



Goals and Priorities

ORA and Denver District

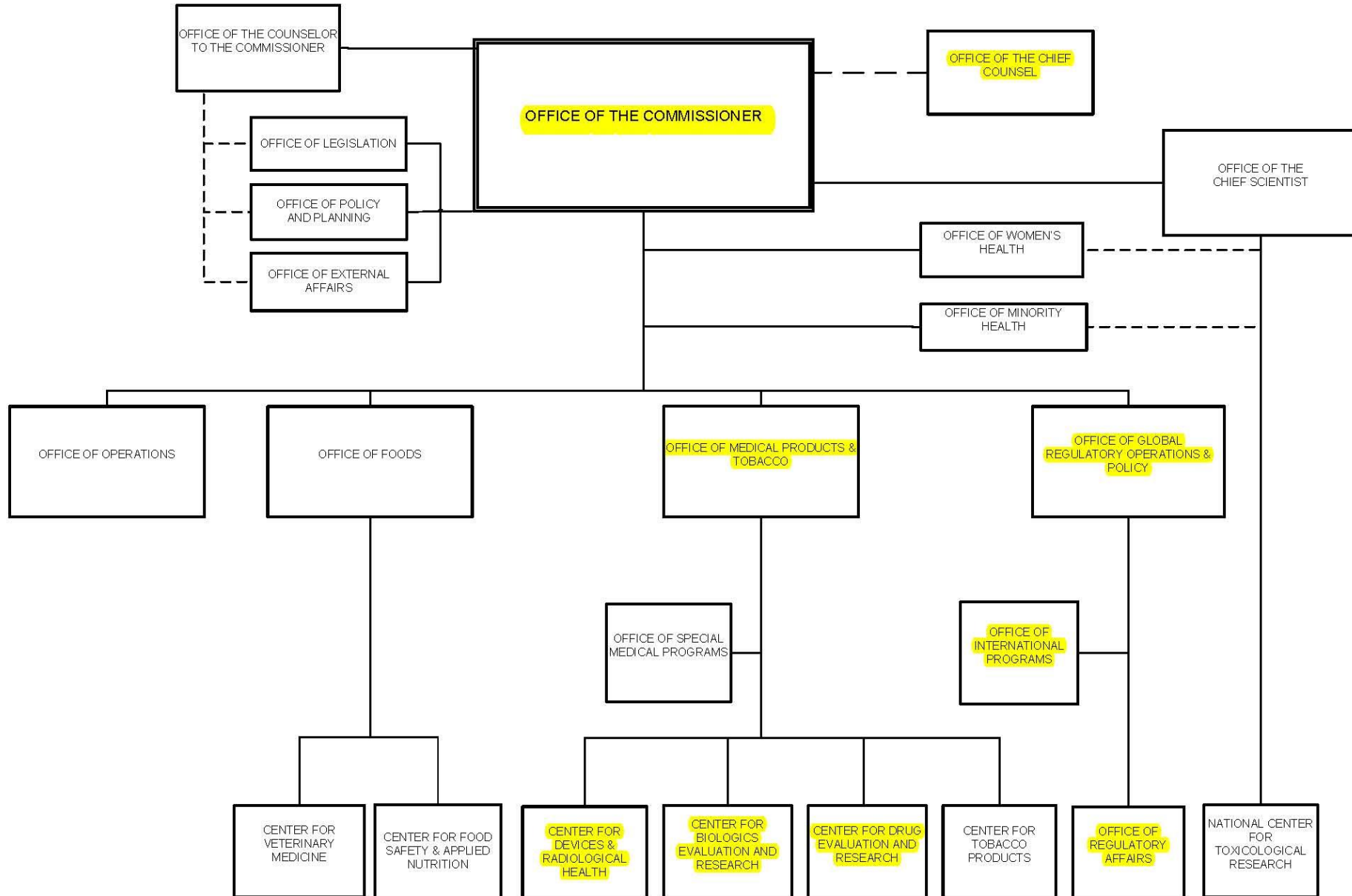
Devin Koontz
Public Affairs Specialist
Denver District Office
Office of Regulatory Affairs
Office of Global Regulatory Operations & Policy



