PET Drug Manufacturing: Current Topics Related to the FDA and USP

June 13, 2017
15:00 – 16:30

Organizers: Sally Schwarz, MS, RPh, BCNP and Steve Zigler, PhD

Moderator: Steve Zigler, PhD

Sponsor:
Coalition for PET Drugs

Program		
15:00 – 15:05	Introduction and Year in Review	Steve Zigler, PhD
15:05 – 15:30	FDA's eCTD Mandate for 2017: Latest Developments	Phillip DeNoble, PharmD
15:30 – 15:55	Harmonizing FDA Regulation and the Practice of Pharmacy: Challenges and Opportunities	Michael Nazerias, MS
15:55 – 16:30	Latest USP Initiatives: Monographs, General Chapters, and Compounding	James Ponto, MS, RPh

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Conflict of Interest

- Employee of Siemens-PETNET Solutions
- I will not discuss investigational agents, nor will I discuss indications or uses of any approved products

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Background

- Session is a continuation of previous sessions
- Topics based on feedback received from PET drug manufacturing stakeholders, including academia, industry, and the FDA
- We continuously need to reach out and address top issues for all stakeholders
- Contact me with comments and ideas anytime!
  steve.zigler@petnetsolutions.com

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YEAR IN REVIEW

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Number of PET Drugs with an Approved NDA

As of April 28, 2016:

8

As of May 9, 2017:

10

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PET Drug NDAs as of May 9, 2017

- Ammonia N 13
- Choline C 11
- Florbetaben F 18
- Fludeoxyglucose F 18
- Florbetapir F 18
- Flutemetamol F 18
- Sodium fluoride F 18*
- Rubidium chloride Rb 82
- Fluciclovine F 18
- Gallium Dotatate Ga 68

*No currently active approved NDA

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Number of Approved ANDAs for FDG

As of April 28, 2016:

37

As of May 9, 2017:

39

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Number of Approved ANDAs for Sodium Fluoride

As of April 28, 2016:

22

As of May 9, 2017:

23

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Number of Approved ANDAs for Ammonia

As of April 28, 2016:	As of May 9, 2017:
25	25

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Number of Approved ANDAs for Choline C 11

As of April 28, 2016:

3

As of May 9, 2017:

4

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Noteworthy FDA Approvals and Events

- FDA approval of two new molecular entities
  - Fluciclovine F 18 (Axumin®) – May 27, 2017
  - Gallium Dotatate Ga 68 (Netspot®) – Jun 1, 2017
- A new FDA approval for Rb 82 generator
  - Rubidium Chloride Rb 82 (Ruby-Fill®) – Sep 30, 2017
- FDA issued two draft guidance documents on the compounding of sterile radiopharmaceuticals – Jan 2017
- Congressional movement on reauthorization of the FDA Prescription Drug User Act – Apr 2017

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Noteworthy USP News

- Finalized three general chapters related to radiopharmaceuticals
  - <821> *Radioactivity*
  - <1821> *Radioactivity – Theory and Practice*
  - <1823> *PET Drugs – Information*
- Began revision of <823> for consistency with other general chapters
- Formed Expert Panel (EP) to review and update monographs for non-PET drugs
  - Published proposed monograph revisions for Fludeoxyglucose F 18 and Ammonia N 13 ***(deadline to comment: July 31, 2017)***
- Compounding
  - Held stakeholder roundtable on compounding of sterile radiopharmaceuticals – Feb 2017
  - Announced plans to establish a new EP to develop a new general chapter <825> to describe standards for compounding of radiopharmaceuticals ***(deadline to apply: July 9, 2017)***
- See www.usp.org
  - Key Issues tab
  - Pharmacopeial Forum (monograph revisions)
  - Call for Candidates (EP)

