

Passion for Quality

Effective CaPa Systems The Biggest Opportunities



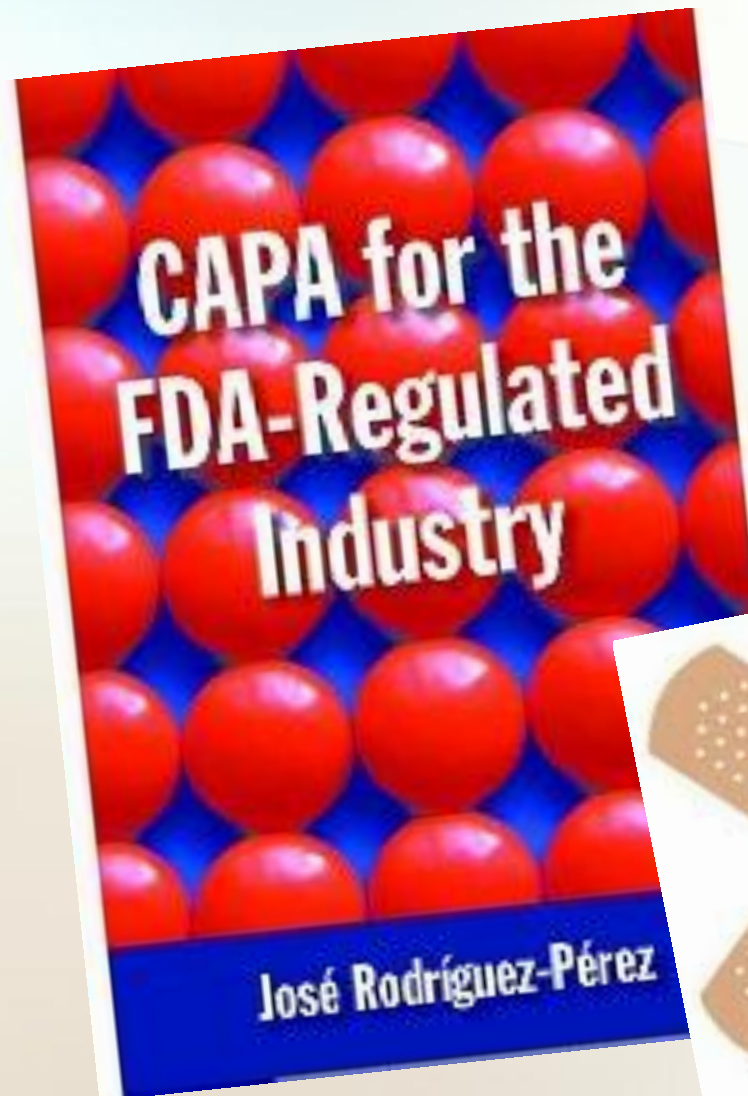
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Passion for CAPA



FD& C Acts

“A drug shall be deemed adulterated if:
... the *methods* used in, or the *facilities*
or *controls* used for, its *manufacture*,
processing, *packing*, or *holding* do not
conform to or are not operated or
administered in conformity with current
good manufacturing practice ...”

General Principles 21 CFR 4

Adulteration includes the failure to manufacture a product in accordance with applicable cGMP requirements, regardless of whether the product appears to meet its final specifications.

FDA Pharmaceutical cGMP (21 CFR 211) 1978

Sec. 211.22 Responsibilities of quality control unit.

- There shall be a quality control unit ... and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

Sec. 211.100 Written procedures; deviations.

- Written production and process control procedures shall be followed Any deviation from the written procedures shall be recorded and justified.

cGMP (21 CFR 211) 1978

Subpart J:Records and Reports

§ 211.192 Production record review.

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.

820.100 Corrective and Preventive Action.

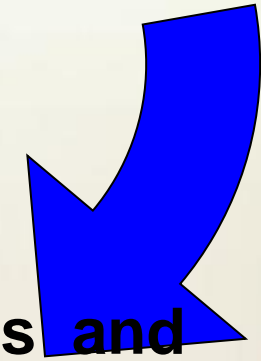
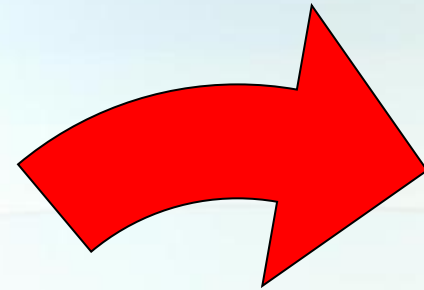
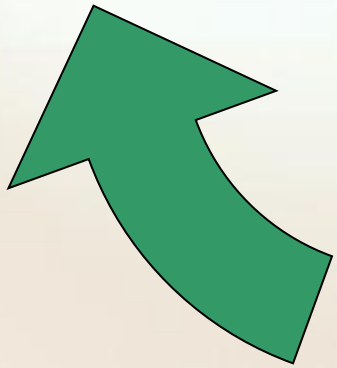
- (a) **Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:**
- ★ (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
 - ★ (2) Investigating the cause of nonconformities relating to product, processes, and the quality system;
 - ★ (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
 - ★ (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
 - ★ (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
 - ★ (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
 - ★ (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.
- (b) **All activities required under this section, and their results, shall be documented.**

The Vicious Circle

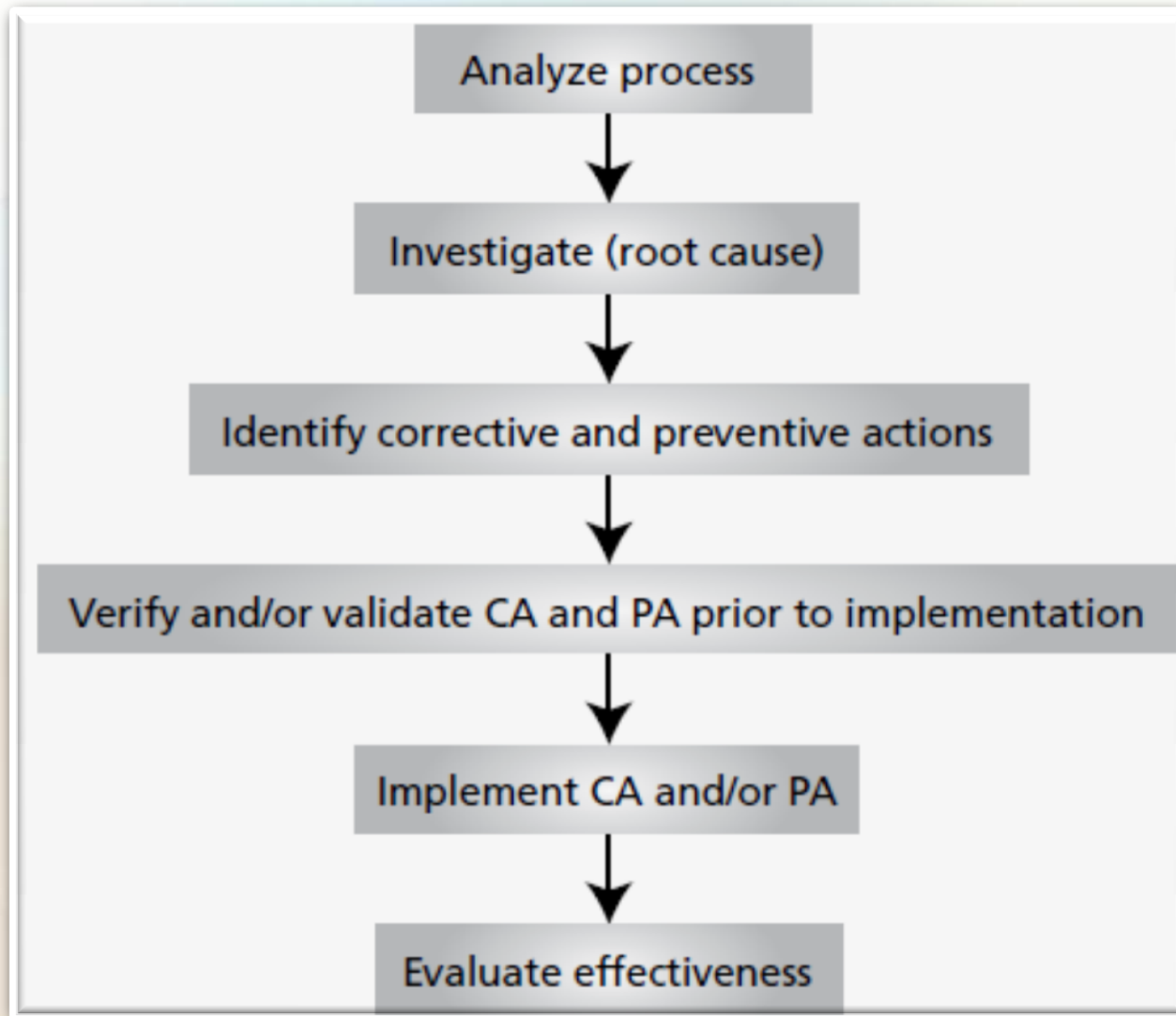
**“Inadequate” Investigations
without root cause analysis**

**Ineffective
Corrective Actions
and lacks of
Preventive Actions**

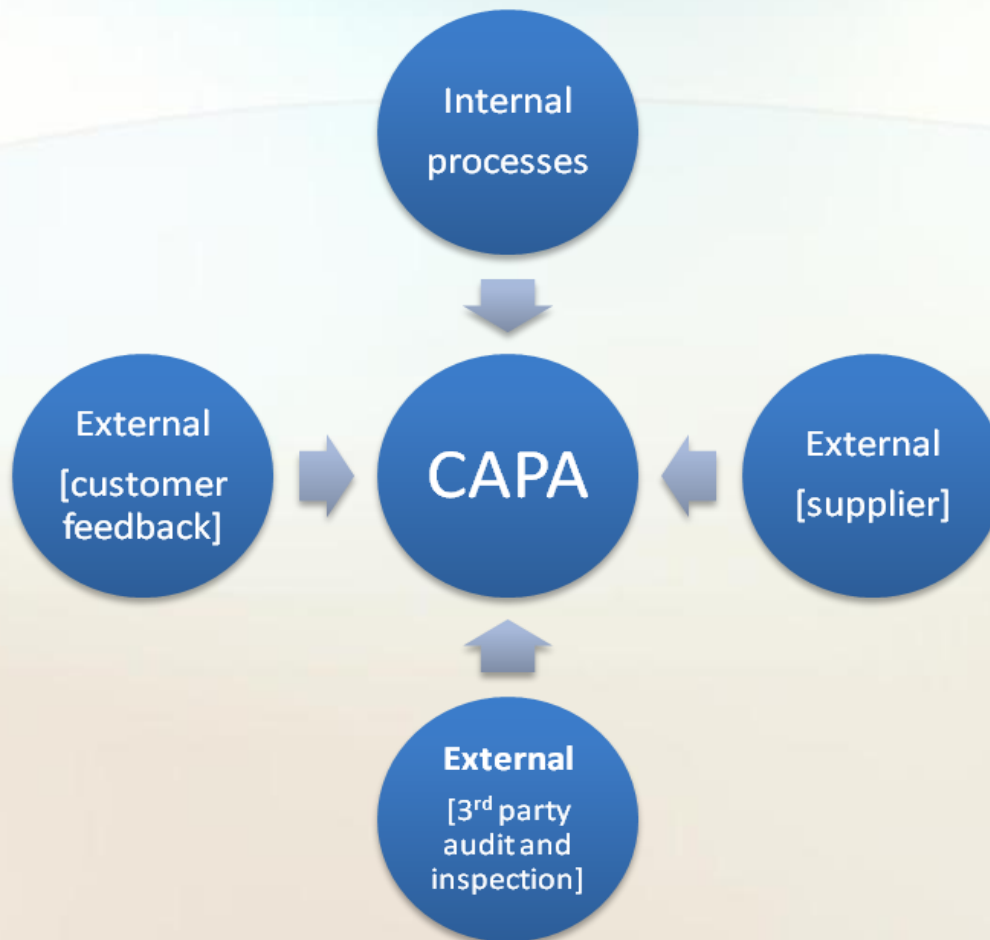
**Recurrent issues and
new problems never avoided**



The correct CAPA flow



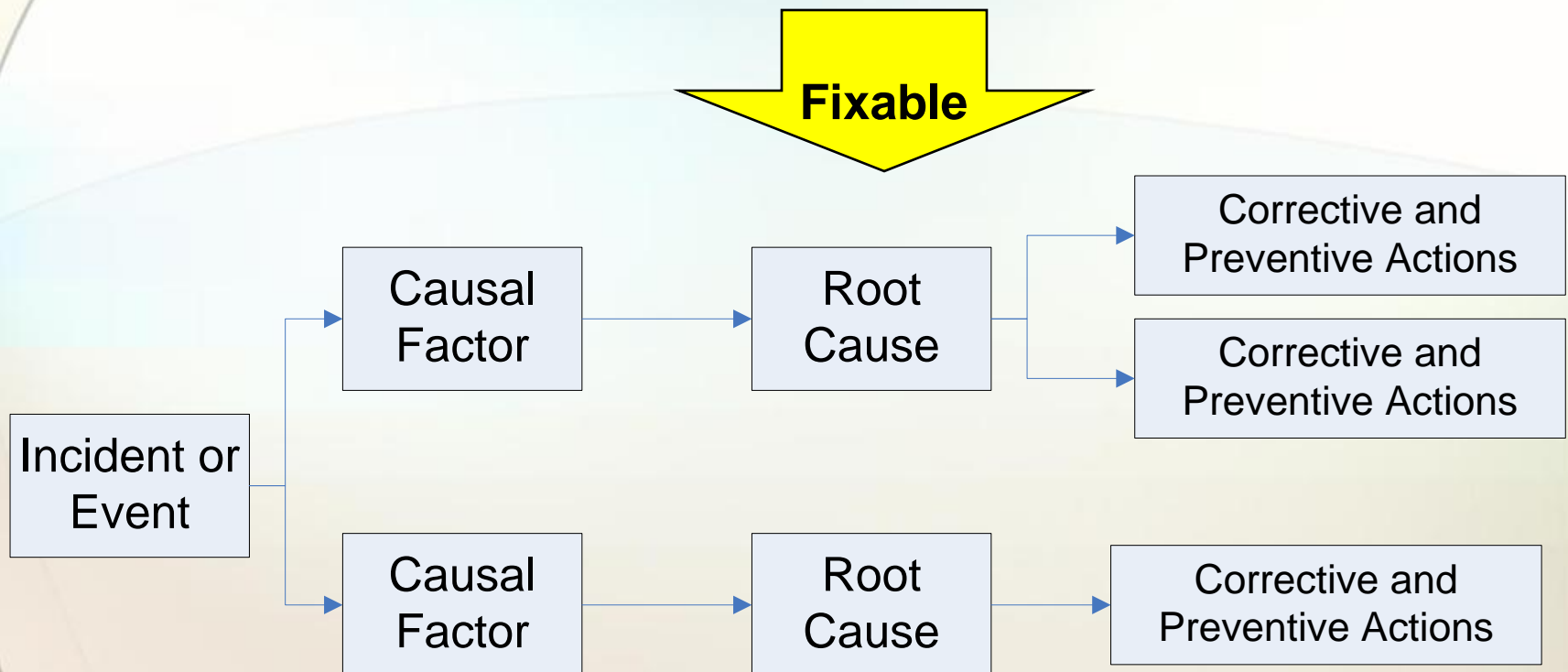
Feeders of the CAPA system



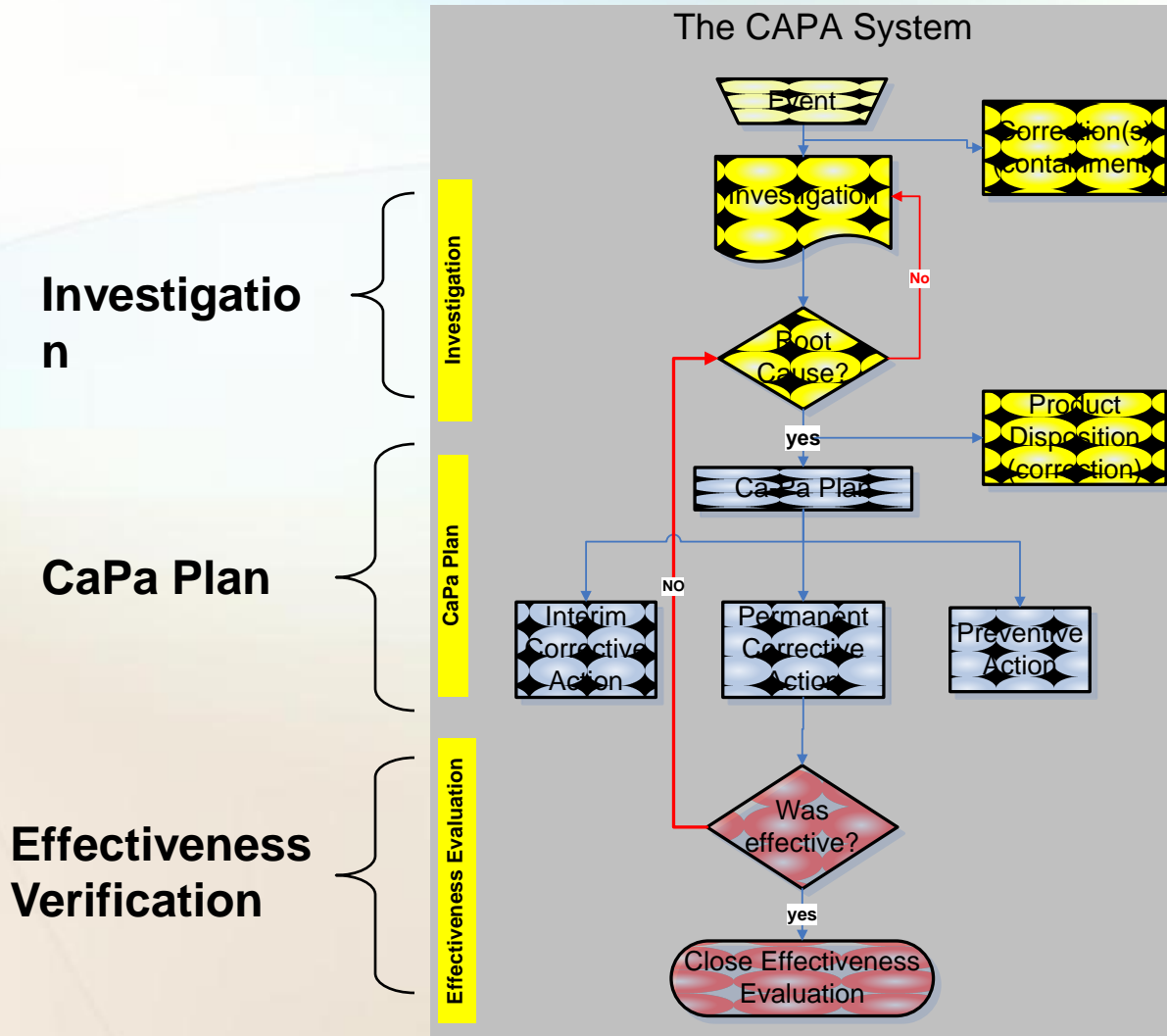
CAPA-centric Focus



Root Cause Identification



The Closed Loop CAPA Process



Key Definitions of the CAPA System

- ✦ Correction / Remedial Action
- ✦ Corrective Action
- ✦ Effectiveness Evaluation
- ✦ Preventive Action
- ✦ Nonconforming Material
- ✦ Factor Causal
- ✦ Root Cause & Root Cause Analysis
- ✦ Timely
- ✦ Trend

Definitions

- ★ **Correction / Remedial Action** – action to eliminate a detected nonconformity. Corrections typically are one-time fixes. A correction is an immediate solution.
- ★ **Corrective action** – action to eliminate the cause(s) of a detected nonconformity or other undesirable situation. The corrective action should **eliminate the recurrence** of the issue.
- ★ **Preventive action** – action to eliminate the cause of a potential nonconformity or other undesirable potential situation. The preventive action should eliminate or **prevent the occurrence** of the potential issue.

More definitions

- ★ ***Nonconforming material*** – material that does not meet quality acceptance criteria as defined by a specification or similar document or material that has been determined to be not fit for use.
- ★ ***Effectiveness evaluation*** – documented process to establish that an action was effective and accomplished the objective that was intended.
- ★ ***Trend*** – a sequence or pattern of data. Analysis of a trend is performed to detect a special cause amidst the random variation of data.
- ★ ***Timely*** – taking action in a timeframe commensurate with the risk and magnitude of the issue and in a manner that would be taken by a reasonable company that is concerned with protecting the public health.

More definitions

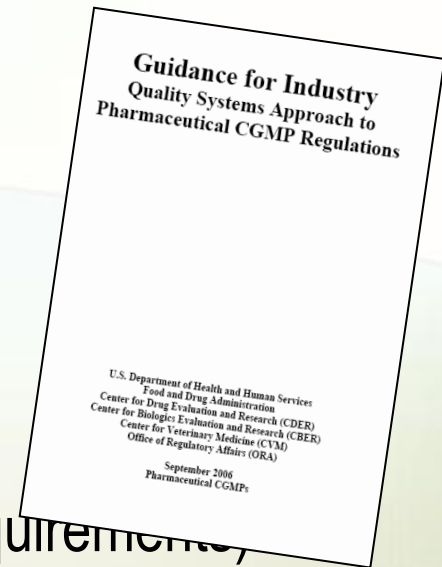
- ★ **Causal Factor** - Any failure (human, equipment or material/component) that directly caused the incident, allowed it to occur, or allowed the consequence to be worse
- ★ **Root Cause** - A gap in a process input or supporting business system that is, at least partly, responsible for the incident
 - ★ Basic reasons why causal factors occur and/or persist
- ★ **Root Cause Analysis** – the analysis necessary to determine the original or true cause of a system, product, or process nonconformity. This effort extends beyond the effects of a problem to discover its most fundamental cause.

cGMP Implementation Tools

★ cGMP Guidance Documents

★ Principles:

- ★ Not requirements
 - ★ Agency “current thinking”
 - ★ Detailed, technical
 - ★ Expression of “How to” meet “what to” do (requirements)
- ✓ Guide to Inspection of Pharmaceutical QC Labs [1993]
 - ✓ Guide to Inspection of Microbiological QC Labs [1993]
 - ✓ “Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production.” [2006]



OOS Guidance (2006)

Contains Nonbinding Recommendations

system, a firm's upper management should appropriately monitor these trends and ensure that

Please note that § 211.192 requires a thorough investigation of any discrepancy, including documentation of conclusions and follow-up. Implicit in this requirement for investigation is the need to implement corrective and preventative actions. Corrective and preventive action is consistent with the FDA's requirements under 21 CFR part 820, subpart J, pertaining to medical devices, as well as the 2004 draft guidance entitled *Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations*, which, when finalized, will represent the

Agency's current thinking on this topic



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OOS Guidance (2006)

Quality Systems Approach to Pharmaceutical cGMP (Sept 06)

- ★ *“Quality System models discuss CAPA as three concept, all of which are used in this guidance:*
 - ★ *Remedial corrections*
 - ★ **Root Cause Analysis** *with corrective action to prevent recurrence*
 - ★ *Preventive action to prevent initial occurrence*

From a local Warning Letter

- ★ “Documentation of several OOS investigations reviewed during the inspection did not contain recommended follow-up and did not address corrective and preventative actions”
- ★ “Failure to comply with 21 CFR Part 211.192. Your firm failed to identify and correct the root cause for the OOS for assay and fill weight for the XXXX product. Your inability to identify the root cause of the OOS results prevent you from implementing the appropriate corrective actions to ensure the quality of each unit being distributed”

Adulteration and CAPA

FDA Enforcement Report for October 18, 2006

October 18, 2006
06-42

RECALLS AND FIELD CORRECTIONS: DRUGS -- CLASS II

PRODUCT

Gilpizide tablets, 10mg, Rx Only, 100 tablet bottles, NDC 0172-3650-60, Recall # D-002-7

CODE

Lot: 146630A, exp. 01/2008

RECALLING FIRM/MANUFACTURER

Recalling Firm: IVAX Pharmaceuticals, Miami, FL, by letters on July 11, 2006.

Manufacturer: IVAX Pharmaceuticals, Inc., Cidra, PR. Firm initiated recall is ongoing.

REASON

Incomplete laboratory testing investigation.

VOLUME OF PRODUCT IN COMMERCE

10,824/100 tablet bottles

DISTRIBUTION

KY and TN

483 Observation

- The investigation report TWR #1484 for finished product testing _____ was specifically for related compounds and impurities testing. For impurities testing, the analysts are instructed to rinse glassware before use as part of their cGLP training.
- In this instance, the investigation states that the analyst omitted to rinse the glassware. Therefore, a new dilution from the original stock solution was made with the impurity levels dropping to below a detectable level upon reanalysis.
- The corrective action for this investigation as stated in the TWR report was the counseling of the analyst in regard to glassware rinsing. According to the attached training record, the analyst was re-trained on the analytical test method STM #599, “Diltiazem HCl Once-A-Day Extended-release Capsule, 240 mg”. **This test method does not address the rinsing of glassware** for related compounds and impurities testing. There was no documented evidence of re-training the analyst on the proper procedure for glassware cleaning.

Inadequate Failure Investigations

- Not completed in a timely manner
- Incorrect assumption that everything is an isolated incident.
- Inadequate trending
- Failure to ensure problems do not extend to other lots
- Blame everything on employee or laboratory error
- Problem recurrence. Root causes are not identified and corrected.

Causal Factor

Root Cause

Human error

- Procedure not clear
- Ambiguous or confusing instructions
- Lack of sufficient details
- Document format not adequate

Procedure not follow

- Training Instructor not adequate
- Insufficient practice or hands-on experience
- Frequency not adequate (insufficient refresher training)

Equipment failure

- Inadequate or defective design
- Inadequate installation or validation
- Historical lack of reliability
- Equipment not included in the maintenance program
- Corrective maintenance inadequate
- Preventive maintenance inadequate

Corrective or Preventive?

Situation	Examples
Name it <i>corrective action</i> only if you already have a product nonconformance or process noncompliance	<ul style="list-style-type: none">• Product failing specifications• Confirmed customer complaint• Use of obsolete documents• Audit finding of product nonconformance or process noncompliance
Name it <i>preventive action</i> whenever the product, process, or system is still in conformance but you discover root causes with the potential to create nonconformities	<ul style="list-style-type: none">• Developing adverse trends from a monitoring system (run chart or control chart)<ul style="list-style-type: none">– Shifts– Trends– High variability, and so on
Name it <i>preventive action</i> if it is purely a recommendation to enhance or improve any product, process, or system	<ul style="list-style-type: none">• Changing to new material or new design• Implement new (enhanced) processes

Eleven Biggest CAPA Opportunities

1. Timeliness
2. Everything is an Isolated Event
3. Root Cause not identified
4. Correcting the Symptoms Instead of the Cause
5. Lack of Interim Corrective Actions
6. Root Causes Identified but not Corrected
7. Lack of True Preventive Actions
8. Lack of Effectiveness Verification of the Action Taken
9. Multiple CAPA Systems without Correlation
10. Abuse of Human Error and Retraining
11. Over-customization of the CAPA System

Timeliness (lack of)