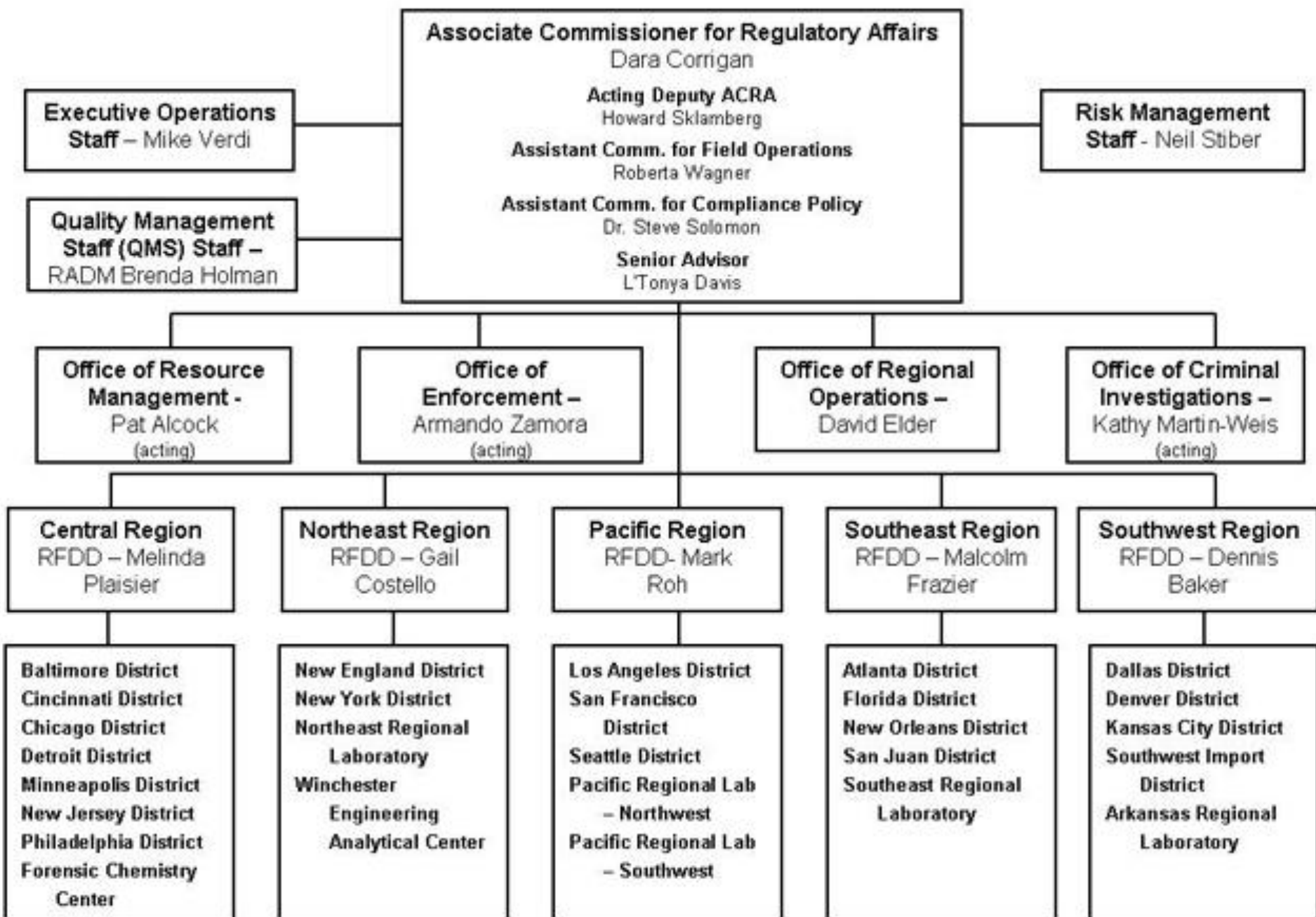
Office of Commissioner (OC) Reorganization

