Quality Management Activity Guiding Questions

Activity Title: The Case of an FDA Letter 1

Activity Guiding Questions:

1. What is the nature of the citation?

_____
_____
_____
_____

2. According to the citation, what were the general responsibilities of the clinical investigator at the site?

_____
_____
_____
_____

3. Keeping Good Clinical Practices (GCP) Guidelines in mind could this citation have been prevented from happening? If so, how?

_____
_____
_____
_____

4. At your tables, discuss and identify any violations cited in the excerpts identified in the citation.

_____
_____
_____
_____

5. As a group explain how this citation affect the safety of the participants.

_____
_____
_____

6. What additional training needed to be provided to the clinical investigators?

_____
_____
_____
_____

Notes Section:

Quality Management Activity Guiding Questions

Activity Title: The Case of an FDA Letter 2

Activity Guiding Questions:

1. What is the nature of the citation?

   _____
   _____
   _____
   _____

2. According to the citation, what were the general responsibilities of the clinical investigator at the site?

   _____
   _____
   _____
   _____

3. Keeping Good Clinical Practices (GCP) Guidelines in mind could this citation have been prevented from happening? If so, how?

   _____
   _____
   _____
   _____

4. At your tables, discuss and identify any violations cited in the excerpts assigned to them. (Share ICH reference)

   _____
   _____
   _____
   _____

5. As a group explain how this citation affect the safety of the participants.

   _____
   _____
   _____
   _____

Notes Section:

Quality Management Activity Guiding Questions

Activity Title: The Case of an FDA Letter 3

Activity Guiding Questions:

1. What is the nature of the citation?

   _____
   _____
   _____
   _____

2. According to the citation, what were the general responsibilities of the clinical investigator at the site?

   _____
   _____
   _____
   _____

3. Keeping Good Clinical Practices (GCP) Guidelines in mind could this citation have been prevented from happening? If so, how?

   _____
   _____
   _____
   _____

4. At your tables, discuss and identify any violations cited with regards to each participant in the excerpts assigned to your group. (Share ICH reference)

   _____
   _____
   _____
   _____

5. As a group explain how this citation affect the safety of the participants.

   _____
   _____
   _____
   _____

6. Was the written response provided by the CI adequate per FDA findings? If not, as a group discuss why is was not and generate a list of the responses provided by CI and the FDA determination.

Notes Section:

Quality Management Activity Guiding Questions

Activity Title: The Case of an FDA Letter 4

Activity Guiding Questions:

1. What is the nature of the citation?

2. According to the citation, what were the general responsibilities of the clinical investigator at the site? And what did he/she failed to do? Include samples of these.

3. Keeping Good Clinical Practices (GCP) Guidelines in mind could this citation have been prevented from happening? If so, how?

4. At your tables, discuss and identify any violations cited in the excerpts assigned to them. (Share ICH reference)

5. As a group explain how this citation affect the safety of the participants.

Notes Section: