

## **ORCA Meeting**

**Wednesday, May 14, 2008**

**Location: Lake Washington Technical  
College, Redmond Campus**



# **FDA Enforcement Updates Audio Conference**

**Kim Trautman, FDA  
Medical Device Quality System Expert**

# **Meeting Handouts**

# Hot Topics

**Kimberly A. Trautman**  
**FDA's Medical Device Quality System Expert**

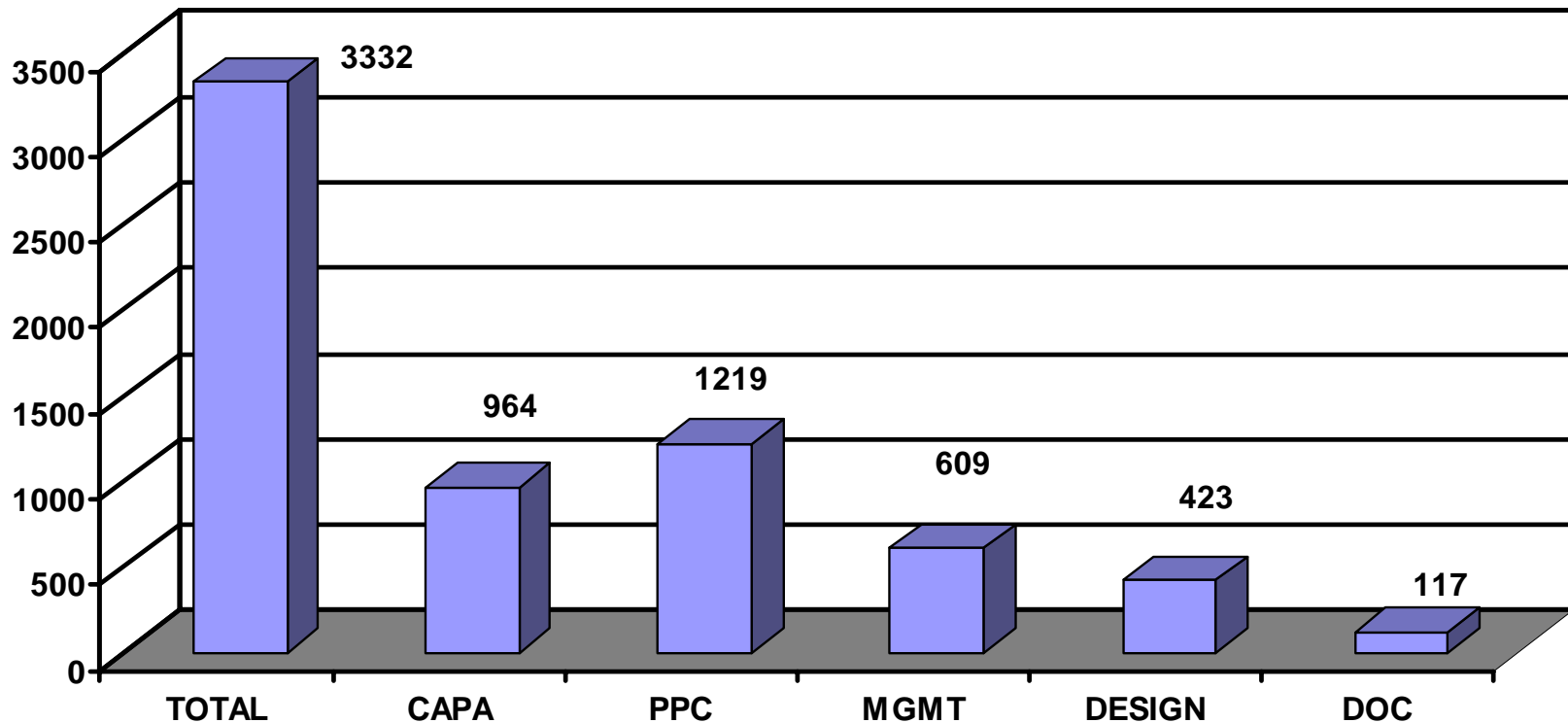
# Overview

- Turbo and Warning Letter Data
- Supplier Control
- Heparin
- AP/pMAP/ISO Audit Report Submission

