Compliance Central with FDA Center
Compliance Directors: Part I

**Tom Cosgrove**, Acting Director, Office of Compliance, Center for Drug Evaluation and Research, FDA

**Carl Fischer**, Senior Advisor, Office of Compliance, Center for Devices and Radiological Health, FDA

**Mary Malarkey**, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, FDA

**Moderated by: John R. Manthei**, Partner, Latham & Watkins LLP
CDER Office of Compliance

Thomas J. Cosgrove, J.D.
Acting Director, Office of Compliance

FDLI Enforcement, Litigation, and Compliance Conference
December 7, 2016
CDER Office of Compliance

**Our mission:** to promote and protect the public health through strategies and actions that minimize consumer exposure to unsafe, ineffective, and poor quality drugs.

**Our vision:** to be a global leader in preventing consumer exposure to unnecessary risk from drugs throughout the drug lifecycle.
Office of Compliance Priorities

• Compliance/enforcement actions
• Quality/safety initiatives
• Data integrity/assurance
• Compounding
• Track and trace
• Clear guidance and standards for compliance
• Program alignment
Office of Compliance Structure

Office of Compliance

- Office of Drug Security, Integrity and Response (ODSIR)
- Office of Manufacturing Quality (OMQ)
- Office of Scientific Investigations (OSI)
- Office of Unapproved Drugs and Labeling Compliance (OUDLC)
- Office of Program and Regulatory Operations (OPRO)
Our Toolbox

- Industry/firm regulatory meeting
- Injunction/shut down
- Consent decree
- Import alerts
- Seizures
- Warning letters
- Untitled letters
- Disqualifications
- Criminal indictments/convictions
- More
Office of Manufacturing Quality (OMQ): Focus

- Compliance and enforcement for:
  - Current Good Manufacturing Practices violations
  - Data reliability issues
  - Compounding
- Global cooperation/training
- Policy/standards development
Primary Considerations CGMP Enforcement

Is the drug “adulterated”?  
- Food, Drug & Cosmetic Act  
- FDA regulations at 21 CFR 210 & 211  
- For API, standards are set forth in ICH Q7

Most important – patient risk  
- High risk → FDA takes quick action.  
- Sub or super-potent  
- Contamination  
- Sterility concerns  
- Other defects
Will FDA Issue an Import Alert?

CGMP Import Alert issued if:

• Violation could cause drug quality defect with potential adverse patient health consequences
• Repeat violations
• Refusal or delay of an inspection
• Significant data integrity violations
OMQ Actions
January to October 31, 2016

- Import Alerts 66-40, 21
- Import Alerts 99-32, 25
- Untitled Letters, 3
- Warning Letters Issued & Cleared, 41
- Injunctions, 2
- Pharmacy Compounding Letters, 48
- Regulatory Meetings, 24

Legend:
- Blue
- Red
- Green
- Orange
- Purple
- Light Blue
Data Integrity Failure Examples

Common problems:
• Lack of controlled access to computer systems
• “Trial” HPLC injections
  – Trial injections in stand alone equipment, outside a quality structure
• Deleted data
• Not recording activities contemporaneously
• Backdating
• Fabricating data
• Copying existing data as new data
• Re-running samples
Data Integrity Draft Guidance

Data Integrity and Compliance With CGMP, draft guidance for industry (April 2016)

Q&A style guidance focused on frequently occurring data integrity lapses with definition of key terms.

When final, will represent our current thinking on data integrity and CGMP compliance.

2016 Example Warning Letters - Data Integrity Violation

• “You repeatedly falsified and omitted information on the certificates of analysis (CoA) you issued to your customers. For example, your firm fabricated the name of an employee, and you used that name as the false signatory authority on the CoA you sent to your customers. You also omitted the name and address of the original API manufacturer and did not include a copy of the original batch certificate. Finally, you included an “expiration date” on your CoA that exceeded the manufacturer’s labeled expiration date, but you had no basis for the extended retest/expiry period.”

• “During the inspection, the investigator recorded dirty warehousing spaces and observed a rodent in the room adjacent to the warehouse at your facility.”
Now Final: FDA Guidance on Quality Agreements

Quality agreements define expectations and responsibilities in a contract manufacturing arrangement up front.
FDA Guidance on Quality Agreements

What is a “Quality Agreement”?  
• a comprehensive written agreement that defines responsibilities of the Quality Units of each party in contract manufacturing of drugs subject to CGMP.

