Agenda

review of 2015 enforcement
emerging enforcement activities
2016 enforcement forecast
implications 2016-2017
Presentation Objectives

1. Review the priority areas of enforcement – and findings – from last year
2. Understand how FDA CDRH’s 2015 enforcement activities are flowing into 2016 and 2017
3. Identify the quality systems implications of FDA’s 2016 enforcement focus points
4. Recognize business implications of FDA’s anticipated 2016 enforcement priorities
5. Improve your business and regulatory plans to better prepare for FDA enforcement initiatives in 2016-2017
enforcement recap
focus area recap
example 483 citations
comparison 2012-2015

REVIEW OF 2015 ENFORCEMENT
Enforcement Terminology

FDA-483

Warning Letter
Purpose of the Inspection

- To assess compliance with CFR, Title 21, Parts:
  - 820 (QS)
  - 803 (MDR)
  - 821 (Tracking)
  - 806 (Corrections and Removals)
  - 807 (Registration and Listing)
- To assess compliance with Electronic Product Radiation Control requirements
2015 Inspections v FDA-483s

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<td>Firms Inspected</td>
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<td>Firms Issued FDA-483s</td>
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source: FDA 2015 Annual Inspectional Report and FY2015 Inspectional Observation Summaries Report
2015 Enforcement Actions

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<tr>
<td>FDA-483s</td>
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</tr>
<tr>
<td>Warning Letters</td>
<td>95</td>
</tr>
</tbody>
</table>
2015 Top 10 FDA-483s

- No, poor DMR integrity, 77
- No, poor SOPs/policies, 377
- Complaint handling, 294
- Purchasing controls, 139
- Process validation, 134
- No MDR SOPs, 129
- Design control changes, 89
- Nonconforming product handling, 114
- CAPA documentation, 97
- Quality audits, 95

source: FDA 2015 Annual Inspectional Report and FY2015 Inspectional Observation Summaries Report
# 2015 Top 20 FDA-483s

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<th>Rank</th>
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<tr>
<td>1</td>
<td>820.100(a)</td>
<td>Lack of or inadequate procedures related to CAPA</td>
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<tr>
<td>2</td>
<td>820.198(a)</td>
<td>Lack of or inadequate procedures related to complaint handling</td>
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<td>3</td>
<td>820.50</td>
<td>Lack of purchasing controls and written, effective procedures</td>
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<td>4</td>
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<td>Lack of or inadequate process validation procedures, monitoring validated processes, etc.</td>
<td>134</td>
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<td>5</td>
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<td>Lack of written MDR procedures</td>
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<td>6</td>
<td>820.90(a)</td>
<td>Lack of or inadequate procedures around nonconforming product and specifications</td>
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<td>7</td>
<td>820.100(b)</td>
<td>Poor documentation and integrity of activities, especially around CAPA</td>
<td>97</td>
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<td>8</td>
<td>820.22</td>
<td>Quality audits – lack of or inadequate procedures</td>
<td>95</td>
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<td>9</td>
<td>820.30(i)</td>
<td>Design changes – lack of or inadequate procedures</td>
<td>89</td>
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<tr>
<td>10</td>
<td>820.181</td>
<td>DMR – not maintained, inadequately maintained, data lacking integrity</td>
<td>77</td>
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<td>11</td>
<td>820.25(b)</td>
<td>Training – lack of procedures or inadequate procedures identifying training needs</td>
<td>72</td>
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<td>12</td>
<td>820.80(d)</td>
<td>Lack of or inadequate procedures for finished device acceptance</td>
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<td>820.80(b)</td>
<td>Lack of or inadequate procedures for acceptance of incoming product, components, etc.</td>
<td>56</td>
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<td>820.70(a)</td>
<td>Lack of or inadequate process control procedures to ensure processes conform to specifications</td>
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<td>15</td>
<td>820.184</td>
<td>Device history records (DHR) not maintained adequately, with integrity</td>
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<td>16</td>
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<td>Procedures to control documents, data integrity not adequately established, written, etc.</td>
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<td>17</td>
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<td>Failure to document adequately process validation activities</td>
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<td>18</td>
<td>820.70(c)</td>
<td>Lack of or inadequate procedures to control environmental conditions</td>
<td>51</td>
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<td>19</td>
<td>820.30(g)</td>
<td>Lack of or inadequate procedures to conduct design validation activities</td>
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<td>20</td>
<td>820.184</td>
<td>Lack of or inadequate device history record (DHR) procedures</td>
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</table>
2015 Focus Area Recap