# Data Analysis

- Analysis of data from FDA's Turbo EIR database.
- Time frame 1/1/2007 to 12/31/2007
- 3332 observations were cited on the FDA-483s for 21 CFR 820 deficiencies
- 200 observations were cited for 21 CFR 803 deficiencies
- 38 observations were cited for 21 CFR 806 deficiencies
- 1 observation was cited for 21 CFR 821 deficiency

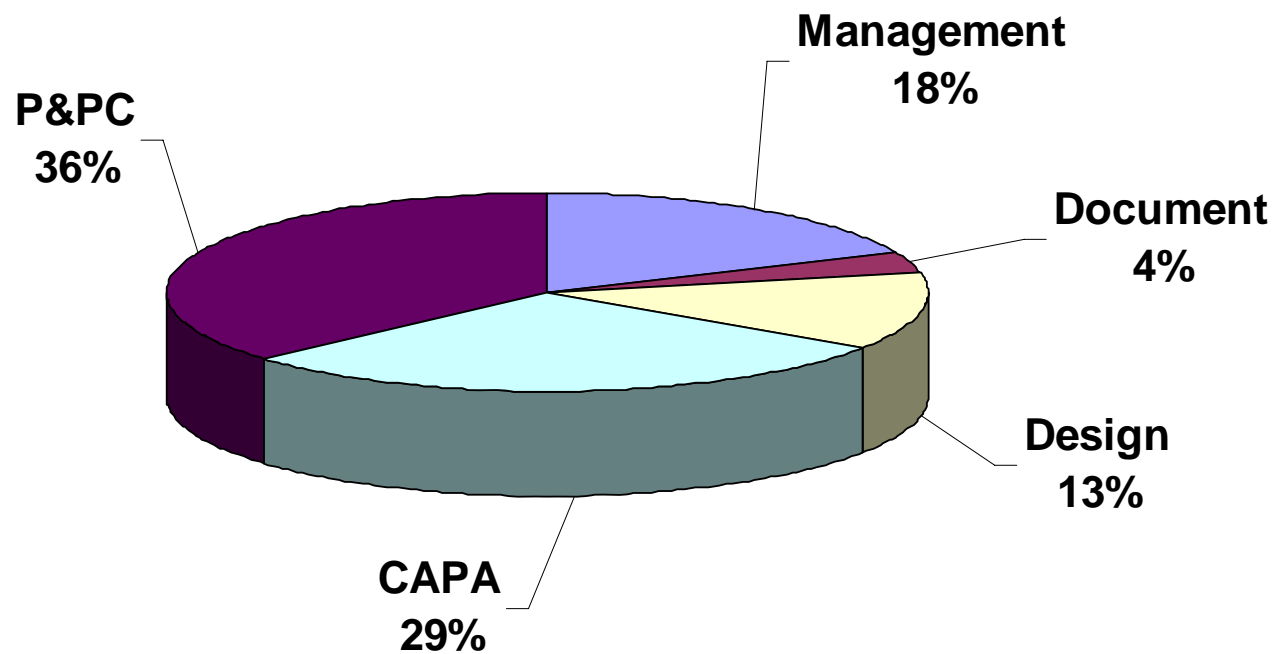
# Number of Observations (n=3332) 1/1/2007 to 12/31/2007



