THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

Compliance is not equal to Quality: An Emerging Regulatory Paradigm

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Compliance is not Quality

Compliance ≠ Quality

"…one device manufacturer can meet FDA requirements and *still* make a poor quality device whereas

a second manufacturer may not comply with all FDA requirements and yet make a high-quality device"

Jeff Shuren, M.D., J.D.,
Director CDRH

*****NOTE: Compliance to regulations is still important, as it is required – a high quality product is not a substitute for a compliant product under our current statutory situation**
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm

Slide courtesy of FDA - R. Newman (Director, Office of Compliance – CDRH)

The Case for Quality

The Case for Quality

Our Future Approach

- Need to emphasize patient safety and product quality across the product lifecycle
- Shared goals among stakeholders

Slide courtesy of FDA - R. Newman (Director, Office of Compliance – CDRH)

Paradigm Shift

FDA Regulatory Paradigm Shift

What does a focus on quality mean for FDA?

- Increased manufacturing and product confidence
- Faster time to markets, better information to drive regulatory decisions, improved resource allocation
- What is most important to patients

Program changes beyond inspections:

- Remove participants from the agency work plan for routine inspections
- Waive pre-approval inspections where appropriate
- Engagement and meetings on issue resolution
- Reduced submission requirements and faster FDA response
- Accelerated approval path
- Competitive market around product excellence

Slide courtesy of FDA - R. Newman (Director, Office of Compliance – CDRH)

Compliance is not equal to Quality.

A ***new regulatory paradigm*** is emerging. It promotes an improved culture of quality that ***emphasizes patient safety and product quality*** across the product lifecycle. The ***goals are shared among stakeholders***.

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