SNMMI Hosts FDA Workshop

On February 21, SNMMI and the U.S. Food and Drug Administration (FDA), Medical Imaging Technology Alliance, and World Molecular Imaging Society hosted "PET Drugs: A Workshop on Inspections Management and Regulatory Issues," at the FDA White Oak Conference Center in Silver Spring, MD. The purpose of the workshop was to provide a forum for exchange of information and perspectives on the regulatory and compliance framework for PET drug manufacturing and thereby improve global understanding of PET drug manufacturing. The workshop organizers included Sue Bunning, MA (MITA), Dalton Clark (SNMMI), Steve Mattmuller, MS, RPh (Kettering Medical Center), Sally Schwarz, MS (Washington University), Henry VanBrocklin, PhD (University of California San Francisco), and Steve Zigler, PhD (PETNET Solutions). The workshop was attended by approximately 150 members of the PET community and the FDA.

Among the specific goals and objectives of the 1-day meeting were to: discuss regulatory compliance for development and manufacturing of PET drugs and pathways for drug applications, application maintenance, and inspections based on Code of Federal Regulations Part 212 (Current Good Manufacturing Practice [cGMP] for Positron Emission Tomography Drugs); share perspectives from industry, academia, investigators, and regulators on inspection findings and trends; and provide information on the management of Part 212 inspections and maintenance of PET New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs). The workshop included 4 sessions, each co-moderated by an FDA staff member and a member of the PET community. The speakers included representatives of PET drug manufacturers from academia, industry, as well as the FDA.

The first session looked at considerations and trends in inspections and compliance, including manufacturing process assessment and preapproval inspections, and recent experience with PET surveillance cGMP inspections of PET manufacturers; and current trends and observations on inspections and PET surveillance inspections through the FDA pilot program for tablet-based inspections for PET drugs. A panel discussion and questions followed. The second session focused on lifecycle management of PET drug applications, including management of PET drug applications (NDA or ANDA), and PET community perspectives on PET drug application, with a follow-up discussion and question period. After lunch, the third session looked at chemistry and product quality assurance, including the microbiological regulatory perspective; product quality and sterility assurance; and chemistry and product quality assurance. The final session covered the changing landscape of PET drugs, labeling requirements for NDAs, and requirements for electronic filing of regulatory applications.

At the Workshop on PET Drug Manufacturing: Sue Bunning, MS, Steve Zigler, PhD, Sally Shwarz, MS, Steve Mattmuller, MS, RPh.

Themes stressed throughout the workshop included: the need for uniformity in FDA inspections of PET drug establishments, a consensus on a science-based risk profile for PET drugs, improvements to training for FDA investigators and the regulated community, and the need for continued dialog between the FDA and PET drug stakeholders. The organizers plan to make slides from the workshop available to the public and are also planning a follow-up session at the upcoming SNMMI annual meeting in New Orleans, LA.

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