Regulation of Laboratory Developed Tests

Dan O'Leary CBA, CQA, CQE, CRE, SSBB, CIRM
President
Ombu Enterprises, LLC
Dan@OmbuEnterprises.com
www.OmbuEnterprises.com
603-209-0600

Ombu Enterprises, LLC

- Ombu is a consultancy based in New England, focused on Operational Excellence and Regulatory Compliance, supporting small manufacturing companies.
  - Ombu offers training and execution in Operational Excellence. Focusing on the analytic skills and a systems approach, Ombu helps companies achieve efficient, effective process and regulatory compliance.
  - Our clients include device manufacturers including IVD manufacturers.

Goose v. Gander

- FDA regulates the “same” device with two different approaches.
  - Manufacturers follow a prescribed route to bring the product to market
    - Clearance or approval, registration, listing, labeling, QSR, post-market surveillance, *etc*.
  - Laboratories follow a different approach based on CLIA
    - High complexity laboratories may bring tests to market following the method validation requirements
- Ombu urges FDA to apply the same regulatory system to both forms of the device

Make v. Buy

- In standard business the choice of a test kit or an LDT test is a make *versus* buy decision
- In the public health/regulated industries the decision is more complex
- The different systems do not provide equal levels of assurance along the supply chain
  - Test reports based on LDTs using ASRs carry a specified notification

FDA Has Four Options

- Do Nothing

- Greatest common multiple approach
  - Apply the current manufacturer's requirements to all IVDs, including LDTs.
  - All LDTs follow the same regulatory scheme as manufacturer’s test kits.

- Least common denominator approach
  - Apply the current laboratory’s requirements to all IVDs, including LDTs.
  - Relax the regulations allowing competent IVD manufacturers to market devices following “laboratory rules”.

- Hybrid Approach
  - Consider the “union” of all the requirements and pick the combination that best protects the public health.

Ombu Recommendations

- Ombu believes that FDA should treat LDTs as IVDs and apply the same regulatory structure:
  - Registration & Listing
  - Approval or Clearance (based on risk classification and current regulations)
  - QSR
  - Post-market surveillance

- Regulation of reprocessing of single use devices provides a model
  - The approach should allow use of CLIA compliant data in lieu of submissions to prevent removing a current LDT from the market.


THANK
YOU