Why?  
• to explain how quality agreements can be used to define, establish, and document the responsibilities of parties involved in the contract manufacturing of drugs subject to CGMP.

Clarifying roles and responsibilities improves efficiency and oversight of outsourced manufacturing operations and relationships between parties...Ultimately improves the quality of drugs that patients consume.
Office of Scientific Investigations (OSI)

Mission
To ensure the safety, efficacy and ethical development of drug products throughout the product lifespan using global strategies and actions that minimize unnecessary consumer risk via compliance and enforcement of
• the integrity of safety/efficacy data submitted to FDA,
• the application human subject protections in clinical trials, and
• the implementation of Risk Evaluation and Mitigation Strategies.

Vision
• Adapt to globalization and the evolving industry
• Master the information revolution
• Foster innovation in public health
• Maximize operational excellence
OSI Program Areas (inspected entities)

Nonclinical → Phase 1,2,3 → Post Marketing

- **Good Laboratory Practice (Testing Facilities)**
- **Good Clinical Practice (Sponsors, Contract Research Organizations, and Clinical Investigators)**
- **Human Subject Protection (Institutional Review Boards)**
- **Human Subject Protection (Radioactive Drug Research Committee)**
- **Bioequivalence/Bioavailability (Clinical Investigators, Contract Research Organizations, Sponsors)**
- **Risk Evaluation and Mitigation Strategy (Applicants)**
- **Post-Marketing Requirements (Applicants)**
- **Post-Marketing Adverse Drug Experience (Applicants)**
Bioresearch Monitoring Program Inspections* (CDER, FY 2015)

- Sponsor (GCP) 6%
- Institutional Review Board/Radioactive Drug Research Committee 9%
- Clinical Investigator 47%
- Good Laboratory Practice 3%
- Bioequivalence 35%

911 BIMO Inspections

*Based on inspection start date – [Complis database as of January 20, 2016]
Clinical Investigator Warning/NIDPOE Letters*
(CDER, FY 2006 - FY 2015)

*Based on letter issue date [Complis database as of January 20, 2016]
NIDPOE = Notice of Initiation of Disqualification Proceedings and Opportunity to Explain
FY 2016 OSI Enforcement

- CI Warning Letter: 7
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- PADE Warning Letter: 3
- Full Disqualification: 1
- BE Untitled Letter: 1
Office of Drug Security, Integrity, and Response (ODSIR): Focus

• Internet pharmacies
• Counterfeit and foreign approved drug actions
  – Indictments/Prosecutions
  – Letters to doctors
• Imports(exports
• Recalls
• Incident response
• International collaborations
• Drug Supply Chain Security Act (DSCSA) implementation ("track and trace law")
The Drug Supply Chain Security Act (DSCSA) of 2013

Federal FD&C Act Sections:

- 581 – Definitions
- 582 – Requirements (product tracing, product identification, verification)
- 583 – Standards for licensure of wholesale distributors
- 584 – Standards for licensure of third-party logistics providers (3PL)
- 585 – Uniform national policy
Goals of the DSCSA

• Develop an electronic, interoperable system by 2023 to identify and trace certain prescription drugs as they move through the U.S. supply chain.

The new system will:
• facilitate the exchange of information by trading partners at the individual package level
• improve efficiency of recalls
• enable prompt response to suspect and illegitimate products when found
• create transparency and accountability in the drug supply chain

• Establish national standards for licensure for wholesale distributors and third-party logistics providers.
The DSCSA Path

3PL & Wholesale Distributor reporting to FDA 2014-2015

Product Tracing & Verification

Product Identification (Serialization) 2017-2018

Product Verification (down to package level) 2019+

Electronic, Interoperable System (product tracing down to package level) 2023

Licensure standards for 3PLs and wholesale distributors
Compounding Actions

Since enactment of the DQSA on November 27, 2013, FDA has:

- Conducted approximately 425 inspections of compounders.
- Overseen over 90 recall events by compounders, and requested numerous compounders to cease operations.
- Issued over 130 warning letters; one addressed violations identified at four facilities.
- Issued over 30 letters referring findings from inspections of pharmacies that compounded their drugs in accordance with the conditions of section 503A to the states.
- Obtained 4 civil consent decrees of permanent injunction.
- Sought several criminal prosecutions.

www.fda.gov
Inspection Observations

• Continue to identify insanitary conditions at many of the compounding facilities inspected
  – Dog beds and hairs in close proximity to sterile compounding room
  – Dead bugs in ceilings
  – Renovations being made without evidence of controls to prevent contamination
  – Compounding by personnel with exposed skin
Other Compounding Actions

- Issued over 20 guidance documents
- Issued final rule and proposed rule describing additions and modifications to the Withdrawn or Removed List (503A and 503B)
- Solicited nominations for 503A and 503B bulks lists and for drugs that are difficult to compound under sections 503A and 503B
- Held 6 meetings of the Pharmacy Compounding Advisory Committee
- Held 4 sets of listening sessions with over 75 stakeholders
- Held 4 intergovernmental working meetings with the states
What’s next....