- **Formation of Offices/Directorates Led by Deputy Commissioners**
 - **Office/Directorate Food & Feed** **Mike Taylor, JD**
 - CVM, CFSAN
 - **Office/Directorate Medical Products & Tobacco** – **Dr. Steven Spielberg**
 - CDER, CDRH, CBER, CTP
 - **Office/Directorate of Global Regulatory Operations and Policy** – **Deb Autor, JD**
 - ORA, OIP

FOOD AND DRUG ADMINISTRATION



Office of Regulatory Affairs Organizational Chart



ORA Changes – ACRA's Immediate Office

Associate Commissioner for Regulatory Affairs (ACRA): Dara Corrigan

- **Assistant Commissioners**
 - **Howard Sklamberg**
 - **Steve Solomon**
 - **Roberta Wagner**
- **Senior Advisor for IT, Robin Crisp**
- **Senior Advisor for Federal/State Relations, Joe Reardon**
- **Senior Advisor/Chief of Staff, L'Tonya Davis**
 - **Communications Director, Peter Ashkenaz**
 - **Executive Operations Lead, Mike Verdi**
- **Chief Scientist, (vacant)**
- **Director, Office of Resource Management, (vacant)**
- **Director, Office of Criminal Investigations, (vacant)**

Commissioner's Priorities for ORA

- **Globalization & Partnerships**
 - Recommendations in “Pathway to Global Product Safety & Quality” Report
 - National Integrated Food Safety System; FSMA Mandates
- **Infrastructure**
 - Science
 - Laboratory
 - IT
- **Operational Efficiency & Productivity**
 - Inspections
 - Recalls
 - Emergency Response
- **Office of Criminal Investigations**

ORA FY12 Priorities

Efficiency/Productivity Improvements

- **Emergency Response**
 - **CORE Network**
- **Recalls**
- **Inspection**
 - **Conduct**
 - **Report Writing**
 - **Evidence Documentation**
- **Enforcement**
 - **Timeliness of W/L close outs/reinspection of non-compliant firms (OAI)**
 - **Streamlining seizure & injunction actions**
- **Miscellaneous Business Process Improvements**
 - **QMS**

ORA FY12 Priorities

Inspectional/Enforcement

Productivity & Resources Study

- **"Efficiency" Initiative – Five Projects**
 - **Eliminate/reduce the collection of documentation for interstate commerce**
 - **Implementation of component inspections for foods**
 - **Institutionalize two system inspections for drugs**
 - **Outsource recall audit checks**
 - **Expand use of hand helds for inspections**



LaTonya M. Mitchell
DISTRICT DIRECTOR

Vacant
Deputy District Director

Cyndy T. Coca
District Director's Secretary

Ronnie G. Masters
Quality Systems Manager

Lawrence A. Sproul
Quality Systems Manager

Vacant
State Liaison

CDR William D. Boden
Emergency Response Coordinator

Devin J. Koontz
Public Affairs Specialist

Donald W. Byars
Administrative Officer
Management & Program Support Staff

Howard E. Manresa
Director
Compliance Branch

Vacant
Director
Investigations Branch

Mark R. Madson
Director
Science Branch

Salt Lake City Resident Post

Albuquerque Resident Post

Animal Drugs Research Center



DEN-DO Staff Growth

	On Board Mid-Year	Ceiling
2001	102	99
2009	111	115
2010	126	145
Current	129	155

Investigations Staffing

- 5 Supervisory Groups
 - 40 CSO's on board
 - 5 vacancies to meet TO
- Specialties:
 - Devices: 7
 - Biologics/Tissue: 7
 - Pharmaceutical: 5
 - Most CSO's are not 100% dedicated to a commodity.

