Method Development Validation and Implementation Program (MDVIP) for Chemical Methods

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MFRPA/FDA Regulatory Methods Update
February 11, 2020

Laboratory Methods (Food)

- Chemical Methods Resources
- Microbiological and Biological Methods Resources
- Macroanalytical Methods Resources
- FDA Foods Program Methods Validation Guidelines
- Laboratory Quality Management Manuals

https://www.fda.gov/food/science-research-food/laboratory-methods-food

Method Validation Guidelines

Chemistry

- 3rd edition October 2019
- **Four** standard levels of performance

https://www.fda.gov/media/81810/download

Nucleic Acid Sequence-Based

- 1st edition September 2019
- **Four** standard levels of performance
- Detection, identification, quantitation of specific DNA sequences

https://www.fda.gov/media/121751/download

Microbiology

- 3rd edition October 2019
- **Three** levels of scrutiny are defined

https://www.fda.gov/media/83812/download

Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products

Chemistry

- 3rd edition, October 2019
- "criteria by which all Foods and Veterinary Medicine (FVM) Program [now Foods Program] chemical methods shall be evaluated and validated."
- 3 New Appendices
  - ✓ Selection of Representative Matrices
  - ✓ Verifications and Extensions of Existing Methods
  - ✓ Modification Criteria for Mass Spectrometry Methods

Appendix 5: Verifications

Different than a Validation and Dependent on the Original Validation Level.

Validation Level of the Original Method (Quantitative or Qualitative)	Requirements for Verification	Notes
Level II SLV to be used routinely/long term	Level II SLV	Must be run prior to the analysis of regulatory samples
Level III MLV or Level IV Collaborative Study or equivalent compendial method; Level II SLV for one time/short term/emergency use	Two matrix spike levels, run in triplicate, along with a matrix blank and a method blank	Must be run prior to the analysis of regulatory samples

Appendix 5: Extensions

- Includes Matrix, Analytes and Platform
- Identification of New Matrix is Method Specific
- Less required for Standard Addition/Isotope Dilution

Technique used in the Original Method	Requirements for Verification	Notes
Methods using isotopically labeled internal standards or matrix matched calibration curves	Spike run in duplicate, along with a matrix blank (if available).	Can be run prior to or concurrent with regulatory samples
All other methods	Two matrix spike levels, run in duplicate, along with a matrix blank (if available)	Can be run prior to or concurrent with regulatory samples

Appendix 6: Modification Criteria for Mass Spectrometry Methods

- Provides guidance on questions
  “When is Method A still Method A?”
  “When does Method A become Method B?”
- **Does** address
  acceptable instrumental modifications to liquid chromatography- and gas chromatography-mass spectrometry methods for determination of chemical analytes in food, feed and cosmetics
- **Does not** address
  extension of methods to new instrument platforms (i.e., different make or model)
  extension to new analytes
  extension to new matrices/matrix types”

