PET Drug Manufacturing: Living in an FDA-Regulated World

June 14, 2016
2:45 – 4:15

Organizers: Sally W. Schwarz, M.S., R.Ph., BCNP and Steve Zigler, Ph.D.

Moderator: Steve Zigler, Ph.D.

Sponsors: Radiopharmaceutical Sciences Council and Coalition for PET Drugs

Program		
2:45 – 2:50	Living in an FDA-Regulated World: Year in Review	Steve Zigler, Ph.D.
2:50 – 3:10	Supply of IND Agents to NCI-sponsored trials by Skilled Academic Sites	Paula Jacobs, Ph.D.
3:10 – 3:30	FDA's eCTD Mandate for 2017: Impact on PET Drug Manufacturers	Ted Hanebach, RAC, Daniel Yokell, Pharm.D.
3:30 – 3:50	Update on the FDA Approval of Ga-68 DOTATATE: Key CMC Elements	Val Nassiri, Pharm.D., MBA, Victor Paulus, Ph.D.
3:50 – 4:10	PET GMP Compliance and Lessons Learned from FDA Inspections	Marc Berridge, Ph.D., Cathy Cutler, Ph.D., Steve Ehrhardt, M.S., Michael Nazerias, M.S.
4:10 – 4:15	Questions	All

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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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Objectives

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

1. Prepare for and successfully comply with requirements for upcoming changes to FDA electronic filing requirements
2. Manage PET GMP compliance and FDA inspections based on lessons learned from other PET drug manufacturers
3. Participate in the multi-center supply of IND agents based on experience of the National Cancer Institute
4. Recognize key elements in the CMC section of a Ga-68 kit and how those elements apply to other PET drug manufacturers

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Background

- Session based on “Dear Colleague” letter I sent on January 15, 2015
- Solicited feedback from all PET drug manufacturing stakeholders, including academia, industry, and the FDA
- Most of the speakers today were respondents
- 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

- As of April 28, 2016, number of PET drugs with an approved NDA:

8

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PET Drug NDAs

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

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Year in Review

- As of April 28, 2016, number of approved ANDAs for FDG:

37

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Year in Review

- As of April 28, 2016, number of approved ANDAs for sodium fluoride:

22

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Year in Review

- As of April 28, 2016, number of approved ANDAs for ammonia:

24

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Year in Review

- Number of FDA inspections for PET drug manufacturers in the last 12 months:

>40?

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Year in Review

- Events of interest:
  - FDA solicited comments on PET GMP Recordkeeping burden (Dec 2015)
  - FDA solicited comments on Generic Drug User Fees (Jun 2015)
  - FDA issued draft guidance document on integrity of data associated with GMPs, including PET GMPs (Apr 2016)
  - Jane Axelrad retired from FDA (Apr 2016)
  - Others?

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USP News

- Finalizing a major revision to general chapter <821> *Radioactivity*
- Working on two new informational general chapters:
  - <1821> *Radioactivity – Theory and Practice*
  - <1823> *PET Drugs – Information*
- Formed Expert Panel (EP) to review and update monographs for non-PET drugs
- See www.usp.org (Key Issues tab)

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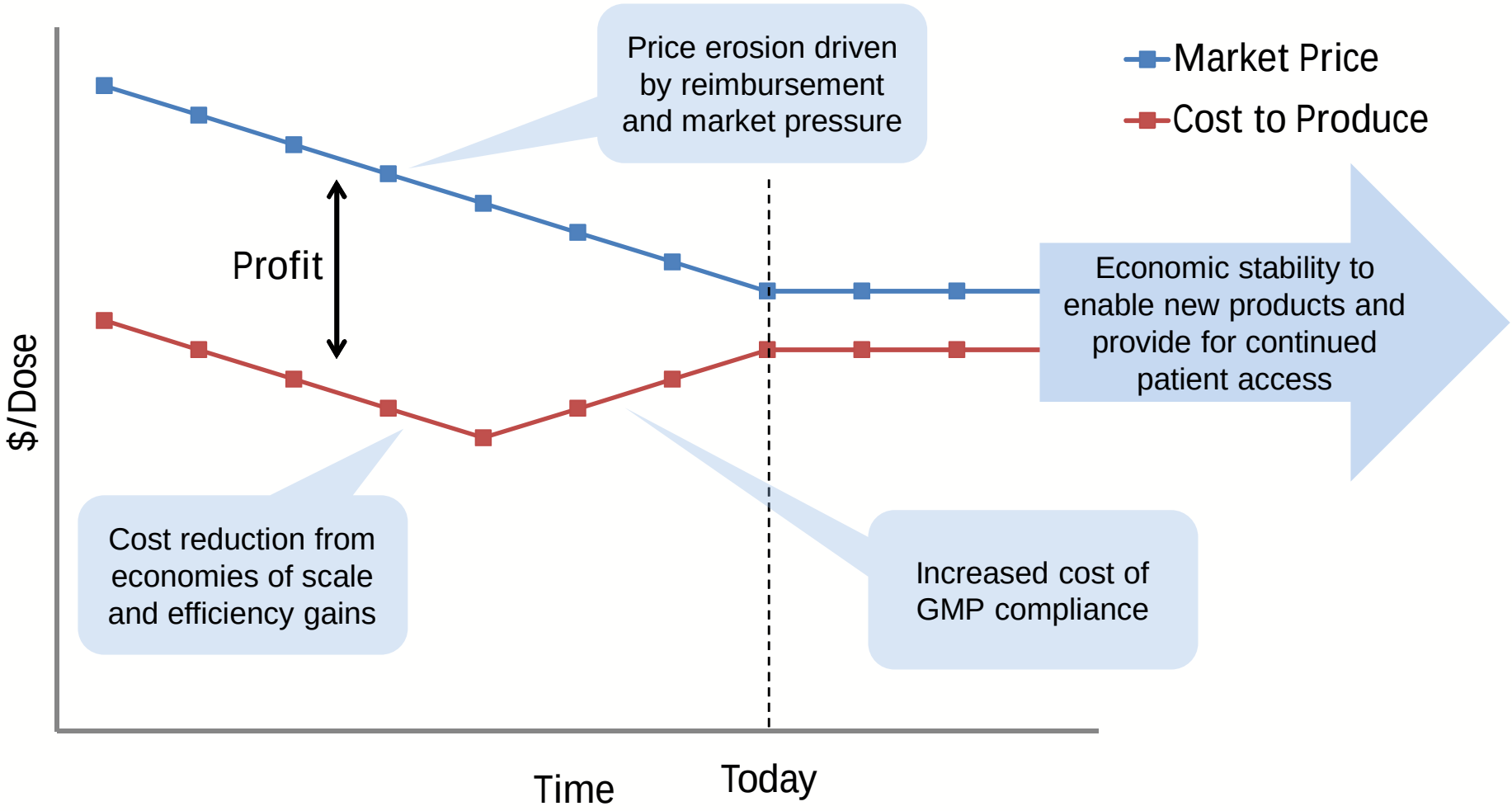
Challenge of Market Sustainability



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