DAIDS Applied Research Training (DART) Quality Management (QM)

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Quality Management Activity

What is it?

The objective of the following activity is to facilitate and generate group work and discussion for participants to be able to know what Quality Management (QM) is and understand its importance as it relates to clinical trials, differentiate the various aspects of quality control and quality assurance present in clinical trials, and recall the concept of the importance of site audit readiness.

During this activity participants will work as a group on a case based-scenario grounded on a Food and Drug Administration (FDA) letter that informed a clinical investigator of objectionable conditions observed during an inspection at his/her site. Participants will reflect, and answer questions related to the scenario. In the subsequent sections you will find the instructions and materials needed in order to complete this activity.

When can I use this Activity?

This activity is good for a variety of events and purposes. The following list shows alternatives ways to use it:

- Self-Reflection and reviewing concepts learned during an event
- New Employee Training
- Cooperative Learning
- Team Building
- Critical Thinking
- Refresher Training
- Risk Analysis
- Individual self-assessments
- Training Meetings/Events
- Conferences
- Group Annual Retreat
- Office/Departmental Meetings

What Materials / Resources do I need?

- Quality Management Facilitator Instructions 16Dec2019
- Quality Management Slide Deck 16Dec2019
- Quality Management FDA Letter Activity 16Dec2019
- Quality Management Activity Guiding Questions 16Dec2019
- Quality Management Activity Answer Key 16Dec2019
- Quality Management Quick Reference Card 16Dec2019

How long does it take?

Allow approximately sixty minutes for the entire activity.

How do I prepare?

First, access the DART website and verify you have access to the course, then proceed with the following steps:

- Open the file: Quality Management Slide Deck 16Dec2019. Review the Power Point presentation and determine if you will want to use this during your activity. Feel free to add information or customize for the needs of your site.
- Open the file: Quality Management FDA Letter Activity 16Dec2019. There are four (4) documents included in this file. Some of these documents are intended to print double-side. Determine if you want to use just one (1) or two (2) of the FDA letter documents or if you will use all four (4) in the activity. Print on standard size paper according to your printer specifications.
- Open the file: Quality Management Activity Guiding Questions 16Dec2019 and print according to the size of your audience (There are four (4) answer key documents included in this file which are associated with the corresponding FDA Letter Activity). Some of these documents are intended to print double-side (for example, notes section after questions section).
- Open the file: Quality Management Activity Answer Key 16Dec2019 and print according to the size of your audience (There are four (4) answer key documents included in this file which are associated with the corresponding FDA Letter Activity). Some of these documents are intended to print double-side (for example, notes section after questions section).
- Open the file: Quality Management Quick Reference Card 16Dec2019. Print quick reference card on cardstock (optional), or standard paper according to your printer specifications and cut to size for distribution to the participants.
- Access the following web link: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zimmermann-ralf-c-02212014 (or copy to your internet browser) to review the official letter and share with your audience if desired.

How do I do it?

Now you are ready for the next steps. As a facilitator do the following:

- Make sure every table nominates a writer and a speaker to document each group response.
- The speaker will report answers to the other groups when called upon by the facilitator.
- Distribute individually or by group table one of the Quality Management FDA Letters Activity.

- Ensure all participants are reading individually the assigned FDA letters. As they read, remind them to take notes in their activity sheet to use during group discussion.
- Make sure table groups discuss the Quality Management FDA Letters as a group.
- Distribute the Quality Management Activity Guiding Questions individually during the activity.
- Remind group of their time frame for reporting answers per activity. (Suggested time period to report per activity five (5) minutes. Adjust as needed).
- Make sure table groups discuss the answers to the FDA Letter Activity Guided Questions as a group.
- Once the participants have completed the FDA Letter Activity, distribute individually the Quality Management FDA Letter Study Answer key.
- Distribute to each participant a copy of the Quality Management Quick Reference Card.
- Share the Quality Management FDA Warning Letter Link.

How can I modify this activity?

Don't want to use the provided FDA Letter case study? That will be perfectly fine! The beauty of this activity is that you have multiple ways to go about it. For example, you can adapt this activity by using a description of a past or existing issue at your site that needs solving and conduct a root cause analysis. Examine the data, trends, Corrective and Preventive Actions (CAPAs) and develop a list of best practices for reduction or elimination of those risks based on scientific approach.

Or, you can have your staff examine the quality procedures, practices and policies at your site to get ready for a monitoring visit and to understand how they all share a common responsibility with regards to quality, and the importance these have to maintain and continually improve their practices and how these impact participants safety.

Another alternative is to have an activity where your staff compare, contrast and differentiate the various aspects of quality control and quality assurance present in their day to day clinical trials and recall the concept of the importance of site audit readiness.