Science Branch Staffing

- 3 Microbiology and 3 Chemistry Sections
 - Also house Animal Drug Research Center
 - 41 Analysts on board
 - 11 vacancies to meet TO
- Specialties:
 - Microbiologists: 22
 - Chemists: 19

Denver District Priorities

- Workplan and Performance Goals
- Working with State Counterparts
- Laboratory
- Quality Management System
- Enforcement



FDA Enforcement Statistics Summary

Fiscal Year 2010

Seizures	10
Injunctions	17
Warning Letters	673
Recall Events	3,799
Recalled Products	9,361
Debarments	13

DEN-DO Enforcement Actions

FY 2011

21	Warning Letters (9 Med Device, 6 drug)
5	Untitled Letters (4 Med Device)
21	Regulatory Meetings
110	Denver District Initiated Recalls
122	FOIA Requests



Top 10 Citations Devices and Drugs

2011 - Device

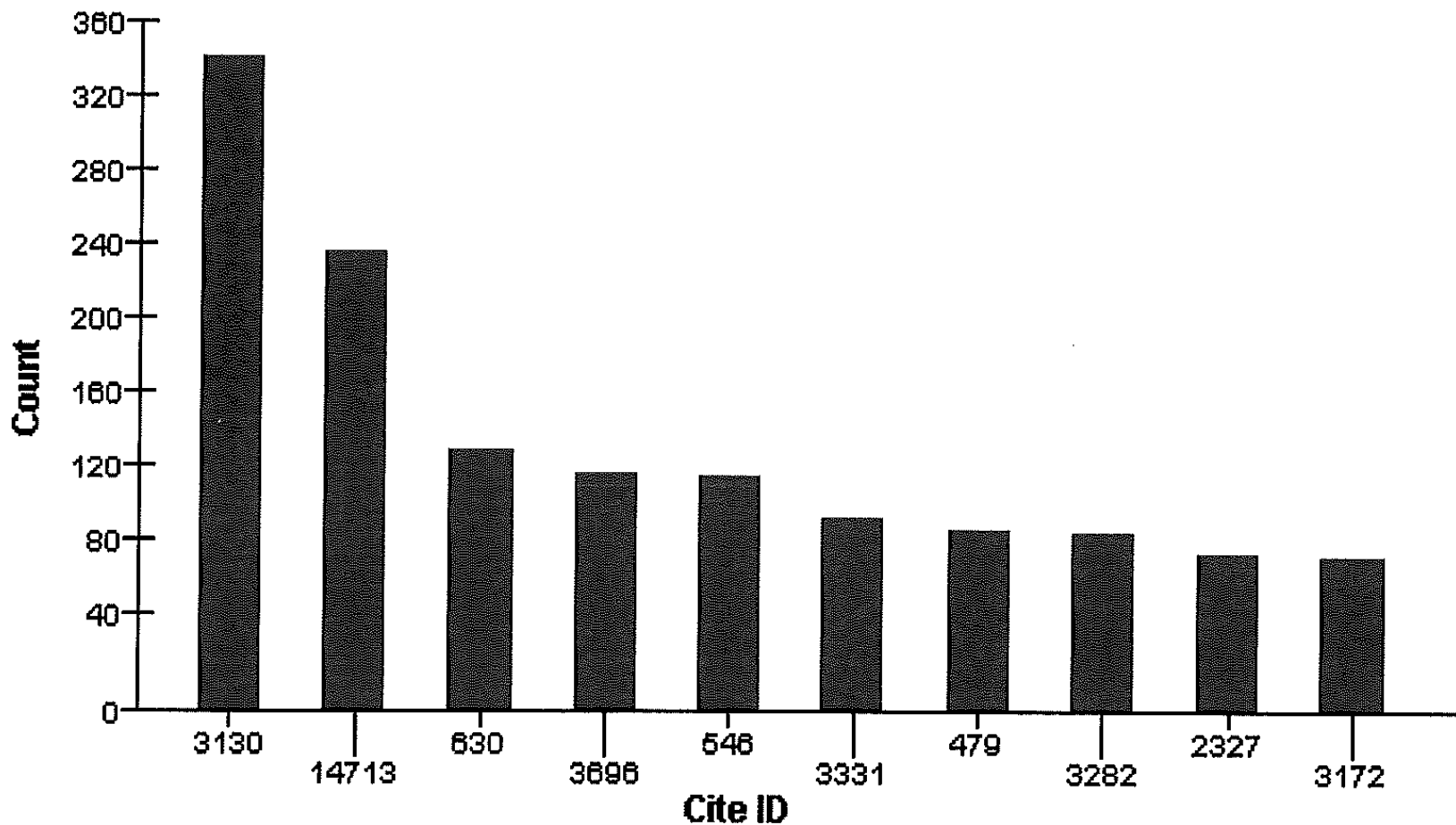
1. 820.100(a) – Corrective and Preventive Action Procedures
2. 820.198(a) – Complaint procedures
3. 803.17 – Written MDR procedures
4. 820.100(b) – Corrective and Preventive Action (Documentation)
5. 820.75(a) – Inadequate Validation (process)