1. Primary focus on procedural controls and their effectiveness
   • Effective SOPs
   • Training
   • Process validation – this is up from previous years

2. Continued emphasis on supplier controls and oversight
   • Purchasing controls SOPs
   • Lack of incoming acceptance controls (39 FDA-483s)

3. Continued emphasis on record and data integrity
   • Especially in production-related records and testing
   • Virtually all FDA-483s reference subpart “Records” as being inadequate or poorly maintained

4. Beginning an emphasis on post-market surveillance
   • Increased number of 483s in complaint handling
   • Increased number of 483s around Medical Device Reporting (MDR) compliance
Example FDA-483 Citation

21 CFR 820.100(a)
Lack of/inadequate procedures related to CAPA

“Procedures for corrective and preventative action have not been established. Specifically, management has not analyzed the development, manufacturing, storage, and distribution of their medical devices to identify sources of quality data to identify quality problems.”

Warning Letter issued in October
(www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm467164.htm)
Example FDA-483 Citation

21 CFR 820.198(a)
Lack of or inadequate procedures related to complaint handling

“Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established. Specifically, your firm’s Customer Complaints Procedure 805...does not describe how records of complaint investigations are coordinated with your Nonconforming Product Procedure 803.”

FDA-483, Wexler Surgical, March 20, 2015
Example FDA-483 Citation

21 CFR 820.50
Lack of or inadequate purchasing control procedures

“Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established. Specifically, your SOP #8036 requires in section 2.4 that “every vendor requires an onsite inspection before the vendor can be approved. However, of the vendors on your approved vendor list, only three (3) have undergone onsite inspections even though all are being used....”

- FDA-483, Biomedix, Inc., December 9, 2015
Example FDA-483 Citation

21 CFR 820.75(a)
Lack of or inadequate process validation procedures, monitoring validated processes, etc.

“Procedures for monitoring and control of process parameters for a validated process have not been adequately established. For example, during the production of ... process parameters are not recorded as part of monitoring and process control.”

FDA-483, Talladium Inc., August 18, 2015
Example FDA-483 Citation

21 CFR 803.17
Lack of or inadequate written MDR procedures

“An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury. Specifically, seven of ten complaints reviewed....”

FDA-483, ARB Medical, August 11, 2015
Warning letter issued in December
(www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm480523.htm)
## 2012-2015 483 Comparison

<table>
<thead>
<tr>
<th>Year</th>
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<td>2013</td>
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<td>820.198</td>
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</tr>
</tbody>
</table>

21 CFR 803.17  Medical Device Reporting  
21 CFR 820.30  Design Controls  
21 CFR 820.50  Purchasing Controls  
21 CFR 820.75  Process Validation  
21 CFR 820.80  Receiving, In-Process, Finished Device Acceptance  
21 CFR 820.100 Corrective and Preventative Action (CAPA)  
21 CFR 820.184 Device History Record (DHR)  
21 CFR 820.198 Complaint Files
2012-2015 WL Comparison

Warning Letters

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Key Points So Far….

- Inadequate procedures and recordkeeping cause most FDA 483s
- Process validation is back in the top 5 FDA-483 observations again
ORA alignment
CPG revisions
Revamp of inspectional tactics
Metrics-based inspections

EMERGING ENFORCEMENT ACTIVITIES
Program Alignment - Commitments

1. Establish Commodity-Based and Vertically Integrated Regulatory Programs
2. Increase Specialization
3. Enhance Training
4. Revamp Agency Work Planning
5. Improve Compliance Policy and Enforcement Strategies
6. Enhance Import Operations
7. Advance Lab Optimization
8. Address Delayering/Streamlining
ORA Operations - Future Structure

Operations

Audit Staff

Pharmaceutical Quality Operations
Director, Alonza Cruse

Biologics Operations
Director, Anne Reid Acting

Medical Devices Operations
Director, Jan Welch

BIMO Operations

Tobacco Operations

Human and Animal Food Operations
Director, Joann Givens

Four Management Teams

Two Management Teams

Three Management Teams

Two Management Teams

12 Management Teams
What does this mean for me?

- Inspectorate specialized by program
- Expanded technical expertise
- Increased ability to keep pace with changes in manufacturing
- Goal of reduced timeframes for decision-making through both streamlining as well as team-based approaches
CPG Revision Activities

