

FDA and the Quest for Standards

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Longstanding Interest in Standards

- Originally regulations in the FDA 510(k) program for me-too devices called for standards
- FDA initiated development of standardized, traceable methods for glucose and hemoglobin
- Couldn't make the sale

FDA and Standards

- Program adjusted for use of special controls
- Program largely based on operative term of “substantial equivalence”
- For class III devices program related to showing “safety and effectiveness”
- Neither regulatory program calls for standards

Not a Deterrent

- Founding member of NCCCLS (Clinical Laboratory Standards Institute or CLSI)
- Active member of ISO Technical Committee 212
- Active member of Global Harmonization Task Force
- Early proponent of CDC standardization network

Interest in Method Standards

- Development of guidances
- Development of special controls
- OIVD web page www.fda.gov/cdrh/oivd

Interest in Material Standards

- Identification of useable standards by CDC, WHO, and NIST; JCTLM
- Experience with use in pre and post market programs

Formal Recognition Process

- Participation – 2 dozen scientists
- Recognition – several dozen CLSI documents

Formal Use Process

- Abbreviated 510(k)s
- Allows conformance to methods
- Allows for partial or complete conformance (usually the latter)

Informal Use

- Pedigreed materials can be used to carry tests over premarket review threshold
- Reference materials can be used to standardize manufacturing practices (QSRs are aligned with ISO requirements)

Incentives and Improved Methodologies

- IVD directive in Europe
- OIVD turbo 510(k) with submission postings
- STARD initiative

Long Journey

- Status quo for routine assays (PSA, troponin, d-dimers) is non-congruence
- Status quo for new assays is an inability to actually evaluate congruence due to lack of any standardized QC or PT material
- Sample procurement complicated by increased awareness of pre-analytical whimsy in systems

Pot of Gold

- Shift toward evidence based medicine
- Current escalation in health care costs is not sustainable
- Consumer interest in quality counts

Crossing the Water -- Plath

Cold worlds shake from the oar.

The spirit of blackness is in us, it is in the fishes.

A snag is lifting a valedictory, pale hand;

Stars open among the lilies.

Are you not blinded by such expressionless
sirens?

This is the silence of astounded souls.