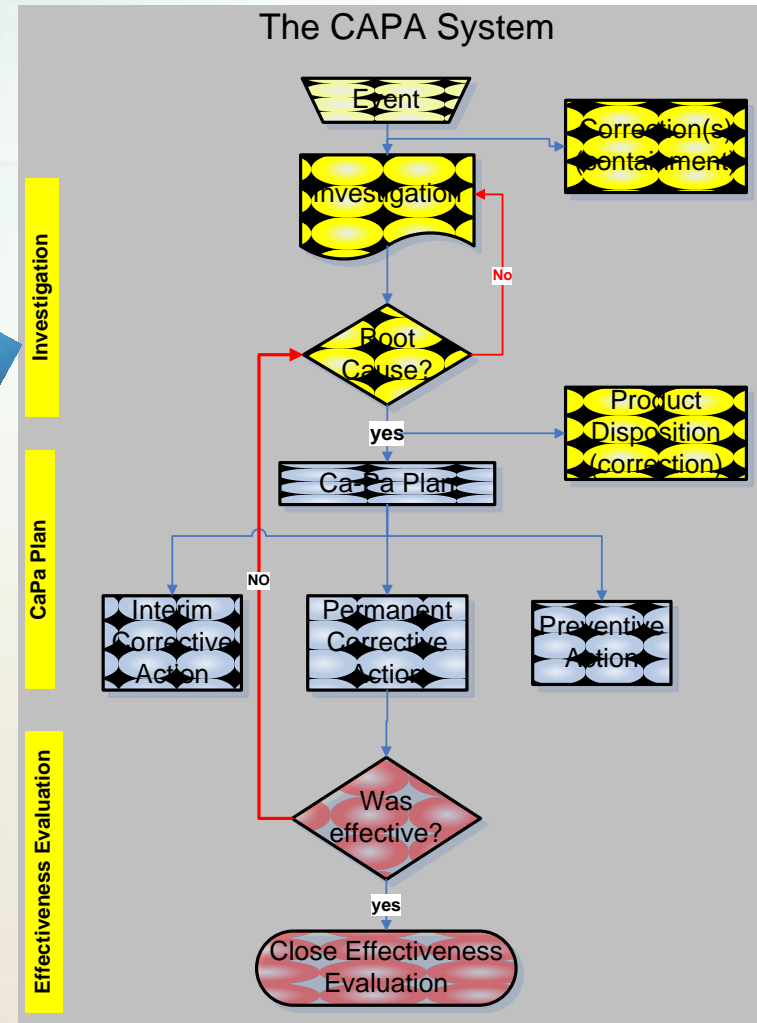
• A lot of focus on “close” within timeframe rather than close it effectively

• ¿30 days for the whole process, including evaluation of the effectiveness???

• 14, 21, 25, 30, 35, 40, 45, 90...



◆ *Timely: taking action in a timeframe reasonable (commensurate with the risk and magnitude of the issue) and in a manner that would be taken by a reasonable company that is concerned with protecting the public health.*



Timeliness

★ *FDA Guide to Inspections of Pharmaceutical Quality Control Laboratories (July 1993)*

- ★ All failure investigations should be performed within **20 business days** of the problem's occurrence and recorded and written into a failure or investigation report.

★ http://www.fda.gov/ora/inspect_ref/igs/iglist.html

★ *United States of America, Plaintiff, v. Barr Laboratories, Inc*

- ★ all failure investigations must be performed promptly, within **thirty business days** of the problem's occurrence, and recorded in written investigation or failure reports

How soon must firms complete CGMP failure investigations?

- The CGMP regulations, at 21 CFR 211.192, establish the requirement for an investigation, but do not explicitly state a time interval for completing it, including the preparation of a report. Our expectation for "closure" of a failure investigation (including any other "unexplained discrepancy") is that the investigation be conducted and reported in a **reasonable time**. The Barr decision called this "timely".
- We see both the 30 day time period in the court decision and the 20 day time period in the referenced inspectional guide as being reasonable or timely; **both are guidance and not requirements.**
- In discussing this topic, it may be helpful to point out what would not be reasonable, like performing an investigation but not progressing to a decision point as recorded in a final report/decision document, delaying a decision on investigation findings beyond the expiration date of the lot(s) in question, or delaying/excluding the investigation from CGMP or application related records which require their inclusion.

http://www.fda.gov/cder/hdn/cnotes37.htm#How_soon

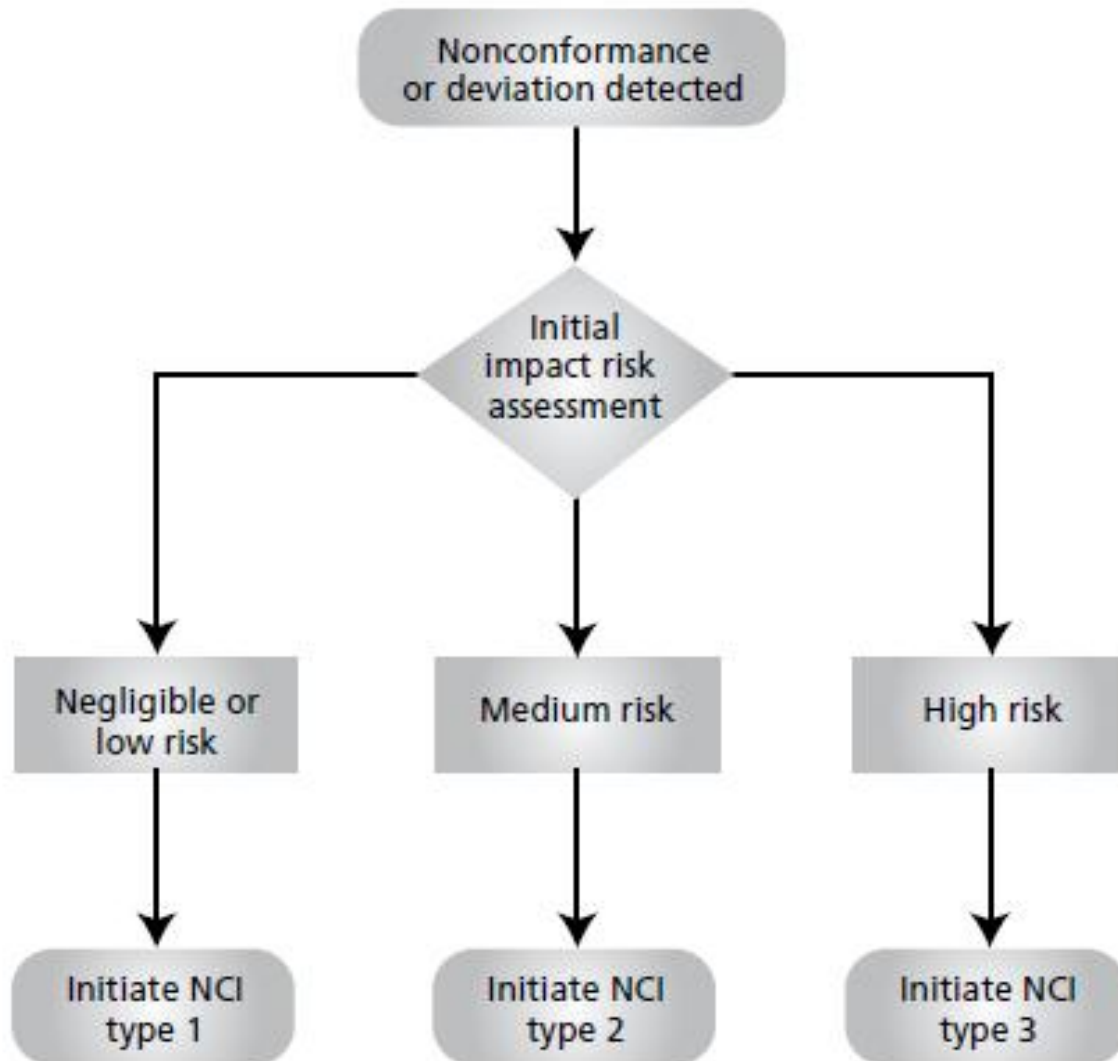
(11/3/07)



Do all nonconformities require a risk analysis, failure investigation, and corrective action?

- The preamble to the October 7, 1996 Quality System regulation provides insight into FDA's position on these matters.
- In comment 159 of the preamble , which relates to the degree of corrective or preventive actions, FDA states **“FDA cannot dictate in a regulation the degree of action that should be taken because each circumstance will be different, but FDA does expect the manufacturer to develop procedures for assessing the risk, the actions that need to be taken for different levels of risk, and how to correct or prevent the problem from recurring, depending on that risk assessment.”**
- A CAPA system should provide mechanisms to assess risk throughout the process.

Tie Timeliness to RISK



Tie Timeliness to RISK

Type 1	Type 2	Type 3
<ul style="list-style-type: none">• Only negligible or low-risk scores are obtained• One week to complete• Document the event and the corrections taken• Monthly track and trending of type 1 NCI	<ul style="list-style-type: none">• At least one dimension had a medium-risk score• 30 days to complete• Document the event, root cause analysis, and the corrections taken• Need to generate a CAPA Plan	<ul style="list-style-type: none">• At least one dimension had a high-risk score• 20 days to complete• Document the event, root cause analysis, and the corrections taken• Need to generate a CAPA Plan

Note: Complete NCI means document approval.

Recent CAPA Observations

-The procedures addressing documentation of corrective and preventive action activities were not implemented.
- CAPA procedures require the documentation of risk assessment. There are no procedures that define or indicate how this risk assessment is/will be determined. At least CAPA records reviewed only indicate the addressed non-conformance was of "minimal impact." There is no documented explanation or rationale for this assessment. At least of CAPA files reviewed lack any required risk assessment.

¿Isolated Situations?

Everything is an Isolated Event (lack of adequate trending)

- !!! Everything is an isolated event !!!
- Is this the first time this situation happen?
 - At this point of time, we only know symptoms: a lot failed some QC test or a customer complained about something.
- The answer to the question is the frequency or recurrence of the situation and it is one of the main elements of the risk management of CAPA process.
- It this is a recurrent issue, then we already have a breakdown of our CAPA system because previous incidents were either not investigated or were not properly corrected.

¿Isolated Situations?

Everything is an Isolated Event (lack of adequate trending)

- Perform a search looking for indications of previous event. This search must cover an adequate timeframe and it needs to be commensurate with the frequency of the process rather than a fixed period of time (i.e. three or six months).
- One year is often used.
- Always include the search query elements as part of the investigation. It's highly recommended that, as part of the review/approval process, someone repeat the search query to verify its results.