# Observations by Subsystem

## 1/1/07 to 12/31/07

### Percentage of Observations by Subsystem



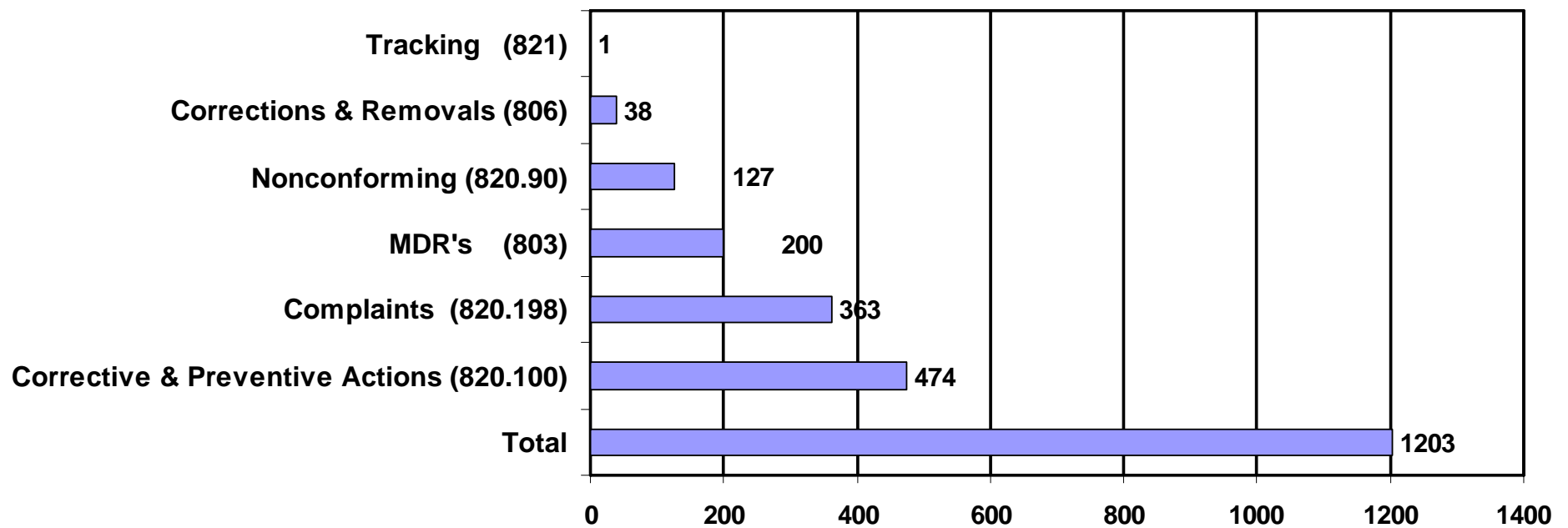
# CAPA Subsystem Data

As reflected in the previous graph, most of the observations were cited for deficiencies in the PPC subsystem

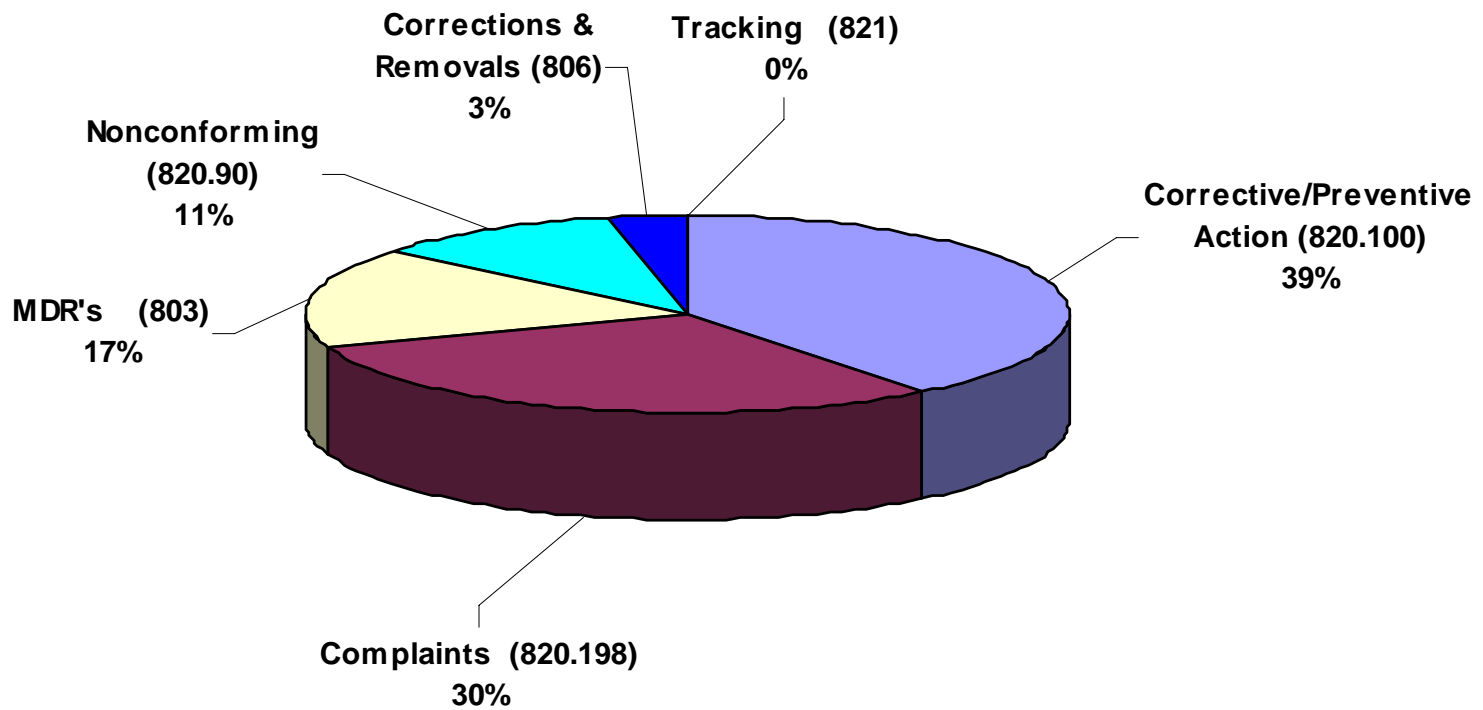
CAPA subsystem had the second highest number of observations

