Agenda

Day 1

8:00 a.m. – 8:30 a.m.  Registration/Continental Breakfast

8:30 a.m. – 10:00 a.m. Welcome and introductions

- Activity 1: Why engage a CMO?
  - Participants in small groups create lists on flip charts as to the benefit/value of using CMOs. These will later be contrasted with the costs and potential hazards/risks.
- CMOs and the product lifecycle
- When your name is on the product: The legal concept of strict liability
- Using a hazard identification tool

10:00 a.m. – 10:15 a.m. Break

10:15 a.m. – 12:00 p.m. Activity 2: Identifying potential issues with a CMO

- Participants use a HIT to first identify things of value (e.g., protection against contamination and mix-ups, having a controlled, consistent process, etc.) and a high-level list of CMO activities (e.g., manufacturing drug substance, formulating drug product, packaging, shipping, etc.) Teams then determine which activity can have a negative impact on each thing of value.
- FDA’s guideline on Quality Agreements (Nov 2016)
- Quality agreement priorities — nice to have or need to have?
  - A worksheet will be developed that allows participants to create an ongoing list of items they may want to consider in their own Quality Agreements.

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:30 p.m. Potential issues — contamination and mix-ups

- Definitions & descriptions
Issues seen in FDA 483s and warning letters and experiences (with discussion)
Roles and responsibilities
Activity 3: Proactive ways to address these potential problems
  ▪ Using information from the HIT in activity #1, individuals can rate for themselves the impact of different types of contamination (micro, cross, etc.) and mix-ups and then ways that these problems can be prevented.
Discussion

2:30 p.m. – 2:45 p.m.  Break

2:45 p.m. – 4:30 p.m.
  Potential issues — SOPs and employee competence/training
  ▪ Definitions & descriptions
  ▪ Issues seen in FDA 483s and warning letters and experiences (with discussion)
  ▪ Roles and responsibilities
  ▪ Activity 4: Proactive ways to address these potential problems
    ▪ Using information from the HIT in activity #1, individuals can rate for themselves the impact of SOPs and having well-qualified employees and ways to ensure well-written SOPs and qualified personnel.
  ▪ Person-in-plant and plant-in-plant concepts
  ▪ Discussion

4:30 p.m.  Summary/Wrap up for the day
Day 2

8:00 a.m. – 8:30 a.m.  **Registration/Continental Breakfast**

8:30 a.m. – 10:00 a.m.

- Activity 5: Review of Day 1
  - Participants are asked to individually go through their notes of Day 1 and identify topics and info that they learned, found interesting, or were reminded of. Small groups then create flip chart lists of 5-6 things they collectively found useful.
  - Potential issues — records and data/information integrity
    - Definitions & descriptions
    - Issues seen in FDA 483s and warning letters and experiences (with discussion)
    - Roles and responsibilities
    - Activity 6: Proactive ways to address these potential problems
      - Using information from the HIT in activity #1, individuals can rate for themselves the impact of data integrity issues and groups can identify ways to detect and prevent them.
    - Discussion

10:00 a.m. – 10:15 a.m.  **Break**

10:15 a.m. – 12:00 p.m.

- Potential issues — technology transfer, controls, change control and validation
  - Definitions & descriptions
  - Issues seen in FDA 483s and warning letters and experiences (with discussion)
  - Roles and responsibilities
  - Activity 7: Proactive ways to address these potential problems
    - Using information from the HIT in activity #1, individuals can rate for themselves the impact of control and validation issues and groups can identify ways to assure these controls and an active validation program are in place.
  - Discussion

12:00 p.m. – 1:00 p.m.  **Lunch**
1:00 p.m. – 2:30 p.m.  
- Potential issues — deviations, rejections, and other quality events  
  - Definitions & descriptions  
  - Issues seen in FDA 483s and warning letters and experiences (with discussion)  
  - Owners and CMO’s joint cross functional teams for deviation investigation techniques.  
  - Roles and responsibilities  
  - Activity 8: Proactive ways to address these potential problems  
    - Using information from the HIT in activity #1, individuals can rate for themselves the impact of quality events, investigations, and CAPA issues. They then will discuss ways that these can be enhanced.  
  - Discussion

2:30 p.m. – 2:45 p.m.  
Break

2:45 p.m. – 4:00 p.m.  
- Potential issues — health authority visits to the CMO  
  - Definitions/descriptions  
  - Issues seen in FDA 483s and warning letters and experiences (with discussion)  
  - Roles and responsibilities  
  - Activity 9: Proactive ways to address these potential problems  
    - Scenarios will be given with groups discussing options that range from inadequate to preferred.  
  - Discussion  
- Monitoring and auditing CMOs  
  - Who and when  
  - What is or isn’t seen or examined during the audit  
  - CPV program at CMO  
  - Roles and responsibilities  
  - Activity 10: Proactive ways to address these potential problems  
    - Participants will identify and discuss barriers to monitoring and auditing and ways to overcome such barriers.  
  - Discussion  
- Other ways that contribute to a successful contact giver/acceptor (CMO) relationship  
- Group discussion — how will you use this information?  
  - Participants will be asked to reflect on the workshop and create a list of “take home actions”. Each participant will be asked to share one idea with the larger group of how they can apply something gained during the two days.  
- Summary & wrap-up
4:00 p.m. Workshop Adjourn