¿Isolated Situations?

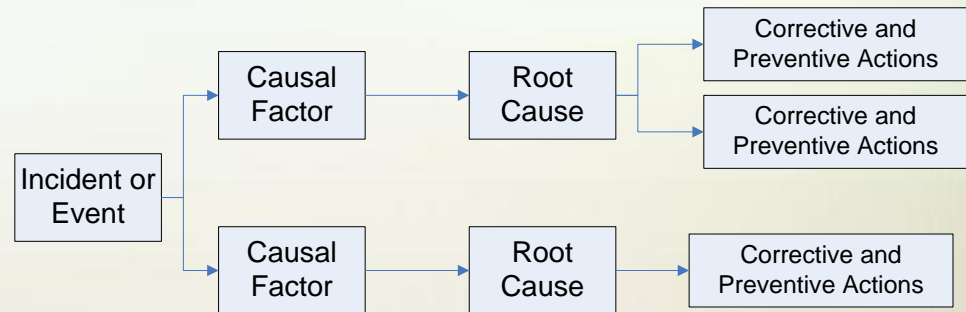
Everything is an Isolated Event (lack of adequate trending)

- Need to consider similar processes
 - It was the first time that a packaging operator was found with some missing training requirements?
 - What about the other department?
- A good trending system is critical
- “In investigating this complaint, you considered it to be an isolated event and did not extend your investigation to product that had been distributed, even though you determined that the equipment X had been used on 93 lots from...”

Root Cause not Identified

Not root cause? → Not Ca-PA

- Lack of adequate root cause analysis system
- Many root cause tools are only included as part of the wish list (tools you could use...)
- Symptoms and causal factor versus root cause
- Typical “root causes”
 - Human error
 - Procedure not follow
 - Equipment malfunctioning
 - Improper performance



Root Cause not Identified

Should is not good enough

- Need a root cause analysis system
 - Not just a tool box
- Need management enforcement
 - Investigations **must** include fishbone
 - Training on root cause tools is not the usual main factor of poor investigation
- Why? Why?.... Is the best tool you can use
- When to stop asking why?
 - When the corrective action is obvious
 - i.e. the procedure was not clear... the CA should be...

Correction(s) instead of Corrective Action(s)

Correcting the Symptoms Instead of the Cause

- Many people unable to properly define correction, corrective action, and preventive action
- A simple question can help you to differentiate between correction and corrective actions”
- ✓ **Will this Corrective Action avoid (prevent) that the cause occur again?**

Typical CA which really are plain corrections:

- Train a non-trained operator
- Reject and destroy a failing product
- Rework some nonconforming material
- Repair a piece of broken equipment

Correction(s) instead of Corrective Action(s)

Correcting the Symptoms Instead of the Cause

Correction

Corrective Action

- | | |
|--|------|
| 1. Train a non-trained operator | 1. _ |
| 2. Reject and destroy a failing product | 2. _ |
| 3. Rework some nonconforming material | 3. _ |
| 4. Repair a piece of broken equipment | 4. _ |
| 5. Properly connect the alarm to the machine | 5. _ |

Lack of Interim Corrective Actions

- Permanent Corrective Actions: It is the action than when implemented will avoid the recurrence of the root cause.
- Interim Corrective Action. One of the most unknown and unused concept in the industry.
 - If the corrective action can not be implemented immediately, then we must establish some interim actions to avoid the recurrence of the situation while the permanent corrective action is implemented.
 - Reasons for delay in the implementation can be several and well justified (need to buy and validate some equipment; need to change procedures, etc...).

Lack of Interim Corrective Actions

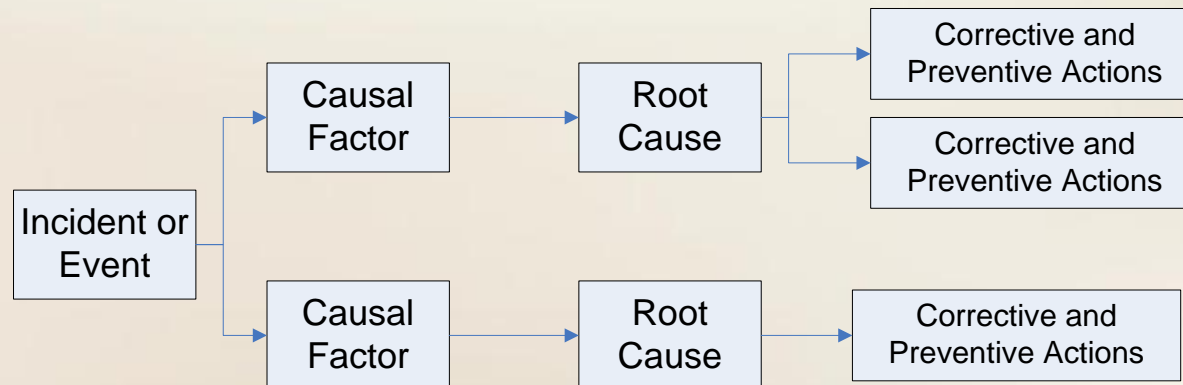
- Not having any interim action in this situation is not acceptable.
- Any action taken to minimize / mitigate the effect of the identified root cause(s) while we are able to implement the permanent corrective action(s).
 - Increase sampling
 - Increase inspection
 - ?

Root Causes Identified but not Corrected

- A simple question will help:

The proposed corrective action(s) will fix all the already identified root cause(s)?

- Always tie the root cause (conclusion) section of investigation report to the CA-PA section
- Do not leave “unattended” root cause(s): You are incubating further problems
 - Do not follow the Pareto principle: try always to fix all causes.



Lack of True Preventive Actions

- **Ca-Pa** versus **Ca-Pa** systems
 - Lack of *in conformance analysis*
 - Relationship between Ca and Pa establish the maturity of the CAPA system
 - Many regulated companies do not have a true CAPA system.
 - **Evaluate, analyze, or investigate, are NOT preventive actions**
 - Typical example of “PA”: to evaluate if there are other incorrect procedures”
- The true Preventive action is to change those incorrect procedures

Example of WL

- -Corrective and preventive action activities were not documented, including the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, and implementation of corrective and preventive actions.
 - Specifically: (b) Temperature recording charts for [redacted] indicated temperatures were outside the acceptable range on at least four (4) occasions. The corrective action required investigating the effect of temperature fluctuations on the product when the freezers were not within the acceptable range. This evaluation was not performed.

Lack of Effectiveness Verification of the Action Taken

- **Effectiveness criteria:** a corrective action will be considered effective if it is able to prevent the recurrence of the **cause**
 - **Not the symptoms**
- Need to ensure that such actions are effective and do not adversely affect the finished device.
 - 80% of devices recalls related to software were caused by an improvement to the software



Lack of Effectiveness Verification of the Action Taken

- The timeframe for this evaluation must be established case by case. Some firms established a fixed period of time.
- Use the “double-digits” rule of thumb: allow enough time to permit the evaluation of at least ten repetitions of the process under evaluation.
 - If the process runs every month, then one year could be a reasonable period.
 - If the process is performed weekly, then three months should be enough.
 - For daily process, one month is a good period of time to establish the effectiveness.

Multiple CAPA Systems Without Correlation

- Customer complaints
- Internal Processes
 - *incoming, in-process, final release, stability*
- Supplier chain
- Sister facilities

.....Firm's management of corrective and preventative actions (CAPA) is inadequate. Specifically, the firm is taking CAPA's under various quality data headings (Incidences, Nonconformities) without correlation into the firm's CAPA system preventing accurate analysis, and timely review.

- Two databases are used to handle complaints, with the result that management is only made aware of some complaints received.

Abuse of Human Error + Retraining

- ◆ ***Human Error*** is NOT a good root cause
 - ◆ It is a consequence
- ◆ Regulators do not like the abuse of human error as root cause
- ◆ Human being always make mistakes (machines does not)
- ◆ Why the human made the mistake?
- ◆ Retraining is not a good Corrective Action
 - ◆ Why the original training did not work?