964 of the 3332 observations were CAPA related

# Number of CAPA Subsystem Observations by CFR Cite -2007

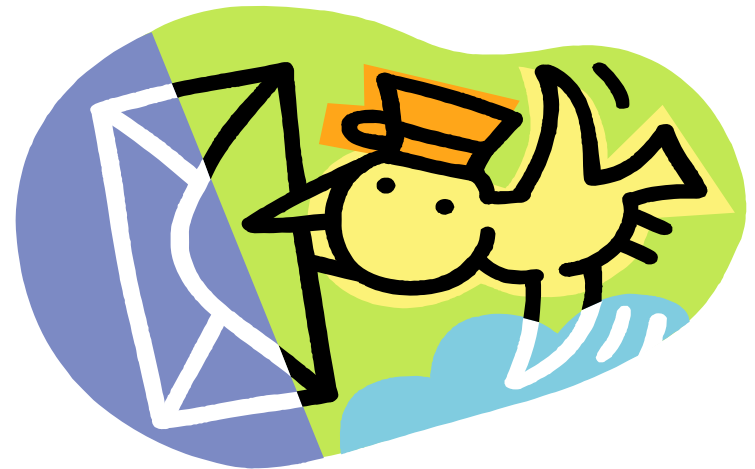


# CAPA Observations by CFR citation - 2007



# Warning Letters with CAPA System Cites 2007

- January – December 2007
- FDA issued 74 Warning Letters to medical device firms for QS/GMP deficiencies
- 62/74 or 84% contained cites for CAPA system deficiencies
- 21 CFR 820.90, 820.100, or 820.198 cites



# Warning Letters CAPA Data

<b>Year</b>	<b># WLS</b>	<b># w/ CAPA cite</b>	<b>%</b>
2007	74	62	84
2006	79	69	87.3
2005	97	85	88
2004	113	89	79
2003	69	61	88

