2014 FDA Food Safety Challenge

Technical Reading

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Submission proof of concept should be comparable to the validation methods described in the FDA's Guidelines for the Validation of Analytical Methods for Detection of Microbial Pathogens in Foods (http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM273418.pdf).

For a brief summary of the guidelines, please see below:

Purpose of the Guidelines

The Foods and Veterinary Medicine (FVM) Program, formerly known as the Foods Program, within the U.S. Food & Drug Administration (FDA or the Agency) is responsible for ensuring the safety of the nation's food supply. FDA accomplishes this through education, inspection, data collection, standards setting, prompt investigation of outbreaks, and enforcement actions when appropriate. The effectiveness of the FVM Program is highly dependent on the quality and performance of the laboratory methods used within the FDA. To ensure that all laboratory methods meet the highest analytical standards possible for their intended purpose, the FDA FVM Science and Research Steering Committee (SRSC) has established criteria by which all FVM microbiological methods shall be evaluated and validated.

Scope of the Guidelines

These criteria apply to all FDA laboratories that develop and participate in the validation of analytical food methods for Agency-wide implementation in a regulatory capacity. This includes all research laboratories, and field labs where analytical methods may be developed or expanded for potential regulatory use.

Method Validation Definition

Method validation is a process by which a laboratory confirms by examination, and provides objective evidence, that the particular requirements for specific uses are fulfilled. It serves to demonstrate that the method can detect and identify an analyte or analytes:

- In one or more matrices to be analyzed
- In one or more instruments or platforms
- With a demonstrated sensitivity, specificity, accuracy, trueness, reproducibility, ruggedness and precision to ensure that results are meaningful and appropriate to make a decision.
- Reliably for its intended purpose. Intended purpose categories include, but may not be limited to emergency/contingency operations; rapid screening and high throughput testing; and,

confirmatory analyses.

- After the method developer has conducted experiments to determine or verify a number of specific performance characteristics that serve to define and/or quantify method performance.
- Applicability of the Guidelines

The guidelines establish evaluation criteria for detection methods of all microbial analytes that may now be or have the potential to be associated with foods, i.e. any microbiological organism of interest (target organism) or the genetic material (i.e. DNA, RNA) , toxins, antigens, or any other product of these organisms. If not specifically identified, all information contained in the guidelines should be extrapolated to the microbial analyte of interest.

Requirements

Method validation shall be required for:

- Submission of a new or original method.
- Expansion of the scope of an existing method to include additional analytes.
- Changes in intended use (i.e. screening or confirmatory).
- Platform extensions or significant parameter changes (e.g. enrichment times, adaptation to another real-time PCR thermal cycler).
- Matrix extensions. The verification of method performance with a new matrix is intended to assure that the new matrix will produce neither high false positive rates (matrix is free from cross reactive substances) nor high false negative rates (matrix is free of inhibitory substances) as defined for the level of validation required and the intended use of the method.
- Modification of a method that may alter its performance specifications. This includes: changes to the fundamental science of an existing method, equivalence issues such as substitutions of reagents/apparatus, changes to some instrument/platform parameters, changes to time/temperature incubation periods, or enrichment media. All but the most minor of changes should be evaluated for effects on method performance.
- In cases where the sample preparation and/or the extraction procedure/analytical method is modified from the existing test procedure and protocol, the new method should demonstrate that the modifications do not adversely affect the precision and accuracy or bias of the data obtained.
- Modification of a method's performance range (e.g. specificity, sensitivity) beyond previously validated levels.

By participating in the Challenge, each entrant who works with pathogenic organisms, such as Salmonella, in support of its submission agrees to follow the requirements for Biosafety Level II laboratory operations, as outlined in the 5th edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL), available at http://www.cdc.gov/biosafety/publications/bmbl5/.