2011 - Device

- 6. **820.181** – No Device Master Record
- 7. 820.50 – Purchasing Procedures
- 8. 820.90(a) – Control Procedures for non-conforming products
- 9. 820.22 – Quality Audit (Procedures)
- 10. 820.198(c) – Complaint Handling



Top 10 Devices Observations Used in Turbo EIR Between 01/01/2011 And 12/31/2011 As of 01/18/2012

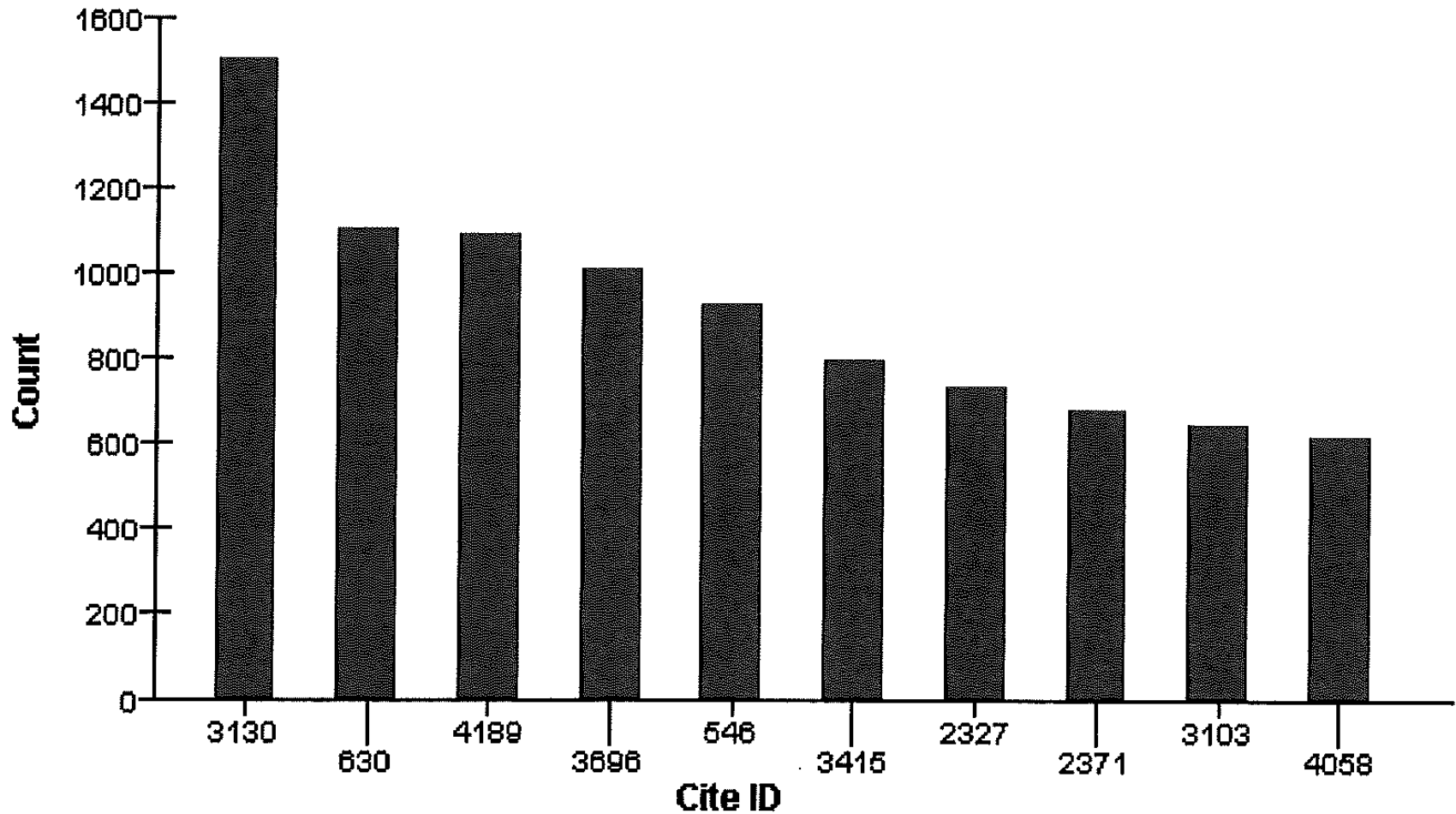


Top Five Device (1998 – Present)

1. 820.100(a) – Corrective and Preventive Action Procedures
2. 803.17 – Written MDR procedures
3. 820.198(a) – Complaint procedures
4. 820.100(b) – Corrective and Preventive Action (Documentation)
5. 820.75(a) – Inadequate Validation (process)



Top 10 Devices Observations Used in Turbo EIR As of 01/18/2012.



TOP FOUR FDA 483 CITATIONS FOR MEDICAL DEVICE FIRMS

Number One

- **Inadequate corrective and preventive actions procedures (CAPA) – 21 CFR 820.100(a).**
 - **For example:**
 - **Failure to analyze processes, service records, quality audit reports, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product;**
 - **Cause of nonconformities relating to product, processes and the quality system are not investigated;**
 - **Actions needed to correct and prevent recurrence of nonconforming product or other quality problems are not identified;**

TOP FOUR FDA 483 CITATIONS FOR MEDICAL DEVICE FIRMS

Number Two

- **Inadequate complaint handling procedures – 21 CFR 820.198(a).**
 - **For example:**
 - **Complaints are not processed in a uniform or timely manner;**
 - **are not documented; or**
 - **have not been evaluated for MDR applicability.**²³

TOP FOUR FDA 483 CITATIONS FOR MEDICAL DEVICE FIRMS

Number Three

- **Failure to document all corrective and preventive actions – 21 CFR 820.100(b);**

TOP FOUR FDA 483 CITATIONS FOR MEDICAL DEVICE FIRMS

Number Four

- **Inadequate MDR procedures – 21 CFR 803.17**
 - **For example:**
 - **Failure to develop, maintain, and implement written MDR procedures**