• Continue to review and revise of all CPGs older than 2010

• Continue to conduct review and revise/eliminate guidance older than 2005

• Update 5-year plan for CDRH to help industry improve device safety, efficacy and innovation

• Create CDRH training steering committee to continuously identify specific training programs for specialized investigators
  • Emerging technologies (3D printing) for instance
Revamp of Inspection Tactics

• By end of 2016, complete draft revisions of
  – Compliance Program Guidance Manuals (CPGM)
  – Investigations Operations Manual (IOM)
  – status of QSIT is currently under discussion

• Harmonization of all inspectional tactics, activities, and training across multiple Centers (CDRH, CDER, CBER, CVM, BIMO with ORA)
  – possible implication is to allow easier integration with international cooperative agreements (with EMA, MHRA, Health Canada, etc.)

• For plan details (as of February 2016), see
  – FDA Program Alignment at http://www.fda.gov/AboutFDA/CentersOffices/ucm477082.htm
Metrics-Based Inspections

• CDRH has been piloting since 2012 and is coordinating with CBER/CDER to harmonize metrics (inasmuch as possible)

• Device manufacturers will be required to submit data for metrics annually such as data related to:
  - product quality complaint rate
  - lot acceptance rate
  - QSMR on-time rate
  - CAPAs stemming from QSMR

• Metrics will be calculated by FDA
• Metrics will be site by site and product by product
• Metrics used to develop annual risk-based inspection schedule
overall
UDI and your QMS
QSIT and CAPA+2
MDSAP
data integrity
postmarket surveillance
international

2016 ENFORCEMENT FORECAST
Overall

• CDRH spent 2015 training dedicated device investigators and specialists
  • focus on traceability of safety and efficacy features and testing
  • long-term goal: eliminate region-based investigators
  • first specialty: radiological and mammography devices

• Increased coordination with DOJ for CIAs

• Elimination of voluntary reliance on ISO audits as part of move toward MDSAP inspections
UDI

Back in 2013...

• revised 21 CFR 803 Medical Device Reports
  • individual AE reports must include UDI from label or package

• revised 21 CFR 806 Corrections & Removals
  • reports have to include UDI on label or package

• revised 21 CFR 820 Quality System Regulation
  • labeling, device history record, complaint and service records, etc.,
    now have to include UDI or UPC
“Wait...are you saying that we should’ve updated all our forms, complaint database fields, and so on, to include UDI back in 2013?”
“Wait...are you saying that we should’ve updated all our forms, complaint database fields, and so on, to include UDI back in 2013?”

**YES** and expect FDA investigators to verify you capture and verify UDI information on:
- complaint forms
- service record forms
- AE/MDR database fields
- report templates
- finished product QC checklists or forms used to document QC prior to release
- etc.
UDI Questions to Expect

• Has the firm updated its complaint handling forms and procedures, etc. since 2013 to request the UDI or UPC from the complainant? Obtain complaints registered after the effective dates of the procedures and training to determine effectiveness of training.
• Did the firm update its design input procedures to identify UDI requirements for new or redesigned products?
• Did the firm update its design control change procedure to clarify when changes create a new version/model – and thus necessitate a new UDI?
• Do finished production QC inspections at the firm include verifying the correct UDI or UPC, its legibility and accuracy?
• Did the firm update its approved vendor list with the UDI suppliers as purchased services? Did the firm qualify the suppliers?
• Verify that all packaging configurations conform to the GUDID record on file – determine if any unfiled changes have been made.
• Has the firm updated its records retention policies and schedules to include 21 CFR 830.360? How did this impact their retention of other production records?
UDI Questions to Expect

• Has the firm updated its complaint handling forms and procedures, etc. since 2013 to request the UDI or UPC from the complainant? Obtain complaints registered after the effective dates of the procedures and training to determine the effectiveness of training.

• Did the firm update its design input procedures to identify UDI requirements for new or redesigned products?

• Did the firm update its design control change procedure to clarify when changes create a new version/model and thus necessitate a new UDI?

• Do finished production QC inspections at the firm include verifying the correct UDI or UPC, its legibility and accuracy?

