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FDANEWS PRESENTS THE

ENSURING THE QUALITY CONNECTION WITH YOUR CMO VIA RISK MANAGEMENT

JUNE 26-27, 2019
MARRIOTT RALEIGH CRABTREE VALLEY
RALEIGH, NC

AN INTERACTIVE WORKSHOP PRESENTED BY FDANEWS AND VALSOURCE

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**