• New legislation...
  – User fee reauthorization
  – 21st Century Cures?

• Continue implementation of DQSA
  (compounding/track and trace)

• Focus on quality/safety and data integrity

• Guidance and standards for compliance

• Program alignment

• More....
Thank You

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Center for Devices and Radiological Health

Carl Fischer, PhD
Senior Advisor
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Center for Devices and Radiological Health
Medical Device QS Surveillance Inspections CY2008—CY2015

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<thead>
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<th>Year</th>
<th>Domestic</th>
<th>Foreign</th>
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<td>210</td>
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<td>2014</td>
<td>1619</td>
<td>594</td>
</tr>
<tr>
<td>2015</td>
<td>1484</td>
<td>620</td>
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### CY2015 QS Medical Device Inspections

<table>
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<tr>
<th>Total Domestic Inspections</th>
<th>Total Foreign Inspections</th>
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</thead>
<tbody>
<tr>
<td>1484</td>
<td>620</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Domestic Inspection Outcomes</th>
<th>Foreign Inspection Outcomes</th>
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</thead>
<tbody>
<tr>
<td>NAI</td>
<td>NAI</td>
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<tr>
<td>49%</td>
<td>39%</td>
</tr>
<tr>
<td>VAI</td>
<td>VAI</td>
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<tr>
<td>41%</td>
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<td>OAI</td>
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<tr>
<td>10%</td>
<td>15%</td>
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</tbody>
</table>
Foreign and Domestic WLs with QS Citations

- Total
- Domestic WLs
- Foreign WLs


- Total: 113, 97, 79, 74, 98, 77, 89, 122, 98, 74, 45, 59
- Domestic WLs: 70, 76, 62
User Facility Inspections

• 17 facilities
• Related to contaminated duodenoscopes and morcellators
• Regulatory approach
• Public workshop on improving hospital-based surveillance systems
Medical Device Single Audit Program

• Auditing Organizations – 6 of 13 authorized to conduct MDSAP audits. All 13 working toward recognition

• 152 Participating manufacturing sites
  – 94 domestic locations
  – 58 international locations

• 117 Audit Reports Received to Date
  – 73 – U.S. Audits
  – 44 – International Audits

• Regulatory Exchange Platform – secure
Benefit-Risk Goals

Opportunity to develop and implement a set of principles that...

• Allow CDRH to arrive at the same risk determinations for medical devices
• Weigh the relative benefits and risks of options for pre and post market product quality and safety activities
• Minimize disruption of care and protect the public health
Examples Related to Product Availability Decisions

- Recall and shortage
- Evaluation of a variance petition
- Continued Access to Nonconforming Product

Examples Related to Compliance and Enforcement Decisions

- Evaluation of whether to send an Warning Letter or take an alternative approach
- Evaluation of potential actions following an inspection of a manufacturer with observed Quality System deficiencies
Compliance ≠ Quality

• Quality is *more* than being free from defect and cannot be achieved by complying with a set of rules

• Quality is about products aligned with the needs of providers and patients that are produced in a reliable and trustworthy manner.

***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.***
Case for Quality Goals

- Identify new metrics for measuring, monitoring, and controlling device quality
- Collaborate on performance and organizational expectations that result in higher quality
- Explore policies and practices that foster a culture of quality
- Advance solutions for increasingly complex and dynamic ecosystems
Case for Quality Vision

Shift the medical device ecosystem to focus beyond regulatory compliance to sustained device quality for improved patient outcomes.
Real World Evidence
Will build upon and leverage the information created everyday as a part of routine health care or real world evidence.