• Did the firm update its approved vendor list with the UDI suppliers as purchased services? Did the firm qualify the suppliers?

• Verify that all packaging configurations conform to the GUDID record on file – determine if any unfiled changes have been made.

• Has the firm updated its records retention policies and schedules to include 21 CFR 830.360? How did this impact their retention of other production records?
QSIT and CAPA+2

- Quality System Inspection Technique (QSIT)
- Provides 5 different subsystems to inspect
- Increasingly, investigators use a “CAPA+2” approach (“CAPA+Production+1”)
- Examine 10 CAPAs and 10 production records
- Examine 1 other area such as:
  - design control – changes, validation, etc.
  - raw material controls (incoming acceptance, supplier qualification, etc.)
  - outsourced production-related controls (control over CMO, etc.)
  - process validation
  - records controls (records retention, data integrity – includes Part 11, etc.)
  - distribution controls (anti-counterfeiting, etc.)
  - postmarket surveillance and MDR
MDSAP

• Assembled by IMDRF members with heavy input from FDA

• Piloted by FDA, Brazil, Australia, Canada, Japan, etc.

• FDA announced in December 2015 that ending ISO 13485 voluntary audit program in favor of MDSAP

• MDSAP is formally effective in 2017
“The MDSAP program provides FDA better assurances than the ISO 13485 Voluntary Audit Report Submission Pilot because FDA’s requirements under 21 CFR 820 or other regulations typically covered during FDA inspections are encompassed within the MDSAP audit model.”

- FDA, *US Federal Register Notice*, 17 December 2015
“The MDSAP program provides FDA better assurances than the ISO 13485 Voluntary Audit Report Submission Pilot because FDA's requirements under 21 CFR 820 or other regulations specifically covered during FDA inspections are encompassed within the MDSAP audit model.”

Consider:

1. Is this the end of FDA being a proponent of ISO 13485:2003...?

2. Is MDSAP an eventual replacement for QSIT...?
“The MDSAP program provides FDA better assurances than the ISO 13485 Voluntary Audit Report Submission Pilot because FDA’s requirements under 21 CFR 820 or other regulations that inspections are encompassed within the MDSAP audit model.”

In December 2016, Health Canada will end its own internal device firm assessment program in favor of *just* having MDSAP as the one regulatory approved method.

# MDSAP v QSIT

## MDSAP Structure

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Marketing Authorization and Facility Registration</td>
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<tr>
<td>Measurement, Analysis and Improvement</td>
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<tr>
<td>Adverse Events and Reporting</td>
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<tr>
<td>Device Design and Development</td>
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<tr>
<td>Production and Servicing Controls</td>
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<td>Purchasing Controls</td>
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## QSIT Structure

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# MDSAP v QSIT

## MDSAP Structure
- Management Oversight and Involvement
- Marketing Authorization and Facility Registration
- Measurement, Analysis and Improvement
- Adverse Events and Reporting
- Device Design and Development
- Production and Servicing Controls
- Purchasing Controls

## QSIT Structure
- Management Controls
- Corrective and Preventative Actions
- Design Controls
- Production and Process Controls

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Data Integrity & Recordkeeping

• Expansion of CDER/CBER’s 2010 data integrity “special focus” inspections to CDRH
  • see FDA BIMO CPG, Attachment A: Computerized Systems
    http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133927.htm

• Review of cybersecurity controls on any computerized medical device (including apps)
  • documentation and validation as part of design control
  • change management as part of postmarket changes and reporting
Data Integrity & Recordkeeping

Data with highest risk criticality (in FDA’s eyes):

• data from automated processes associated with product production or testing
• lot release data
• sterility and safety data
• postmarket surveillance data
FDA Investigator Instructions

“If a firm is keeping electronic records, determine if they are in compliance with 21 CFR Part 11. At a minimum, ensure that:

(1) the firm has prepared a plan for achieving full compliance with part 11 requirements and is making progress toward completing that plan in a timely manner

(2) accurate and complete electronic and human readable copies of electronic records, suitable for review, are made available

(3) employees are held accountable and responsible for actions.

If initial findings indicate the firm’s electronic records may not be trustworthy and reliable, or when electronic recordkeeping systems inhibit meaningful FDA inspection, a more detailed evaluation may be warranted.”