2011 - Drug

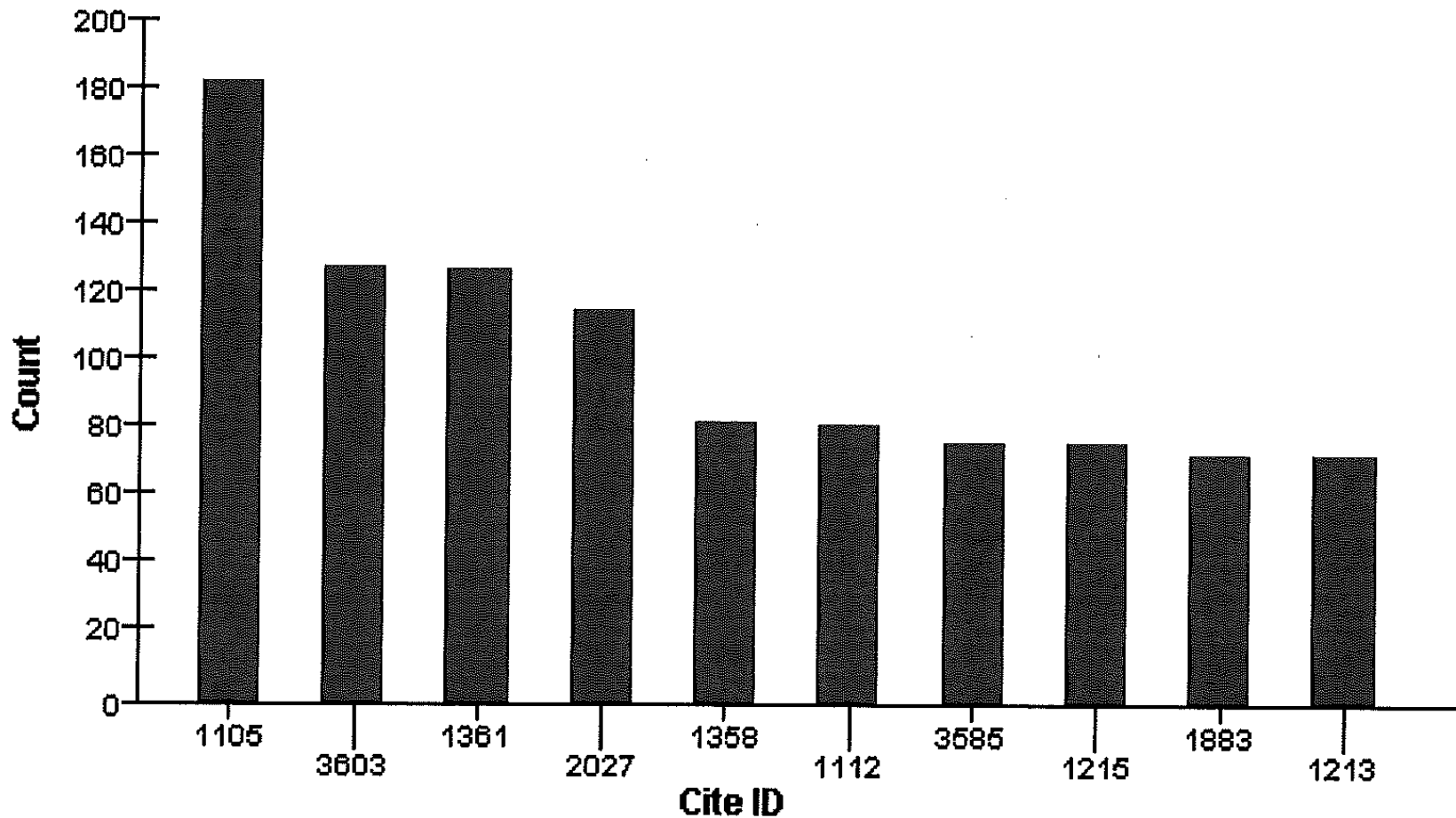
1. 211.22(d) – Quality Control Unit (R&P)
Not in writing/followed
2. 211.160(b) – Laboratory Controls
3. 211.100(a) – No Written Procedures for
production/process controls
4. 211.192 – Batch Failures
5. 211.100(b) – Written Procedures are not
followed

2011 - Drug

6. 211.25(a) – Employee Training
7. 211.110(a) – Control Procedures not established (mfr processes)
8. 211.67(b) – Written Procedures not followed (cleaning and maintenance of equipment)
9. 211.165(a) – Testing and Release procedures
10. 211.67(a) – Inadequate Cleaning intervals



Top 10 Drugs Observations Used in Turbo EIR Between 01/01/2011 And 12/31/2011 As of 01/22/2012