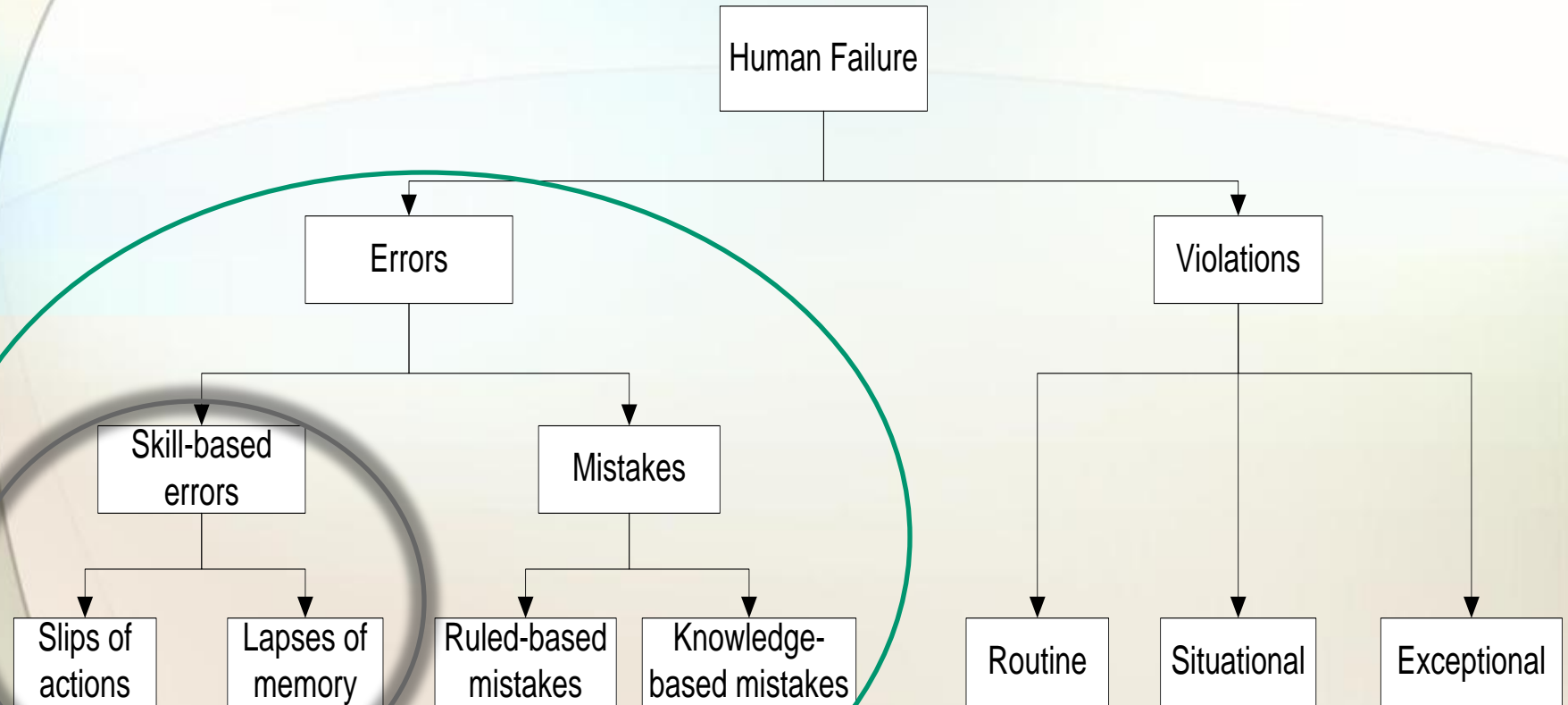
Key Points to Consider

- ✓ Human errors are **NOT** root causes
- ✓ Human errors are **symptoms** or consequences of deeper causes
- ✓ Refrain to use **human error** (or procedure not followed or similar) as **root cause** and **retraining** (refresher, awareness, counseling, orientation, etc.) as **corrective action**

Human Errors and Memory

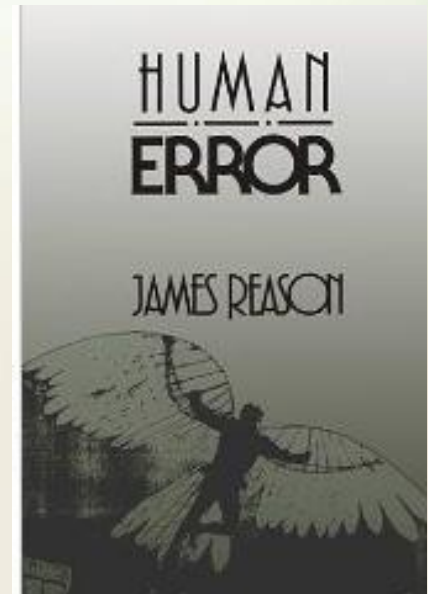
- Lack of attention and lack of memory play a significant role in all categories of human errors. Slips, lapses, and mistakes are all more common when situational factors divert our attention.
- However, in the FDA regulated industries, these factors should be negligible because we are not supposed to rest on our memory for remember how to do things.
- Batch records exist for one purpose.

Type of Human Failures



Human Errors and Human Factors: James Reason's bottom line

- *Fallibility is part of the human condition*
- *We can't change the human condition*
- *We can change the conditions under which people work*
- *Human beings will always make errors*
- *Naming, blaming and shaming have no remedial value*



Training as Human Factor

Evidence of training? →



But the key question must be...

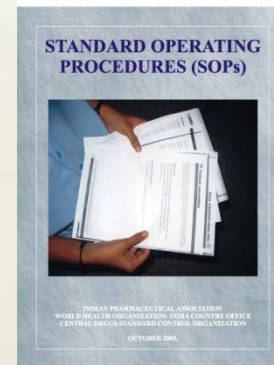
Was it effective?



Human Factors related to Training



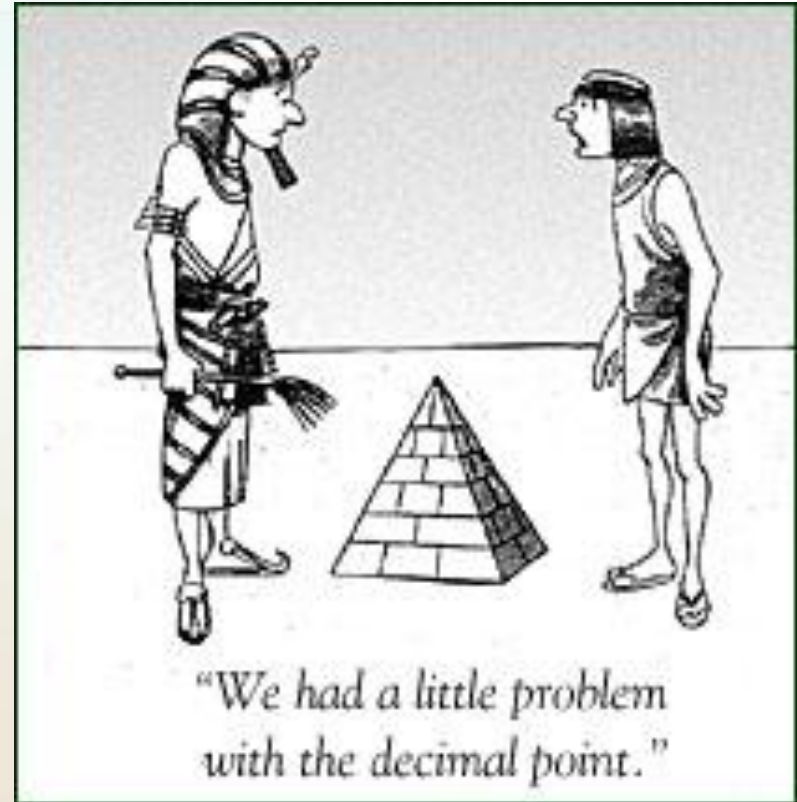
- **Training evidence?**
 - *Trained in the current version of the procedure?*
- **Was effective?**
 - *Adequate content?*
 - *Adequate training deliver methodology?*
 - *Adequate training ambient?*
 - *Adequate training instructor?*
 - *Adequate language?*
 - *Enough practice?*



Over-customization of your CAPA System

- !\$%@??-wise software
- Users do not understand the software features or capabilities
- Correction and remedial action
- Etc...

Some "GOOD" CAPAS



ISSUE: A customer complaint is received in August 2008 due to the foil seal and the cap's liner heavily burnt. Packaging date was October 2007)

Root Cause Analysis: Human Error

- Inappropriate handling of a damage bottle as a result of a jam at the induction sealer station. It is most likely that during a conveyor stoppage the operator either failed to remove all of the defective bottles under and near the induction sealer

Corrective Action:

- Retraining on the procedures was given **to operators** and this should adequately address the issue
- A commitment was issued to modify the induction sealer guides edges of Line 2 and to conduct an assessment of the conditions of the other packaging lines

ISSUE: discrepant data for Content U test: The sample weight printout was identified as lot xxxx and the empower sample set was identified as yyyy

Root Cause Analysis: Human Error

- QC associates and QC Scientist did not follow SOP

Corrective Action:

- Involved personnel were refreshed of the SOP (one of them was absent and she was refreshed throughout a phone call)

Preventive Action:

- A commitment was created to evaluate the possibility to limiting to one batch and one validation stage per test. This will simplify the testing and check by process and consequently reduce potential errors

More “GOOD” CAPAs

Root Cause Analysis: Human Error

- The QC Associate incorrectly prepared the Assay for X & Y (trace minerals) standard solution by diluting it in 200 mL volumetric flask instead of a 100 mL volumetric flask as specified in the Procedure

Corrective Action: new standard dilutions were made, following the current Product Monograph and the Assay test for X & Y was repeated with the original solutions

Preventive Actions:

- Mentoring session form was completed
- Assay for X & Y method was discussed with the analyst

More “GOOD” CAPAs

Root Cause Analysis: Human Error

- The analyst did not prepare the standard C solution according to procedure. She prepared the standard C as follow: Pipet 30.0 ml of Standard B solution into 100 MI volumetric flask instead of pipet 30.0 ml of Standard A solution into a volumetric flask.

Corrective Action:

- The analyst was oriented to assure that prepare the standard accordingly to the procedure. She was re-trained in the X USP raw material monograph

Preventive Actions: none

Examples

Effective Corrective Actions

Situation: did not follow procedures

- Verify all parameters
- Mix well
- For a few seconds
- As soon as possible
- Mix for a minimum of 30 seconds
- Mixed adhesive can be used until it is difficult to dispense

Examples

Effective Corrective Actions

- **Situation:** Frequent mistakes regarding line clearance's items. Items not really verified or incorrectly verified

Current verification method:

Humidity ✓

Temperature ✓

Pressure ✓



Improved Verification method:

Humidity: 39%

Temperature: 23 C

Pressure: 12.3 ATM

Seven seconds...?