# Turbo Data on Process Validation Observations 1/1/2007 to 12/31/2007

3332 Observations for QS/GMP

150 Observations for Process Validation

[820.75(a)-(c)] = 4.5 %

# Turbo Data on Process Validation Observations

820.75(a) – Lack of validation; documentation =  
72%

820.75(b) – Lack of SOPs for monitor and control  
= 12%

# Turbo Data on Process Validation Observations

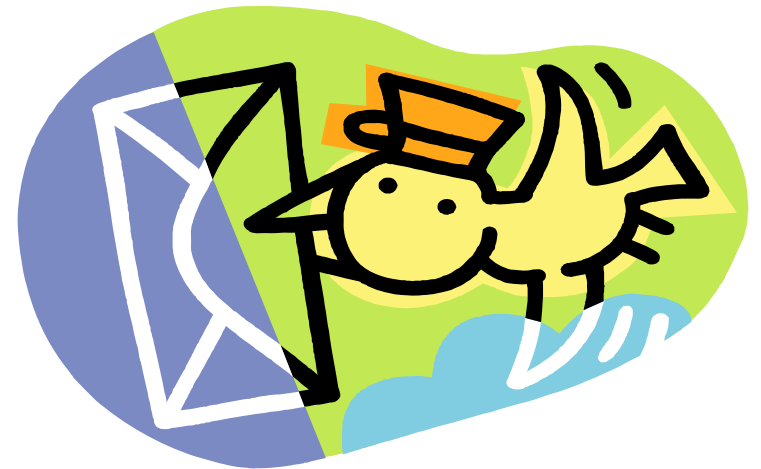
820.75(b)(1) – Lack of qualified people = 0%

820.75(b)(2) – Lack of documentation for monitor/  
control, people, equipment = 4.7%

820.75(c) – No evaluation of changes and/ or  
revalidation = 11.3%

# Warning Letters with Process Validation Cites 2007

- 74 Warning Letters issued in 2007 to medical device manufacturers for QS/GMP deficiencies
- 24 contained citations for deviations from 820.75
- 24 out of 74 letters = 32%



