MDDT Summary of Evidence and Basis of Qualification (SEBQ)
Template
Applies To: CDRH
Date Effective: 8/22/2017

USE THIS TEMPLATE ONLY WHEN A MDDT IS BEING QUALIFIED
A SUMMARY IS **NOT** REQUIRED FOR NOT QUALIFIED DECISIONS

Note to MDDT Summary of Evidence and Basis of Qualification Decision Authors:
The MDDT Summary of Evidence and Basis of Qualification (SEBQ) is intended to present an objective and balanced summary of the scientific evidence that served as the basis of the decision to qualify a MDDT. The summary will be reviewed by Office Management, FOI staff and then posted on our MDDT Website.

General Notes on this Template:
If you include any pictures or figures, make sure to include alternative text for 508 compliance [Right click on the picture/figure -> Format -> click on the Web Tab -> Enter an alternative text description]

Tables and Graphs

- Make sure each is adequately titled and numbered to identify the data summarized.
- Include the numerator and denominator, as appropriate.
- Include footnotes or legends to simplify graphics.
- Label graph axes with appropriate labels and units of scale.
- Include p-values and indicate levels of significance reached, if applicable.

DELETE THIS PAGE AFTER PREPARING THE SUMMARY.

MDDT Summary of Evidence and Basis of Qualification Decision for [MDDT Name]

BACKGROUND

MDDT Name: **[MDDT name]**

Submission Number: **[Qsub number]**

Date of Submission: **[Received Date]**

Contact: **[Company Name and Contact Info]**

TOOL DESCRIPTION AND PRINCIPLE OF OPERATION

[Briefly describe what the MDDT is and what it does, as well as the principle of operation. Include version number/date of the MDDT that was included in the qualification package.]

QUALIFIED CONTEXT OF USE

[This should be identical to the language in the letter to the requester that qualifies the MDDT. The qualified context of use should include any limitations as well as the following:]

- Conditions for Qualified Use - describe how to use the tool in a regulatory submission; for example, NAM used for strength testing, COA for secondary endpoint, etc. Include all conditions for use of the qualified MDDT; these can include assay specifics, boundary conditions, etc.
- Proposed labeling or promotional claims based on MDDT - Include any information/promotional claims/language that would be appropriate for the tool user to include in the labeling based on use of the qualified MDDT

SUMMARY OF EVIDENCE TO SUPPORT QUALIFICATION

[This section should include a summary of available evidence/data used to support the MDDT qualification. This section should also include information on how the available scientific evidence demonstrates that the MDDT is reliable and accurately measures what it is intended to measure, is scientifically plausible, and is reasonably likely to predict the outcome of interest.]

[The type of evidence needed will vary depending on the tool type and context of use. Evidence may include performance characteristics of the tool that would affect the usefulness of an MDDT such as accuracy, precision (repeatability and reproducibility), ability to detect change, and validity. The type of evidence may also include:

- Design verification
- Bench performance data (summaries of test reports)
- Animal performance data (summaries of test reports)
- Clinical data (including summaries of test reports and all appropriate (pre-specified) statistical analyses to demonstrate the relationship between the tool and the COU)

- Human factors testing (summaries of usability reports)
- Literature references (a summary and a description of how the article supports qualification)

DISCUSSION OF THE EVIDENCE STRENGTH TO SUPPORT QUALIFICATION

[This section should include a discussion of the following:]
- Accuracy and Precision
- Predictive Ability
- Extent of Prediction (Capture)

ASSESSMENT OF ADVANTAGES/DISADVANTAGES OF QUALIFICATION

[This section should include a discussion of how the advantages of using the MDDT outweigh potential disadvantages of making decisions based on measurements obtained using the MDDT within the specified context of use. This section should include assessment of the following:

Assessments of Advantages of Using the MDDT: This should take into account the following factors:
- The type of advantage(s)
- Magnitude of advantage
- Likelihood of an advantage

Assessments of Disadvantages of Using the MDDT: This should take into account the following factors:
- Type(s) of disadvantages
- Magnitude of risk
- Likelihood of risk
- Risk mitigation

Additional Factors for Assessing Advantages and Disadvantages of Using the MDDT: The following factors may apply:
- Degree of certainty
- Novelty of technology

See MDDT guidance for details on the factors above.]

CONCLUSIONS

[This section should include a conclusion statement(s) of the information above and the qualification decision.]

CONTACT INFORMATION FOR ACCESS TO TOOL

[This section should include information on who the device developer can contact (e.g., tool developer) to access the tool. This section should also include the version of qualified tool.]