- FDA Enforcement Compliance Policy Manual, Attachment A
  http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133927.htm
Data Integrity & Recordkeeping

• Who is authorized to access the system and enter/change data? How is this tracked and reviewed? How was this tested?
• Are there written procedures for system validation, data collection, and computerized system security?
• Are original data entered directly into an electronic record at the time of collection or are data transcribed from paper into an electronic record? What happens to the raw data after its transcribed?
• How is recorded data reviewed? By whom? Are they qualified?
• In databases, how are missing information and unexplained inconsistencies documented and corrected?
• Are there edit checks and data logic checks for acceptable ranges of values (such as in database systems and spreadsheets)?
• Are there controls in place to prevent, detect, and mitigate effects of computer viruses (and malware) on data and software?
Postmarket Surveillance

June 2014  Pew Trust outlines in report to US Senate the shortcomings of FDA’s current postmarket surveillance activities for medical devices (especially in light of FDA’s weak premarket review activities)

July 2015  US Senate approves funding increase for FDA to improve postmarket safety surveillance of medical devices

November 2015  Draft report from US Senate investigation on duodenoscopes questions effectiveness and value of FDA’s current medical device postmarket surveillance activities

December 2015  FDA announces 2016 priority guidance documents around postmarket surveillance
  • Medical Device Reporting Policy
  • Postmarket Surveillance Studies
  • Emerging Postmarket Device Signals

January 2016  FDA initiates development of National Medical Device Evaluation System (NMDES) ... to be completed no later than end of 2017
Postmarket Surveillance

• Increased inspection emphasis on reviewing:
  • How safety and efficacy characteristics from design control trace into postmarket surveillance decisions and reporting
  • How firm makes and documents MDR and recall decisions
  • Tracking and closure of recalls
  • How firm handles complaints – including decision logic
  • Verifying any changes in device characteristics have traceability from original design through to current design

Caution! Design control records for many Class II devices are sloppy at best!
Postmarket Surveillance

• Expect a lot of questions around:
  • early signal detection for safety issues – how? why? who?
  • statistical analyses of complaints and adverse events
  • senior management involvement and review
  • flow of complaint and AE data into CAPAs, supplier re-qualifications, internal audits, etc.
  • role of component suppliers in signal detection

Note: some of these will just be pure information gathering to feed into guidances
International

• Trusted Trader Program with US Customs and Border Protection

• Increased international inspections, especially in North America for firms not involved in MDSAP
  • involvement in MDSAP pilot currently lowers risk rating

• Increased use of PREDICT data to identify high-risk international inspection targets
  • more import problems, the greater the likelihood of inspection
Key Points So Far….

- Inadequate procedures and recordkeeping cause most FDA 483s
- Process validation is back in the top 5 FDA-483 observations again
- FDA will expand its efforts in international enforcement
- CAPA+2 is the current guiding inspection tactic until MDSAP in 2017
- Enforcement will increasingly focus on postmarket controls (and the integrity of data supporting such controls)
- UDI enforcement will really kick-in by mid-2016, especially in QMS
business implications
upgrading your quality system

IMPLICATIONS FOR 2016-2017
Business Implications

• Need to retain clear records demonstrating device safety and efficacy – from initial design control through postmarket decision-making (e.g., poor recordkeeping will be costly)
• Expect 2 investigators per inspection (more likely than not)
• Class II device costs will increase due to UDI implementation
• QMS costs will temporarily increase in 2016 to address required SOP, form, etc. revisions (and attendant training) to address UDI requirements from 2013
• Be able to show progress on Part 11 compliance and effective data integrity throughout the lifecycle (creation thru archival)
• Increased liability risks from public enforcement of poor design control records and postmarket surveillance actions
Business Implications

• Improve **supply chain controls** to avoid public enforcement
• Expect **FDA internal processes will change** because of revisions to older CPGs – include policy interpretations
  • !CAUTION! this may include some “sacred cows” such as internal audit reviews
• Consider restructuring your QMS to **follow the 7-area MDSAP framework** (rather than QSIT)
• Make sure to **include relevant IMDRF (and GHTF) guidelines** as references in SOPs and policies
• By late 2017-2018, expect FDA to cite **IMDRF guidelines** (as FDA began citing ICH guidelines in 2008) in Warning Letters, especially to international firms
Upgrading Your QMS
Upgrading Your QMS

Minimum QMS procedures to update to reflect UDI:

1. Labeling inspections and quality control
2. Device history record components
3. Complaint handling
4. Servicing
5. Design input
6. Design output
7. Design change control
8. Design history file template (e.g., contents)

plus all the various forms, templates, checklists, database fields, reports, etc. ...and TRAINING
“SOPs detail the **regularly recurring** work processes that are to be conducted or followed within an organization. **SOPs will fail if they are not followed.**”


http://www.epa.gov/QUALITY/qs-docs/g6-final.pdf
“SOPs detail the regularly recurring work processes that need to be conducted or followed within an organization. SOPs will fail if they are not followed.”