Post Market Benefit Risk Initiative
Patient focused, appropriately scoped and informed decisions by manufactures and FDA

Case for Quality
Will identify and promote practices that result in high-quality devices and adapt FDA regulatory approaches to align with those practices
Compliance Central: CBER Update
FDLI Enforcement, Litigation and Compliance Conference

December 7, 2016
Mary Malarkey, Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research/FDA
Office of Compliance and Biologics Quality

OCBQ – Director, Mary Malarkey
OCBQ - Deputy Director – Melissa Mendoza

Division of Case Management
DCM Director, Bob Sausville

Division of Inspections and Surveillance
DIS Director, Carrie Mampilly

Division of Manufacturing and Product Quality
DMPQ Director, Jay Eltermann
DMPQ Deputy Director – Laurie Norwood

Division of Biological Standards and Quality Control
DBSQC Director - Dr. Bill McCormick
OCBQ’s mission is to ensure the quality of products regulated by CBER over their entire lifecycle through pre-market review and inspection, and post-market review, surveillance, inspection, outreach and compliance.
Postmarket/Inspectional: Drugs and Devices

**One Warning Letter based on inspection of multiple facilities  ***as of November 30, 2016
Biological Drugs and Devices GMP/GTP Compliance Actions – FY15 – FY17*

• **Warning Letters**
  – CGMP deviations/need for premarket review and approval (1271.10(a))
  – Need for premarket review (device)

• **Untitled Letters**
  – Unapproved device
  – Unapproved biological drug
  – Need for premarket review and approval (1271.10(a))
  – QS regulation deviations/need for premarket review (device)
  – CGMP deviations

* as of November 30, 2016
BIORESEARCH MONITORING

• **Disqualification of an IRB.** The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines, per 21 CFR 56.121(b), that:

1. The IRB has refused or repeatedly failed to comply with any of the applicable regulations, and
2. The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.
First Order of Disqualification for an IRB

• Order dated February 29, 2016
• Texas Applied Biomedical Services
dba Texas Applied Biotechnology Research Review Committee IRB
dba TABS Research Review Committee IRB # 1
http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/complianceenforcement/ucm369514.htm
Some Current Priorities
New Technology/Product Initiative

• Prepare staff in CBER and ORA for review and inspection of new products, often breakthrough therapies.
• Develop agile approaches to introduce new technologies/manufacturing processes.
• “Horizon scanning”
Implementation of New Regulations

• Final rule, “Submission of Food and Drug Administration Import Data in the Automated Commercial Environment,” ACE
Implementation of Voluntary Reporting Program

• Draft Guidance for Industry – “Submission of Quality Metrics Data”
  • “FDA is initiating a voluntary reporting phase of the FDA quality metrics reporting program.”
  • Lot Acceptance Rate (LAR); Product Quality Complaint Rate (PQCR); Invalidated Out-of-Specification (OOS) Rate.
  • Excludes blood and blood components, vaccines, allergenics and human cells, tissues and cellular and tissue-based products.
• Facilitating development of donor screening tests and vaccines for Zika – providing guidance to industry.
• Working closely with our colleagues in ORA to provide guidance and support, at present in SJN-DO and FLA-DO.
• Continue to be part of an intergovernmental working group facilitating importation and exportation by providing communication channels between all relevant government components: CBP, HHS/BARDA, FDA, CDC, USDA/APHIS, DOT, FWS, DOC/BIS
Public Access to CBER

CBER website:
http://www.fda.gov/BiologicsBloodVaccines/default.htm

Phone: 1-800-835-4709 or 301-827-1800

Consumer Affairs Branch (CAB)
Email: ocod@fda.hhs.gov
Phone: 301-827-3821

Manufacturers Assistance and Technical Training Branch (MATTB)
Email: industry.biologics@fda.gov
Phone: 301-827-4081

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Adulterated
Misbranded
Unapproved
Health fraud
Data integrity
CGMP violations
GCP violations
Compounding
More…
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• enable prompt response to suspect and illegitimate products when found
• create transparency and accountability in the drug supply chain

• Establish national standards for licensure for wholesale distributors and third-party logistics providers.
The DSCSA Path

- Licensure standards for 3PLs and wholesale distributors
- 3PL & Wholesale Distributor reporting to FDA 2014-2015
- Product Tracing & Verification
- Authorized Trading Partners 2015
- Product Identification (Serialization) 2017-2018
- Product Verification (down to package level) 2019+
- Electronic, Interoperable System (product tracing down to package level) 2023
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• New legislation...
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  – 21st Century Cures?
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• Focus on quality/safety and data integrity
• Guidance and standards for compliance
• Program alignment
• More....
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