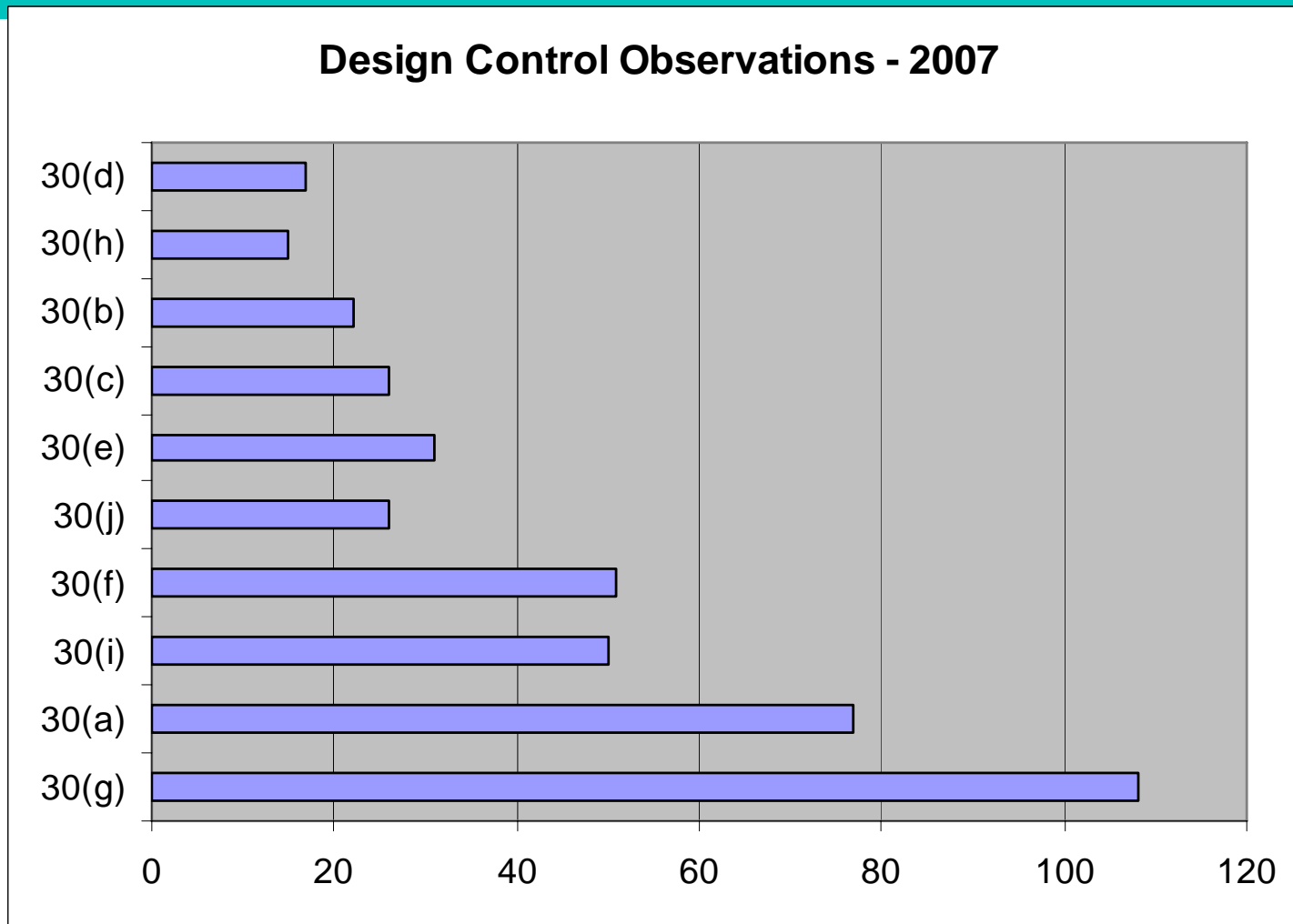
# Warning Letters PV Data

<b>Year</b>	<b># WLs</b>	<b># w/ PV cite</b>	<b>%</b>
2007	74	24	32
2006	79	27	34
2005	97	39	40
2004	113	33	29
2003	69	24	35
2002	42	23	55

# Design Control Observations - 2007

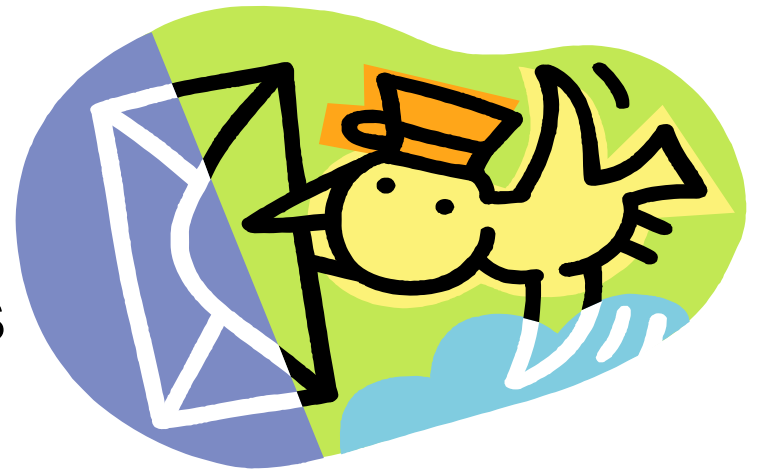
30(g)	Validation	108/423 = 25.5%
30(a)	General	77/423 = 18.2%
30(f)	Verification	51/423 = 12.1%
30(i)	Changes	50/423 = 11.8%
30(e)	Review	31/423 = 7.3%
30(j)	DHF	26/423 = 6.2%
30(c)	Inputs	26/423 = 6.2%
30(b)	Planning	22/423 = 5.2%
30(d)	Outputs	17/423 = 4.0%
30(h)	Transfer	15/423 = 3.5%

# Design Control Observations - 2007



# Warning Letters with Design Control Cites 2007

- January – December 2007
- FDA issued 74 Warning Letters to medical device firms for QS/GMP deficiencies
- 42/74 or 57% contained cites for Design Control deficiencies
- 21 CFR 820.30



# Warning Letters Design Data

<b>Year</b>	<b># WLS</b>	<b># with Design cite</b>	<b>%</b>
2007	74	42	57
2006	79	47	59.5
2005	97	49	51
2004	113	57	50
2003	69	39	57

# Control of products and services obtained from suppliers

GHTF Draft Proposed Guidance

**Title:** Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers.

***Out for comment until September 15, 2008.***

<http://www.gh tf.org/sg3/sg3-proposed.html>

# Control of products and services obtained from suppliers

For the purposes of this document, a product or service is one which is purchased or otherwise received by the manufacturer. In addition, a supplier is anyone that is independent from the manufacturer's quality management system.

# Control of products and services obtained from suppliers

This includes a supplier that may be part of the manufacturer's organization but operates under a separate quality management system.

