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FDA Initiatives and Regulatory Trends for Life Sciences

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Before We Begin

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- All attendees are muted upon entry to the event
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Dirk Dusharme, Moderator

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Dirk Dusharme is Quality Digest's editor in chief. A well-known and long-time industry journalist with deep roots in electronics and engineering, Dirk often covers technological trends, test and measurement, and supply chain reduction.

QUALITYDIGEST

Presenter – Larry Spears

34 years at the US Food and Drug Administration (1977 to 2011). His last role was Deputy Director for Regulatory Affairs.

- FDA positions included:
  - Director and Deputy Director of Division of Enforcement
  - Compliance Officer - FDA law, regulations, and policy as it relates to compliance and enforcement programs

Director in Enterprise Risk Services for Life Sciences for a Big 4 consulting firm

- Leveraged FDA insights to help clients with quality and risk strategies in the areas of regulatory governance, contract manufacturing, and validation.

Larry Spears
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FDA Expectations of the Industry

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- Appropriately designed, validated and labeled products
- Understanding and application of the regulations
- Integrity in all phases of the product lifecycle
- Internal auditing and monitoring of activities
- Timely submission of reports to FDA, especially for significant product changes and adverse events

Device Law and Regulation

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- Federal Food, Drug and Cosmetic Act (FFDCA) is the primary governing law
- All FDA regulations under Part 21 Code of Federal Regulations (CFR)
- Regulations are “pre-market” or “post-market” and designed to ensure safety & effectiveness
- Some regulations are very prescriptive, e.g. IVD, hearing aids, certain types of labeling
- Some regulations applied broadly, e.g. 21 CFR Part 11

Device Guidance Documents

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- Guidance Documents are designed to convey Agency thinking regarding regulations

Regulatory Initiatives/Trends

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- Commissioner Endorsed Program Alignment for 2015 and "… next 5 years .."
- Business Case for Quality
- "New" data dashboard of inspection, compliance and recall data
- Continued global expansion and collaboration with regulatory partners

Highlights of Program Alignment

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- Establish Office of Regulatory Affairs (ORA) Senior Executive Program Directors
- Jointly develop new inspection approaches
- Invest in expanded training across ORA and the Centers
- Expand compliance tools
- Optimize FDA laboratories
- Create specialized investigators, compliance officers, and first line managers

Business Case for Quality

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- Program launched in 2011
- Data analysis flagged device manufacturing quality risks
- Analysis found fewer complaints, less investigations/lot and smaller quality units for firms that invested in quality systems
- Partnership between FDA and device industry to find ways to improve quality

FDA Transparency Initiative

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- Started before 2009 … expanded considerably since then
- Involves FDA sharing data & information publicly
- FDA website posting of Warning Letters and some “Untitled” letters
- Newer posting of FDA 483 inspection summaries, compliance data, and recall data
- Premarket data available, e.g. 510(k)

Globalization Impact on FDA

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- Quality Systems inspections focused on purchasing controls, risk management and corrective and preventive action (CAPA)
- Collaboration on inspection information, pre-market reviews, adverse events, etc.
- Enhanced screening of imported products
- Greater reliance on post-market safety signals to target resources

Warning Letters Defined

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".. Correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal FD&C Act, its implementing regulations and other federal statutes. Warning Letters should only be used for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act".

Regulatory Procedures Manual (RPM), Chapter 4.

Warning Letter Triggers

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- Lack of marketing approval or clearance
- Incomplete or inadequate transfer of product and process design to production
- Signals of limited quality assurance control, e.g. inadequate CAPA system, unresolved production problems, complaints, clusters of medical device adverse event reports (MDRs), ineffectively managed high risk recalls, etc.
- Failure to adequately respond to inspection observations

Communications With FDA to Reduce Warning Letter/Other Risk

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- Well-developed and timely responses to investigator questions during inspections
- Appropriate documentation and reporting of corrections
- Requesting closeout at end of each inspection day
- Preparing for inspection closeout and possible FDA 483

Q&A

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QUESTIONS ???