2023 MEMBERSHIP APPLICATION

MEMBERSHIP BENEFITS

Membership in the Coalition is more than just a subscription. Member organizations play critical roles as the Coalition advances scientific and regulatory principles associated with the manufacturing of PET drugs. Working together through the Coalition, members ensure the reliable supply of safe and effective PET drugs throughout the United States. Below is a summary of membership benefits:

1. Stay Informed
The Coalition is the leading clearinghouse of regulatory information on PET drug manufacturing, including regulatory standards established by FDA, USP, ICH, and other authorities. Through stakeholder meetings, social media, and teleconferences, and a soon-to-be developed online forum, member organizations stay up to date on critical regulatory issues associated with PET drug manufacturing. In addition to the latest developments, the Coalition also maintains a deep history of PET drug regulations. As a Coalition member, your organization has access to stays abreast of regulatory issues pertinent to PET drug manufacturing.

2. Get Involved
The Coalition is nothing without its members. Member organizations actively participate in the identification of issues and priorities. Through surveys, social media, teleconferences, and stakeholder meetings, Coalition members are involved in all aspects of Coalition activities, including strategy development, strategy execution, legislative initiatives, comments on proposed regulations and guidance documents, white paper development, and others. As a Coalition member, your organization will have the opportunity to be an active participant in these activities and more.

3. FDA Workshops
Since its inception, the Coalition has organized several FDA workshops, most recently the FDA workshop on PET inspections and other regulatory topics in February 2020. For more information on this workshop, follow this link. Coalition members were involved in all aspects of the workshop, including the development of the agenda, topics for discussion, and follow-up. The Coalition has begun collaboration with the FDA, SNMMI, MITA, and WMIS to hold an FDA workshop in the Fall of 2023.

4. Symposia
The Coalition has organized numerous symposia to increase awareness of compliance and regulatory issues that threaten the availability of safe, effective, and cost-effective PET drugs. These symposia, which typically take place during meetings of the Society of Nuclear Medicine and Molecular Imaging, often attract audiences with more than 100 attendees. The primary goals of these symposia are to ensure proper recognition of the unique manufacturing and quality characteristics of PET drugs, and to discuss any current regulatory issues facing coalition members.

5. Stakeholder Meetings
Stakeholder meetings provide a forum for Coalition members to collaborate with other stakeholders on key topical issues associated with PET drug manufacturing. Through these meetings, members seek common ground and find practical solutions. These meetings also provide a voice for members to the Coalition leadership on strategic topics and initiatives. An annual meeting will be established for the election of Board Members and Coalition leadership.

6. Publications
The Coalition recently published a peer-reviewed manuscript describing the February 2020 FDA workshop on inspectional and regulatory issues for PET drug manufacturers. The paper provides a summary of the workshop as well as recommendations for future policy and regulatory directions for the FDA. The paper, which appeared in the Journal of Nuclear Medicine, illustrates how Coalition members can be involved in scientific and regulatory issues associated with PET drug manufacturing. Future publications will include technical reports on specific topical issues, press releases, and additional submissions to peer-reviewed journals.

7. Web-based Resources
The Coalition recently upgraded our website (www.petdrugmanufacturers.org) to provide access to a wealth of regulatory and quality material, cross-references to important records from meetings, and links to other resources for PET drug manufacturers. This ensures access to information and a historical record of events as the field evolves. In the very near future, the Coalition plans to expand access to this information through an online forum, social media platforms and other electronic forms of communication.

8. Education
The Coalition has been active in the development of educational materials related to PET drug manufacturing. Recent efforts include the development of content for the SNMMI’s Qualified Systems Personnel Training Program (QSPTP) and the FDA’s internal training program for field investigators. Future educational programs will include training for audits, risk management, best practices, and other compliance needs.

Membership Categories and Application on the following page...
MEMBERSHIP CATEGORIES AND FEES

**Academic Facilities and Small Manufacturers.** Members with one or two cyclotron-based PET drug manufacturing facilities. **$1,500 yearly fee** (July 2023 through June 2024)

**Large Manufacturers and NDA/ANDA holders.** Members with more than two cyclotron-based PET drug manufacturing facilities. Also includes members with an approved NDA/ANDA, but without any cyclotron-based PET drug manufacturing facilities. **$3,000 yearly fee** (July 2023 through June 2024)

**Other.** All other entities with a vested interest in PET drug manufacturing, including trade associations, professional organizations, IND holders, equipment manufacturers, consultants, etc. **$1,000 yearly fee** (calendar year)

MEMBERSHIP APPLICATION

**Company Name**

__________________________________________________________

**Voting Member Name*** ____________________________________________________________________________

**Title** ______________________________________________________________________________________

**Mailing Address**

______________________________________________________________________________________________

**City** __________________________ **State/Province** __________________________ **Postal Code** __________________________

**Country** __________________________ **Telephone** __________________________ **Email** __________________________

**Membership Category (select one):**

☐ Academic Facility or Small Manufacturer

☐ Large Manufacturer and/or NDA/ANDA holder

☐ Other, Please specify: ____________________________________________________________

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**Signature** **Printed Name** **Date**

Please complete and email this form to the Coalition’s Executive Director, Charles Metzger (cmetzger@petdrugmanufacturers.org)

The Coalition Executive Committee will review your application and contact you within 14 days.