

# Quality by Design

## Workshop Participant Informant Interview Guide

### I. Respondent Information

1. What is the full name of your organization?
2. What is your job title?
  - a. Can you please describe your role in the organization and your main areas of responsibility?
3. How long have you been in your current position?
4. If you had other workshop attendees contribute to the responses for this interview, what are their job titles and their roles in the organization?
5. What therapeutic area or areas is your organization involved in?
6. What type or types of products does your organization develop? IF NEEDED: For example: drugs, devices, diagnostics.
7. For all of the activities your organization conducts, do you think your organization conducts them independently of each other or would you describe them as closely integrated?

## II. Organization's Experience with QbD QRM Prior to Workshop Attendance

1. What were some of the reasons or motivations for your organization to initially consider the QbD-QM principles?
2. How receptive would you say your organization was to QbD-QRM before you attended the workshop?
3. Was there support for QbD-QRM at a level that allowed for implementation of the QbD-QRM principles?
  - a. IF YES, can you give us an example of how the institution provided support?
4. Was there a QbD-QRM champion within the organization before you attended the workshop?
  - a. IF YES, Can you describe the functional role and organizational location of this champion?
  - b. IF YES, What did this person do to champion these principals? What makes him/her a champion?
  - c. IF YES, Can you tell me about any previous CTTI workshop experience this QbD-QRM champion had?
    - i. IF CHAMPION NEVER ATTENEDED A WORKSHOP, How did this person become a champion of QbD-QRM?
5. Was information about QbD-QRM disseminated across the organization?
  - a. IF YES, How was it disseminated?
  - b. IF YES, Who received this information?
  - c. IF YES, When or at what phase in the project planning process was QbD-QRM information distributed?

6. What barriers to implementing the QbD-QRM were encountered, for example [BELOW]
  - a. What regulatory barriers were encountered?
  - b. What financial barriers were encountered?
  - c. What cultural barriers were encountered?
7. Were these barriers within a specific unit or across the organization?
8. Of the barriers encountered, which were overcome?
  - a. FOR BARRIERS IDENTIFIED IN #8, what were your strategies for overcoming them?

### III. Organization's Experience with QbD QRM After Workshop Attendance

1. What were some of the reasons or motivations for your organization to ask you to attend the workshop?
2. How receptive would you say your organization was to QbD-QRM after you attended the workshop?
  - a. Do you think this level of receptiveness is different than it was before you attended the CTTI workshop?
3. Is there currently support for QbD-QRM at a level that allows for implementation of the QbD-QRM principles?
  - a. IF YES, can you give us an example of how the institution provides support?
4. Was a QbD-QRM champion identified after you attended the workshop?
  - a. IF YES, Can you describe the functional role and organizational location of this champion? IF MORE THAN ONE CHAMPION, COLLECT INFORMATION ON ALL.
  - b. IF YES, What does this person do to champion these principals? What makes him/her a champion?
  - c. IF YES, Did this person attend the QbD-QRM workshop?
  - d. IF CHAMPION NEVER ATTENEDED A WORKSHOP, How did this person become a champion of QbD-QRM?
5. Was information about QbD-QRM disseminated across the organization after you attended the workshop?
  - a. IF YES, How was the information disseminated?
  - b. IF YES, Who received this information?

- c. IF YES, When or at what phase in the project planning process was QbD-QRM information distributed?
6. What barriers to implementing the QbD-QRM were encountered after you attended the workshop, for example [BELOW]
  - a. What regulatory barriers were encountered?
  - b. What financial barriers were encountered?
  - c. What cultural barriers were encountered?
7. Were these barriers within a specific unit or across the organization?
8. Of the barriers encountered, which were overcome?
  - a. FOR BARRIERS IDENTIFIED IN #8, what were your strategies for overcoming them?
9. Can you think of any barriers others may encounter when trying to implement the QbD-QRM principles?
10. What do you think others could do to overcome these barriers?
11. What other mechanisms for facilitating adoption of the QbD-QRM principles could CTTI promote?

## IV. Evaluation of CTQ Principles and Tool

1. Did your organization use the QbD Critical to Quality Factors Tool to implement the QbD-QRM principles?
  - a. IF YES, How did the organization use the document, for example, was the entire document reviewed, or was there a step by step consideration of each factor?
2. Which of the principles would you say worked the best?
3. Which of the principles would you say didn't work very well?
4. Which sections of the Tool did you find to be least relevant to your organization?
5. Which sections of the Tool did you find to be the most relevant to your organization?
6. Were there any other items you felt should be added as principles?
  - a. IF YES, What were they?
  - b. IF YES, How did you operationalize them and use them in your own organization.
7. Overall, what did you think about the format of the Tool?
  - a. Did you find the layout of the Tool to be user friendly? Do you have any suggestions for improving the layout of the Tool?
  - b. Did the format of the Tool make it easy to disseminate and share the information with others?
  - c. How would you improve the format of the Tool to make it easier to share with others?
  - d. What did you think about the readability of the Tool? What would you do to improve it?

## V. Evaluation of Workshop

1. How helpful was the workshop in understanding the QbD-QRM principles?
2. Where there parts of the workshop you felt could have been skipped?
3. What topics or sessions did you feel were missing from the workshop?
  - a. Did you feel like you had all of the information you needed when you went back to your organization?
4. Were you able to take away what you learned at the workshop and apply it to your work?
  - a. IF NO, What could be done at future workshops to help researchers take what they learned and apply it?
5. What do you think was the biggest takeaway from the workshop?
6. What other information or tools do you think were missing from the workshop?

## VI. Measuring the Impact of QbD QRM

1. What impact has QbD-QRM had on your research?
2. Do you have or plan to have a formal way to measure the effectiveness of QbD-QRM?
  - a. IF NO, Is this something you have considered?
  - b. IF YES: What **qualitative** measures will you use to assess the effectiveness of QbD-QRM?
  - c. IF YES: What **quantitative** measures will you use to assess the effectiveness of QbD-QRM?
  - d. IF YES: Do you have any results available from these assessments you would be willing to share with us?
  - e. IF YES, Have you modified the QbD-QRM approach based on your results?
  - f. IF YES, Do you have any further suggestions for modification of the Tool based on these results?