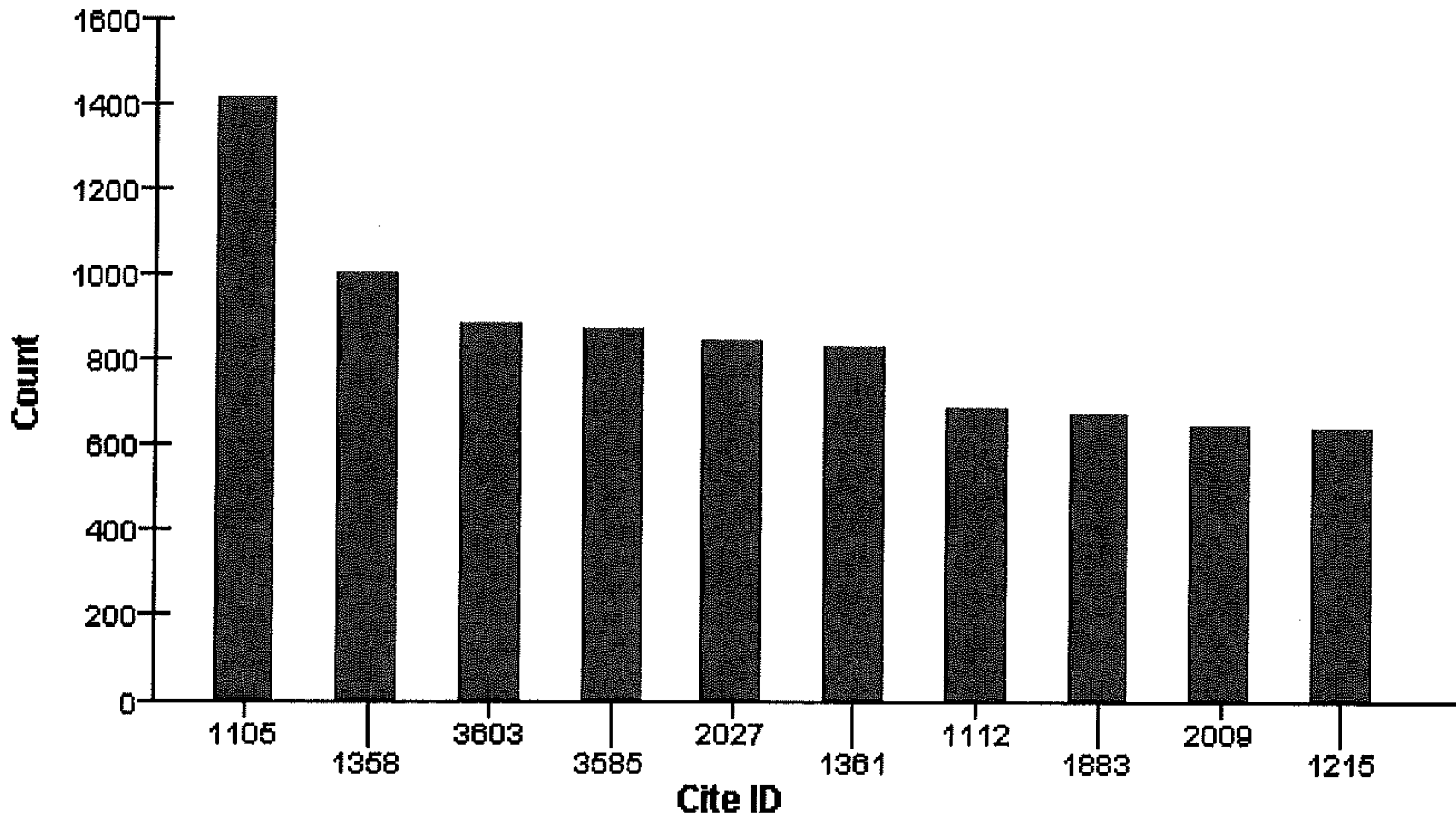


Top Five Drug (1998 – Present)

1. 211.22(d) – Quality Control Unit (R&P)
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2. 211.100(b) – Written Procedures are not followed
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5. 211.192 – Batch Failures



Top 10 Drugs Observations Used in Turbo EIR As of 01/22/2012.



Review of Post-Inspection Responses



- FDA will allow firms **15 business days** after the FDA 483 was issued, to provide a response
- If received within 15 business days,
 - FDA will perform a detailed review of the response before determining whether to issue a warning letter.
 - Any warning letter issued will recognize receipt of the response and the adequacy of the firm's corrective actions.

Review of Post-Inspection Responses, cont.

- **Ongoing or promised corrective actions generally will not preclude the issuance of a warning letter.**
- **Responses received after 15 business days will be evaluated separately from the warning letter**

Warning Letter Close Out

- **If FDA determines that a firm has adequately corrected Warning Letter violations, FDA will send a close-out letter.**
 - Applies to Warning Letters issued after September 1, 2009.
- **FDA will indicate close-out on its website:**



- <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

Questions?