# Control of products and services obtained from suppliers

In other words, if the supplier is not a part of the manufacturer's internal audit (quality audit) scope, then the supplier is under a separate quality management system and is considered an internal supplier.

# Control of products and services obtained from suppliers

Corporations or companies that have corporate quality policies and procedures do not necessarily place all divisions or groups under the same quality management system.

# Control of products and services obtained from suppliers

Therefore, one division or group can be an internal supplier to another division or group within the same corporation/company. Internal suppliers are to be controlled in a similar way as external suppliers are controlled.

# Heparin

- FDA regulatory expectations of increased Purchasing Controls and Acceptance Activities in relation to the increased risk for Medical Device manufacturers that produce devices which contain or are heparin coated.
- FDA information for Device Manufacturers can be found at the following cite:  
<http://www.fda.gov/cdrh/safety/heparin-notice.html>

# http://www.fda.gov/cdrh/ap-inspection/

The screenshot shows a Microsoft Internet Explorer browser window titled "Third Party Inspection - Microsoft Internet Explorer". The address bar contains the URL "http://www.fda.gov/cdrh/ap-inspection/". The page content includes the FDA logo and the text "U.S. Food and Drug Administration" and "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH". The main heading is "Third Party Inspections" with a sub-heading "Accredited Persons Inspection Program". The text describes the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and its implications for third-party inspections. A link is provided for "Additional Information on the Accredited Persons Inspection Program (Including a List of Authorized Accredited Persons)". Below this, the "Pilot Multi-Purpose Audit Program (PMAP)" is introduced, mentioning a letter from the U.S. FDA and Health Canada (HC) dated September 7, 2006. Two links are provided: "September 2006 Letter" and "Questions and Answers [PDF]". The browser's taskbar at the bottom shows the Start button, several application icons, and the system clock displaying "2:16 PM".

**Third Party Inspections**

**Accredited Persons Inspection Program**

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law on October 26, 2002. Section 201 of MDUFMA establishes a new subsection "g" to section 704 (Factory Inspection) of the FDCA, which requires FDA to accredit third parties (Accredited Persons) to perform inspections of eligible manufacturers of Class II or III devices. This is a voluntary program. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of requesting inspection by an Accredited Person (AP). However, inspections by APs are limited to manufacturers who meet certain conditions.

- [Additional Information on the Accredited Persons Inspection Program \(Including a List of Authorized Accredited Persons\)](#)

**Pilot Multi-Purpose Audit Program (PMAP)**

On September 7, 2006 the U.S. FDA and Health Canada (HC) mailed a letter to U.S. FDA Accredited Persons for Inspection and HC's Third Party Auditing Organizations, called Canadian Medical Devices Conformity Assessment System (CMDCAS). The letter announces a pilot multi-purpose audit program (PMAP) that will allow qualified auditing organizations in both programs to perform a single inspection that both agencies can use. The purpose of the pilot is to evaluate the effectiveness of performing a single third party inspection/audit of medical device manufacturers' quality systems that would meet the needs and regulatory requirements of both countries.

- [September 2006 Letter](#)
- [Questions and Answers \[PDF\]](#)

# ISO 13485 Audit Report Submission to FDA

- Any ISO Audit Report from a Conformity Assessment Body certified by a GHTF regulator. Manufacturer can submit the report and any related responses to a CDRH email account with PDF file within 30 days from the close of the ISO audit.

# ISO 13485 Audit Report Submission to FDA

- Office of Compliance will review per Compliance Program 7382.845 (June 15, 2006) and determine Situation 1 or 2 (fully expect only non-violative reports to be submitted).

# ISO Audit Report Submission to FDA

- After review Office of Compliance will issue a letter to the firm confirming their inspection status with FDA and telling them that they will be taken off the routine work load plan for 1 year.
- However, FDA would come in for PMA pre-approval inspections and For Cause inspections where necessary.

# Update - ISO Audit Report Submission to FDA

- Copy of the letter concurrently transmitted to the District for work load planning. No electronic means at the moment to push to FACTS.
- One year would start from the 30 day after the close of the inspection date.
- Allowed to use this process a couple of times in a row, to be determined.

# Conclusion

Thank you for your time and  
attention!

**QUESTIONS?**