What to expect over the next 5 years?

Laboratory Perspective

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Methodology/Technology

- Advances in methodology and technology will allow laboratories to more quickly identify food contaminants and better characterize them
  - Faster recalls
  - More outbreaks identified and solved
- These advances require new skills, different techniques and/or new technology
  - Train current analysts
  - Hire analysts with different skills
- May also require structural changes to labs
  - Molecular Flow

Methodology/Technology

- Whole Genome Sequencing (WGS)
  - Pathogen characterization
    - Replace PFGE, Serology, Antibiotic Resistance Testing
  - Better outbreak detection
  - Requires advanced molecular skills
- MALDI-TOF (Mass Spectrometry)
  - Pathogen identification
  - Quicker than current methods/technology used
  - Brings chemistry technology into microbiology lab

ISO 17025 Accreditation

- ISO/IEC 17025:2005 standard is quickly becoming the industry standard for regulatory laboratories. It assures the laboratory's clientele that the results produced are of high quality and legally defensible.

- MFRPS Standard 10 requires that labs either be accredited to ISO 17025 or have a quality system in place which incorporates ISO managerial and technical requirements ("ISO Like").

- The regulatory program drives the need for labs to maintain/expand the scope of accreditation.

ISO 17025 Accreditation

- The costs to maintain ISO accreditation or to meet Standard 10 requirements are significant.
  - Depending on lab size and/or number of methods, accreditation costs can average around $10,000/year but maintaining a Quality System, including "ISO like", can run over $1 million/year for a larger lab.
- While there have been some federal grant opportunities to help offset these costs, those grants may not always be available.
  - FDA ISO CAP and FDA AFRPS CAP
    - Labs pursuing ISO accreditation were awarded $300,000/year
    - Labs already accredited were awarded $150,000/year

ISO 17025 Accreditation

- FDA ISO CAP scheduled to end in 2017 and AFRPS CAP scheduled to end in 2020
  - Future funding may be reduced or non-existent
- Given Standard 10 and other state/federal expectations, labs need to find a way to maintain ISO accreditation or "ISO like" system.
  - Funds from State Legislature
  - New/Existing Federal Grants
  - Funds from Regulatory Programs

Federal Acceptance of State Data

- Regulatory testing is an inherent function of state governmental laboratories. The state regulatory agencies work in partnership with the federal agencies to ensure the safety of the food supply while also guaranteeing both state and federal compliance is achieved.
- FDA has invested millions of dollars over the past decade to support state food and feed testing laboratories.
  - This investment helps state food and feed laboratories achieve or expand their accreditation to the ISO/IEC 17025:2005 standard.
- This has built the infrastructure for state laboratories to perform regulatory testing that is accurate and generates defensible results.

Federal Acceptance of State Data

- Given that accredited state labs have the infrastructure and the already established role in regulatory testing, FDA can use state laboratories to conduct domestic regulatory testing that falls under the lab's scope of accreditation.

- Such use of accredited state laboratories strengthens an IFSS and expands the nation's capacity to perform regulatory testing.

- Because the data is reliable and actionable, it allows faster response for product recalls which increases public health protection.

Federal Acceptance of State Data

- Ideas to consider moving forward:
  - Institutionalizing the concepts of GOODSamples
  - Improving laboratory handling and preparation procedures
  - Upgrading data sharing capabilities (eLEXNET)
  - Developing a national laboratory curriculum standard
  - Further training development and delivery
- APHL White Paper: Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories