medical Center
Small Entity vs. Commercial PET
Every ANDA has a hero...
Inspection Experience

• Chief Executive Officer vs. a Vice President
• Those in the know say;
  “Never give more than what they ask for!”
• Sterility Assurance;
  “If and when is it ever appropriate to reduce monitoring?”
Electronic Submissions: aka our Achilles' Heel
Review Letters from Rockville

- Container closure system: Hospira
- 21 CFR 212 regulations for PET drugs and the guide state only a COA is needed for a component.
- Same container closure system used by Peoria, our reference drug
Within FDAMA of 1977, 21 CFR 212 regulations, PET drug guidance;

“What’s Appropriate for PET Drugs”

- Standardize SOP’s
- COSTS, electronic submission’s burden
- Components, if approved once with NDA and/or a ANDA, it’s good for everyone
- Inspection meetings