Routine activities – NOT one-offs

Have to set humans up to successfully follow
Upgrading Your QMS

Summary of 11 steps to take overall to implement an up-to-date recordkeeping schedule and core FDA data integrity controls
Key Points Recap

- Inadequate procedures and recordkeeping cause most FDA 483s
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- FDA will expand its efforts in international enforcement
- CAPA+2 is the current guiding inspection tactic until MDSAP in 2017
- Enforcement will increasingly focus on postmarket controls (and the integrity of data supporting such controls)
- UDI enforcement will really kick-in by mid-2016, especially in QMS
- Update your QMS now to avoid public embarrassment and enforcement in 2016 – UDI, data integrity, SOP effectiveness
Business Implications Recap

• Need to retain clear records demonstrating device safety and efficacy – from initial design control through postmarket decision-making (e.g., poor recordkeeping will be costly)
• Expect 2 investigators per inspection (more likely than not)
• Class II device costs will increase due to UDI implementation
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• Improve supply chain controls to avoid public enforcement
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Agenda Recap

review of 2015 enforcement
emerging enforcement activities
2016 enforcement forecast
implications 2016-2017
Next Steps

1. Review CDRH’s list of various proposed 2016 guidance documents at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm467223.htm

2. Review the summarized key points covered in this presentation with your teams and ensure your 2016 plans address these items

3. Recap any specific, relevant points from this presentation for your senior management – make sure identify any business implications unique to your organization or planned activities

4. Skim through CDRH’s program alignment updates (see current version http://www.fda.gov/AboutFDA/CentersOffices/ucm477082.htm)

5. Book 30 minutes on your calendar 2x a year to check-in with the CDRH Learn webpage (http://www.fda.gov/Training/CDRHLearn/default.htm) for any updated presentations that you could take advantage of in your internal training, preparing for a new guidance, reviewing FDA expectations for new rules, etc.
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About Your Presenter

John Avellanet gives practical, compliance solutions and streamlines quality systems for clients around the world. Winner of the 2009 & 2011 Best of Business Services award by the Small Business Commerce Association, Mr. Avellanet has earned international acclaim for his business-savvy, pragmatic FDA compliance advice.

He most recently served as the industry expert reviewer for the international standard, BSI 10008 Evidential Weight and Legal Admissibility of Electronic Information (2015). He is the lead expert for the ISPE GAMP Data Integrity Working Group.

In 2014, he co-authored the book, Pharmaceutical Regulatory Inspections, with several current and former regulatory agency officers, and his industry classic, Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine (2010), was originally featured at BIO 2011 and garnered multiple five-star reviews from industry publications, blogs, Amazon.com readers, and former FDA officials.

He has a breadth of experience designing, implementing, and being accountable for quality systems and compliance programs for FDA, DEA, ICH, GHTF/IMDRF, and ISO. For more than 15 years, John was directly accountable for regulatory compliance, records management, and information technology, most recently as a C-level executive for a Fortune 50 combination device firm.

In 2006, Mr. Avellanet founded his independent lean compliance consulting and training firm, Cerulean Associates LLC.
About Your Presenter

Recent Resume Highlights

- Industry Expert Reviewer, BSI 10008 *Evidential Weight and Legal Admissibility of Electronic Information*
- Lead author of 2 certification courses for US RAPS
- Lead Expert, ISPE GAMP Data Integrity Working Group
- Independent Reviewer for DOJ-Dr. Comfort Corporate Integrity Agreement
- 2010 and 2011 Top 10 FDA Compliance Blog
- 2010 Top 50 Pharma/Biotech Blog
- 2009 and 2011 Best of Business Services Award
- 2008-2012 Guest Lecturer at NIH
- 2006 Lifetime Achievement Award – Who’s Who of Biopharma & Device Executives

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