A State’s First Year Experience with FDA Grant to Gain ISO Accreditation

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AAFCO Lab Services Committee Meeting - January 17, 2017
Division of AES

- Bureau of Inspection and Incident Response
- Bureau of Agricultural Environmental Laboratories
- Bureau of Licensing and Enforcement
- Bureau of Scientific Evaluation and Technical Assistance
Feed Program

- Animal feeds, including pet foods, are regulated through the inspection of production and distribution establishments and laboratory analysis of samples. Registrants, including ingredient suppliers, are required to submit samples of their products to Department certified laboratories for testing. Results from these sample analyses are reported to the state feed laboratory and appropriate regulatory action is then taken by the enforcement program.
- Previously – FDA BSE Program
Decision to Apply

• Provide a stronger regulatory presence and create a risk-based feed safety program.
• Expanded surveillance samples will reduce potential for contaminants in the feed supply.
• Laboratory component will enable laboratory to obtain ISO 17025 accreditation to support program. The quality system can be used to generate data from sample analysis to be used for entire program through data sharing.
• Partnership with FDA to provide comprehensive response to feed safety emergency issues.
Animal Feed Regulatory Program Standards (AFRPS) Grant

• Preparation of Application
  – Competition B
  – Crystal Ball
  – Research
  – Budget (Salaries, Training, IT/Software, Travel, Equipment, Facility A&R, Subcontracting, Supplies and Contracts)

• Upon/After Receipt
  – Received grant ($300K for program and $300K for laboratory)
  – Tracking Spreadsheets/Documentation
  – Expenditure Processes
  – Reports
Year 1 Requirements

- Acquire ISO 17025 Accreditation Standard
- Train all key laboratory staff on the requirements for implementation and maintenance of the standard
- Appoint a Quality Manager
- Identify methods to be placed under scope
- Enroll in suitable proficiency testing programs
- Enroll in FERN, participate in conference calls and support activities
- Enter data into eLEXNET
- Submit a signed sampling agreement with the state animal feed regulatory program
- GAP Analysis (initial, mid-year, end-of-year)
Year 1 Requirements

• Participate in an on-site lab assessment by the FDA Office of Regulatory Science
• Establish a timeline/accreditation plan of incremental steps to accreditation
• Establish mentor/mentee relationship
• Prepare and submit quarterly Accreditation Plan
  – Accreditation Activities
  – Training
  – Proficiency Tests
  – Audits and Management Review
  – ISO Documents to be written
  – Worksheets/Records to be developed
  – Iso-Compliant practices to be deployed in the lab
Laboratory Considerations

- Timeline/Planning
- Monthly Status Meetings
- Facility Enhancements
- Quality Management System
  - Quality Manager
  - Framework (Document Control)
  - SOP Generation Process
  - Deadlines for Completion/Implementation
- Selection of Accrediting Body
- Method Development Needs
- Partnership with Feed Program
Overall Experience

• Very structured
• Organized
• Time commitment
• Effective
• Good communication with FDA and other states
  – Face to Face Meetings (Required Meetings/Training)
  – Monthly Conference Calls
  – Onsite visit
• Strong resource base
  – Foodshield, APHL, AFDO, AAFCO, FDA, MFRPA
Future Plans

- Years 2-5
- ISO 17025 Accreditation
- Scope Expansion
- Emergency Response
Year 2-3 Requirements

- Create and implement a Quality Manual and Management System P&P
- Conduct at least 1 internal audit & management review to ID non-conformance
- Develop improvement plan to address each non-conformance
- Meet requirements for suitable proficiency testing
- Participation in FERN and lab assessments by FDA
- Adequate training for laboratory to meet ISO 17025 requirements
- All data generated is entered into eLEXNET and shared with FDA
- Participation in mentoring program/collaborate with other accredited labs
- Support implementation of the sampling agreement at beginning of year 2
Acknowledgements

• Chris Amason
• Lisa Brown
• Alex Caldwell
• Sharon Jones
• Patrizia Lemma
• Billy Meeks
• Hina Patel
• Teresa Rygiel
• Ethel Thuotte
• Taleya Williams

• Kelly Friend
• George Hayslip
• Neil Richmond
• Eric Sespico
• Christine Smith
• Shaness Thomas
• Wanda Young
Questions?

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