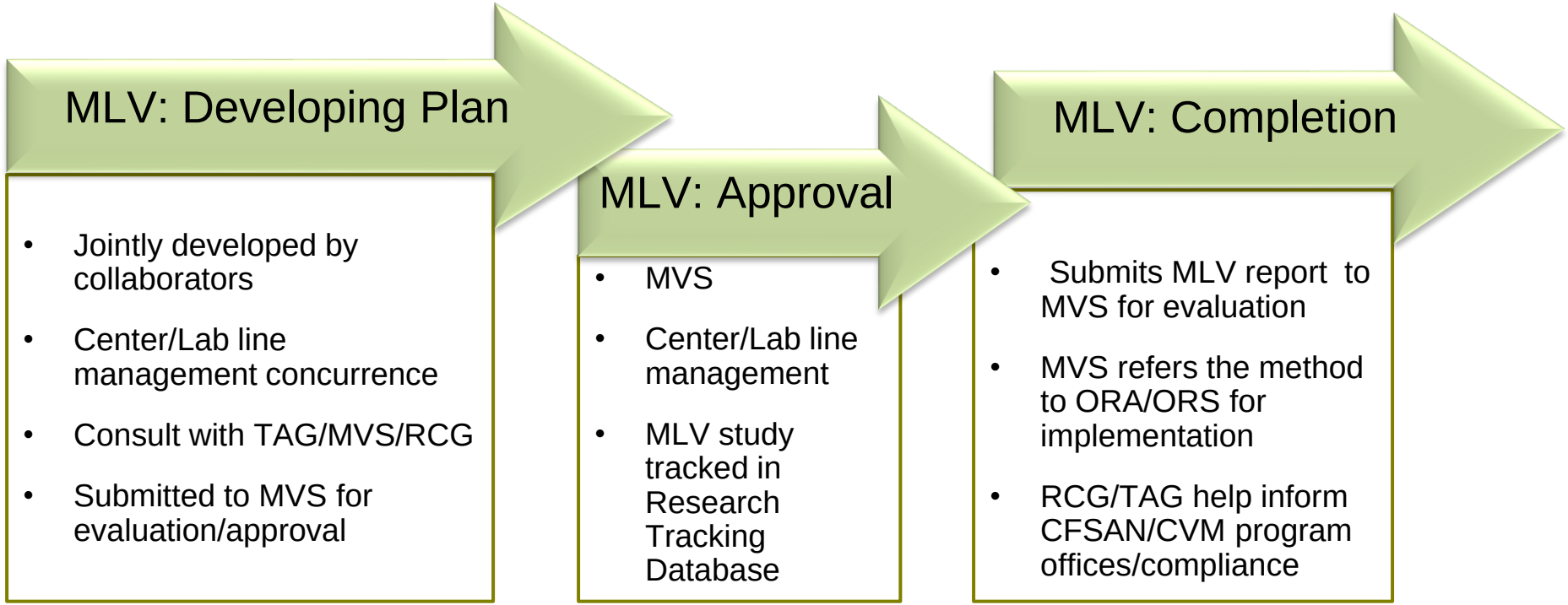
Future Changes

- Appendix 7: Considerations for Multi-analyte Methods
- Validation Guidelines for Whole Genome Sequencing

Technical Advisory Groups (TAGs)

- Allergens and Gluten
- Aquaculture
- DNA-based Species Identification
- Economic Adulteration
- Elemental Analysis
- Food Additive/Nutrients/Dietary Supplements
- Interagency Residue Control
- Mycotoxins
- Persistent Organic Pollutants
- Pesticides
- Portable Devices
- Seafood Methods
- Non-Targeted Screening
- Veterinary Drugs and Feeds

MDVIP Process: Multi-Lab Validations



RCG: Research Coordination Group; TAG: Technical Advisory Group; MVS: Method Validation Sub-committee

Completed Multi-Laboratory Validations

- LC-MS/MS Determination of Mycotoxins
- LC-MS/MS Determination of Sulfites
- EAM 4.7 ICP-MS Determination of Elements
- LC-MS/MS Determination of Chloramphenicol and Nitrofuran Metabolites in Aquaculture Products
- ICP-MS Determination of Iodine in Foods
- GC-FID Determination of Phytosterols in Foods

Current Multi-Laboratory Validations

- LC-MS/MS Determination of Antibiotic Residues in Distiller's Grain
- LC-MS/MS Determination of Glyphosate in Soy, Corn, Eggs and Wheat
- GC-MS/MS and LC-MS/MS Determination of Pesticides
- UV Detection of Cu Color Additives in Olives
- xMAP Food Allergen Detection Assay
- LC-ICP-MS Speciation of Arsenic in Seafood

Future Multi-Lab Validations?

- LC-MS/MS Determination of Veterinary Drug Residues in Milk and Milk powders
- LC-HRMS Determination of Active Pharmaceuticals Ingredients in Dietary Supplements
- PCR Determination of Allergens (peanut, walnut, crustacean)
- Toxic Elements in Bottled Water
- LC-MS/MS Determination of per-polyfluorinated alkyl substances (PFAS) in Foods

Acknowledgements

Major Contributors

John Callahan

Greg Diachenko

Doug Heitkemper

Sunee Himathongkham

Phil Kijak

Shaun MacMahon

Michael McLaughlin

Palmer Orlandi

Marianna Solomotis

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Questions?