*Team
Work*





Business Excellence Consulting

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Fecha	CAPA Expert: Value	Value
Mayo 13 a junio 17 (6 viernes)	Best Sampling Practice	Regulatory Trending Analysis for the
Mayo 13	Estadísticas Aplicadas	Diseno de Experimentos
Mayo 20	Preparación para el examen de certifica	2011
Junio 21 y 22	Preparación para el examen de certifica	2011
Junio 27-28 y 29 (3 días)	Preparación para el examen de certifica	2011
Agosto 6 y 9 (2 días)	Preparación para el examen de certifica	2011
Octubre 6 a Noviembre 12 (6 sábados)	Preparación para el examen de certifica	2011



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Curso Medical Devices (CBA) 2010

Business Excellence Consulting surgió en el año 2005 y nuestra trayectoria se



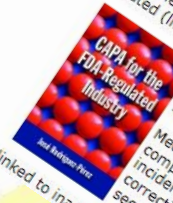
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CAPA FOR THE FDA-REGULATED INDUSTRY

New book published by ASQ

linked to inadequate CAPA systems.



Best seller book "CAPA FOR THE FDA-RELATED INDUSTRY" published October 2010 by ASQ Quality Press.

Medical devices, biopharmaceutical, and traditional drug manufacturing companies devote an important part of their resources to dealing with corrective, investigation, and preventive actions. The CAPA system. It is second to none in terms of frequency and criticality of its deviations and most of the regulatory actions taken by the FDA and foreign regulators are linked to inadequate CAPA systems. This guidance book provides useful and up-to-date

Valuable CAPA System Information and Help

This site is devoted exclusively to the CAPA (Corrective Action - Preventive Action) world. Here you can find information, counseling, training and almost everything related to root cause, investigations and the CAPA world. Our focus are the life-sciences regulated industries (a.k.a FDA regulated firms) and we can help your company wherever your are located (literally) and whoever regulated you.

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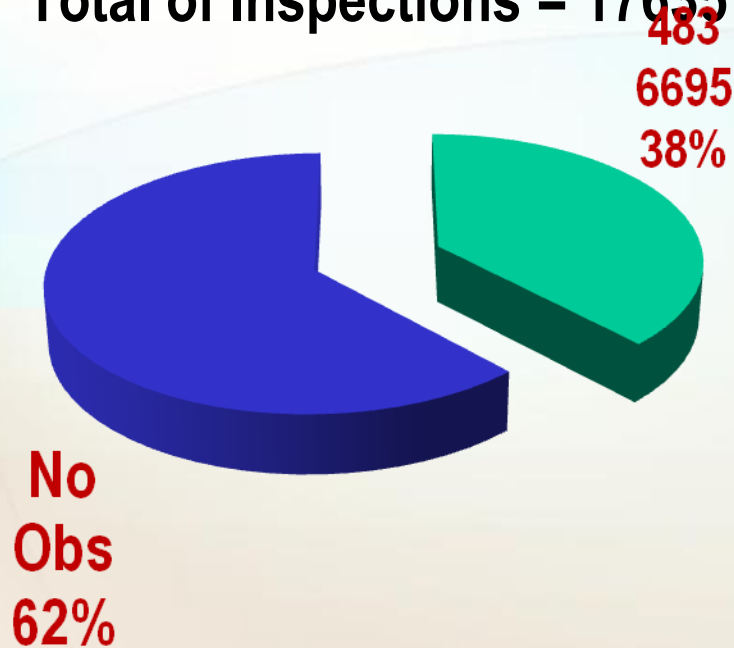
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Fiscal Year 2010 FDA Enforcement

Classification
 Total of Inspections = 17635



673 Warning Letters

- 204 Medical devices

Year	# WLS	# w/ CAPA cite	%
2010	89	81	91
2009	77	68	88
2008	98	86	88
2007	74	62	84
2006	79	69	87
2005	97	85	88
2004	113	89	79
2003	69	61	88