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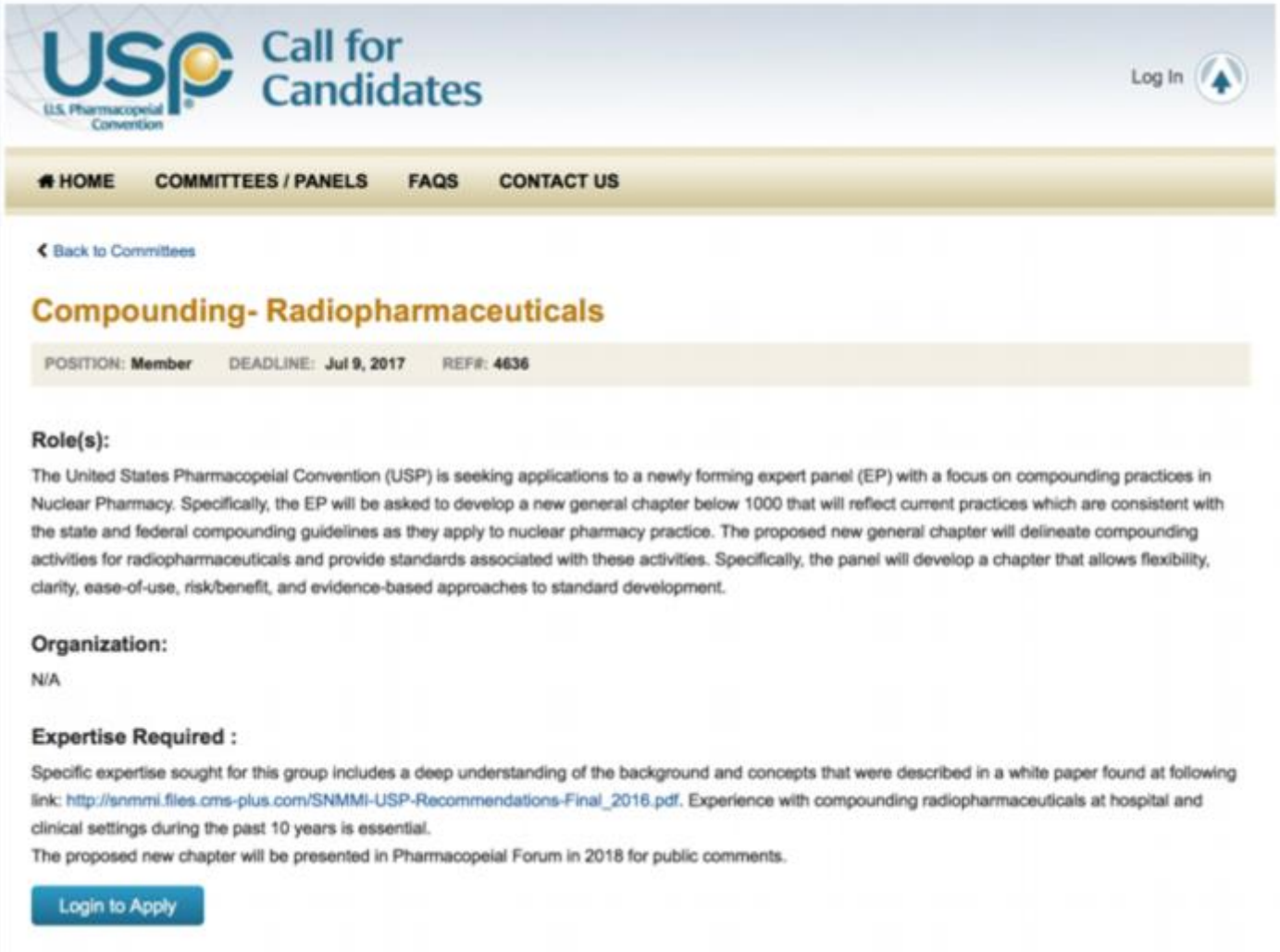
USP Call for Candidates



USP U.S. Pharmacopeial Convention Call for Candidates

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Compounding- Radiopharmaceuticals

POSITION: **Member** DEADLINE: **Jul 9, 2017** REF#: **4636**

Role(s):

The United States Pharmacopeial Convention (USP) is seeking applications to a newly forming expert panel (EP) with a focus on compounding practices in Nuclear Pharmacy. Specifically, the EP will be asked to develop a new general chapter below 1000 that will reflect current practices which are consistent with the state and federal compounding guidelines as they apply to nuclear pharmacy practice. The proposed new general chapter will delineate compounding activities for radiopharmaceuticals and provide standards associated with these activities. Specifically, the panel will develop a chapter that allows flexibility, clarity, ease-of-use, risk/benefit, and evidence-based approaches to standard development.

Organization:

N/A

Expertise Required :

Specific expertise sought for this group includes a deep understanding of the background and concepts that were described in a white paper found at following link: http://snmmi.files.cms-plus.com/SNMMI-USP-Recommendations-Final_2016.pdf. Experience with compounding radiopharmaceuticals at hospital and clinical settings during the past 10 years is essential.
The proposed new chapter will be presented in Pharmacopeial Forum in 2018 for public comments.

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