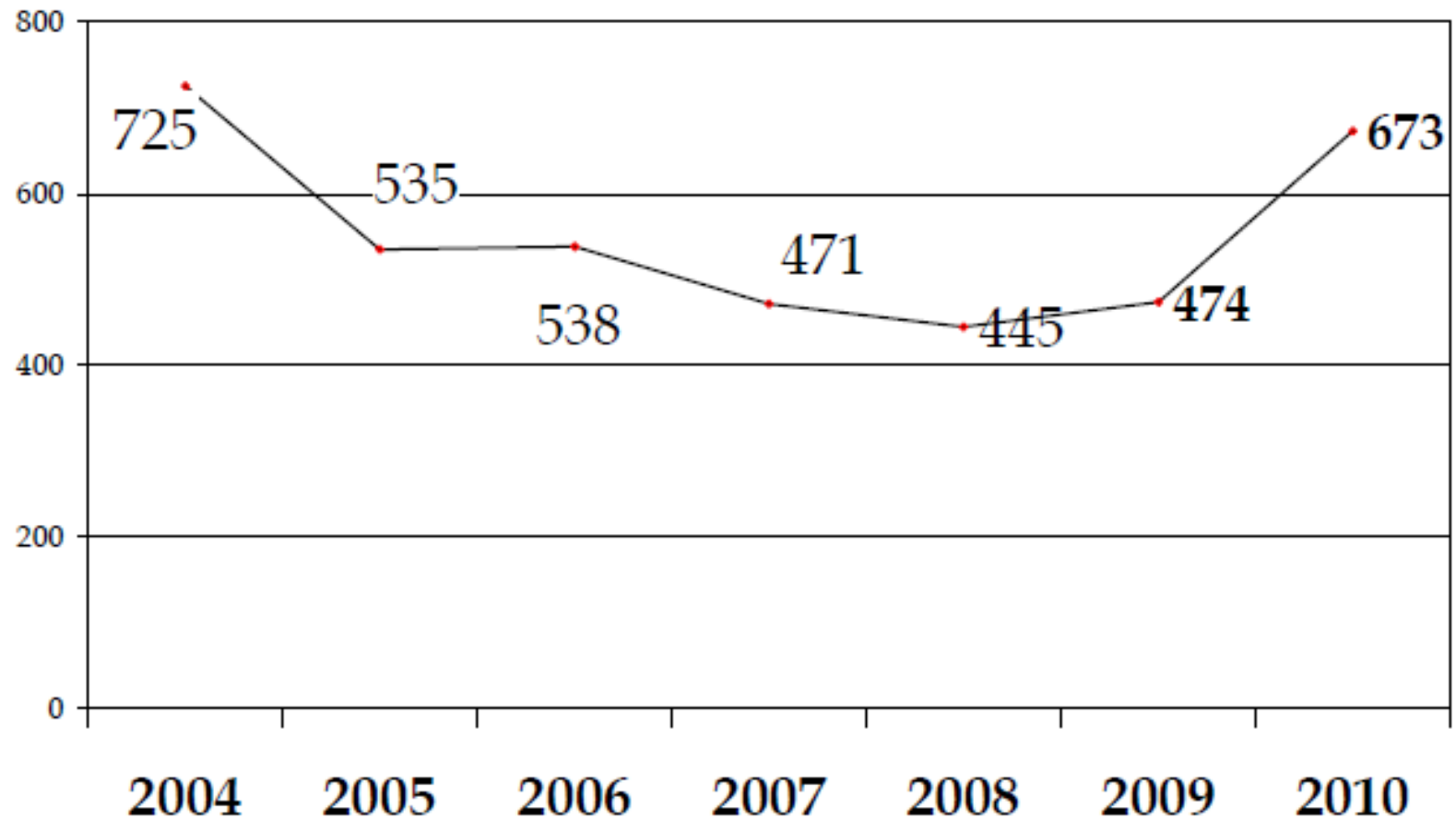
Total of Warning Letters=

673

FDA Enforcement Statistics Summary FY 2010

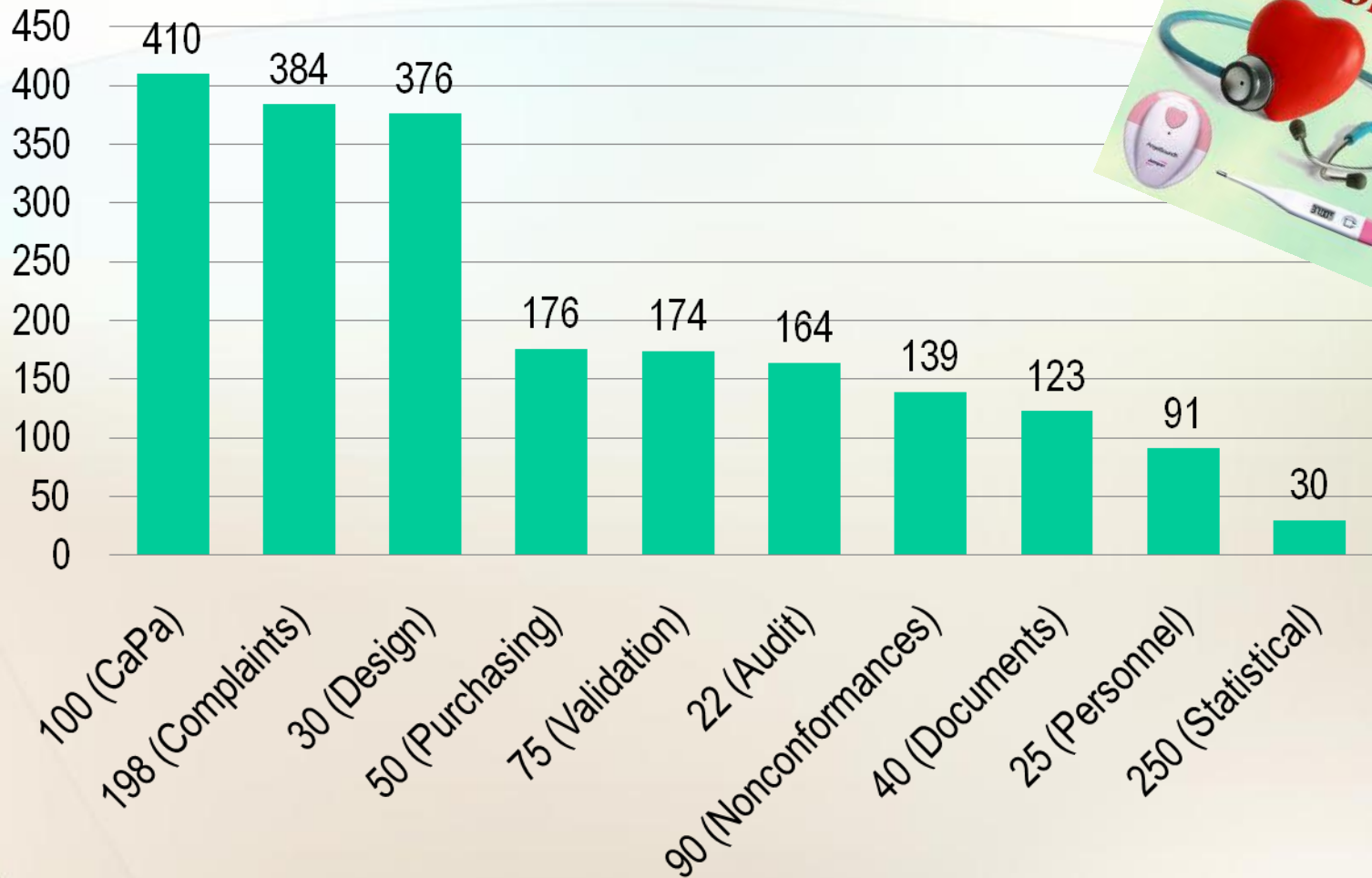
Seizures	10
Injunctions	17
Warning Letters	673
Recall Events	3,799
Recalled Products	9,361
Debarments	13

FDA Warning Letters Fiscal Years 2004 - 2010



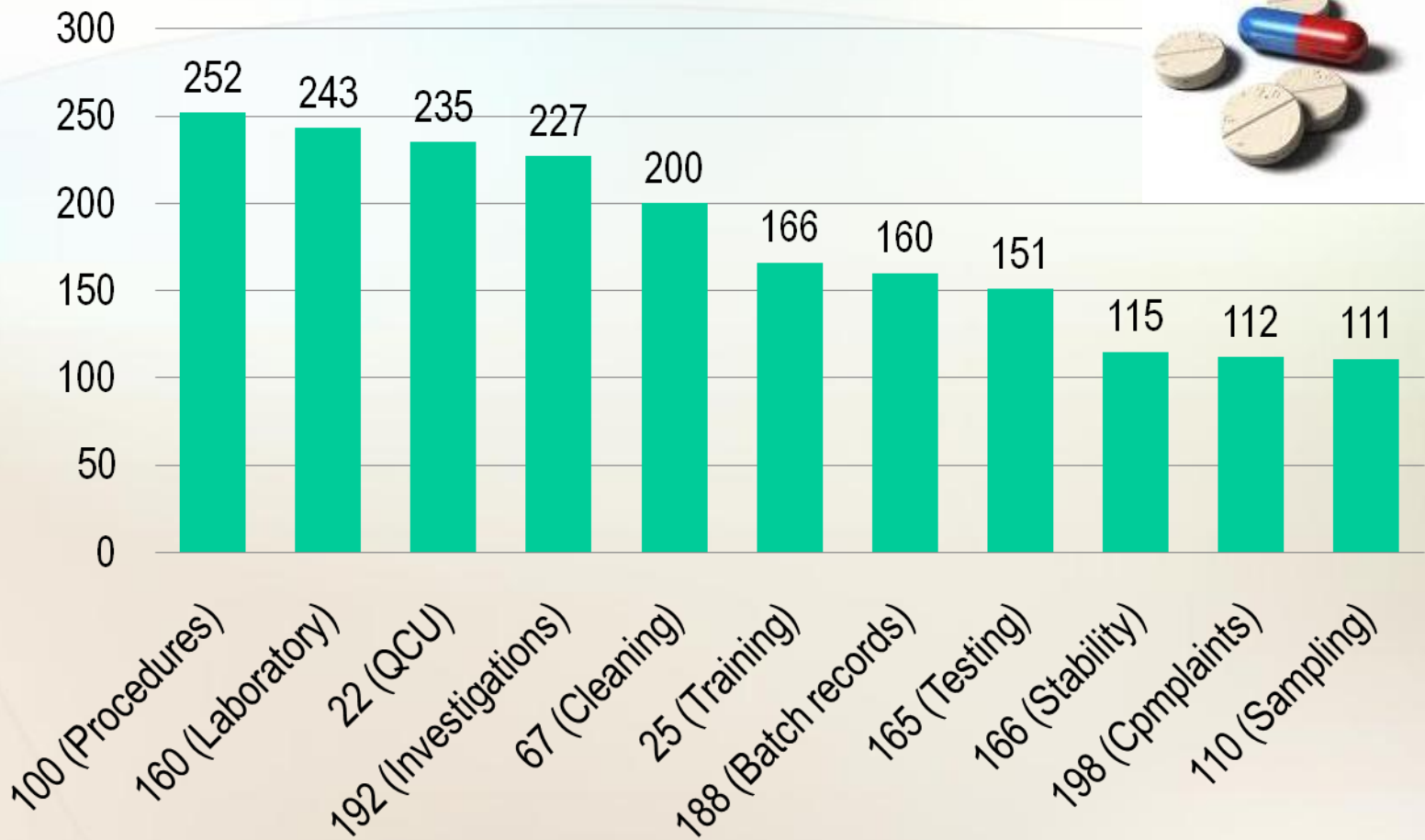
QSR Top Observations FDA-wide FY2010- 817 Inspections with 483 (3,619 Observations total)

Medical Device Observations



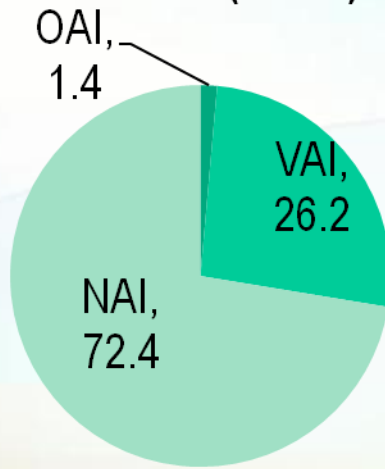
cGMP Top Observations FDA-wide FY2010- 646 Inspections with 483 (3,367 Observations total)

Drug Observations

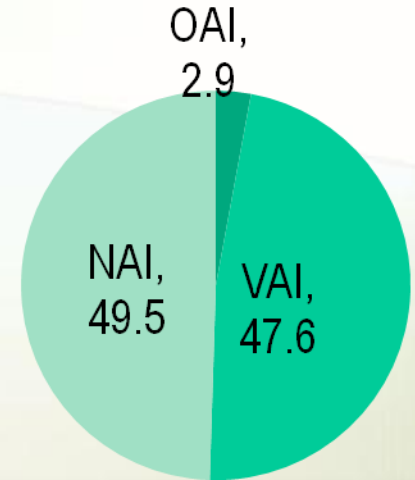


Inspection Results FY 2009 + FY 2010

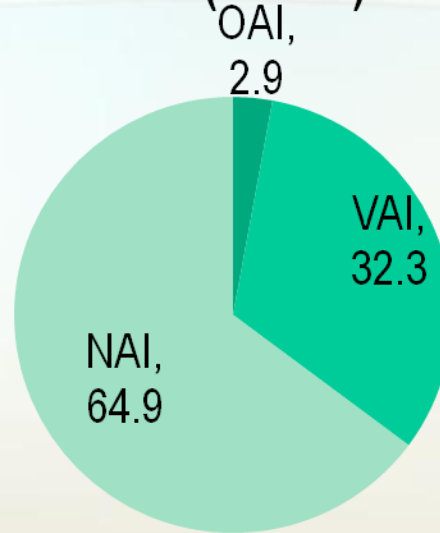
Atlanta (1898)



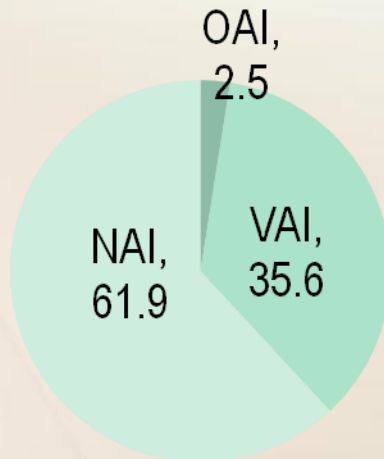
SJN (511)



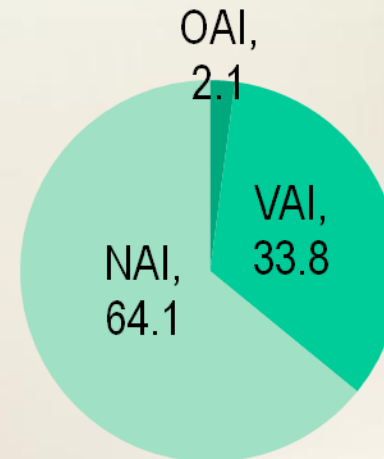
FDA (31762)



CHI (974)



N J (1193)



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