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CDER's Risk-Based Site Selection Model for cGMP Inspections

2007 PDA/FDA JOINT REGULATORY CONFERENCE

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Sawye Brenda Wang, IE
Team Leader, DCRMS
Office of Compliance
Center for Drug Evaluation and Research



Risk-Based Site Selection Model History

- **The Risk-Based Model Working Group Formed in 2003.**
- **Implemented a nationally consistent approach to surveillance evaluation of factory operations by inspection for FY2005.**
- **Continue to Refine the Models for FY2006 and FY2007.**

Tiers

Tier 1

- Specific sites in this category vary each year
- 100% of sites are inspected

Others

- All Drug sites not in Tier 1
- About 25% of sites are Inspected
- Selection at each field office discretion

*Outdated
Decision*

FY06 Risk-Based Site Selection Model Factors and Components

- Size
- Establishment Type
- Last 3 District Decisions
- Field Alerts
- Recalls

Duration (year) since Last
CGMP Inspection

- Non-Application Rx
Products
- Sterile/Non Sterile
- Therapeutic Class

- Control
- Contamination

Facility
Risk

Outdated
Information Risk

Product
Risk

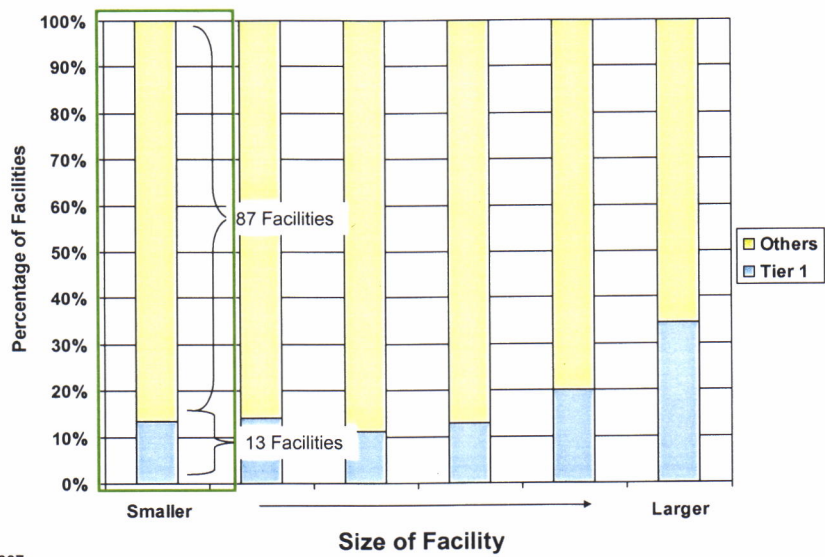
Process
Risk

Total
Score

*Depends on product
availability
of product
in store*

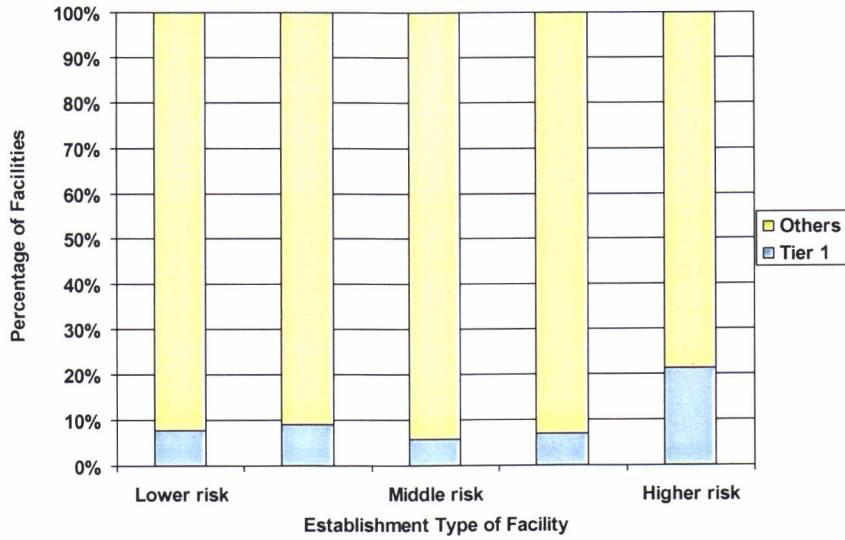
FY 2007 Sites Distribution

Facility - by Size



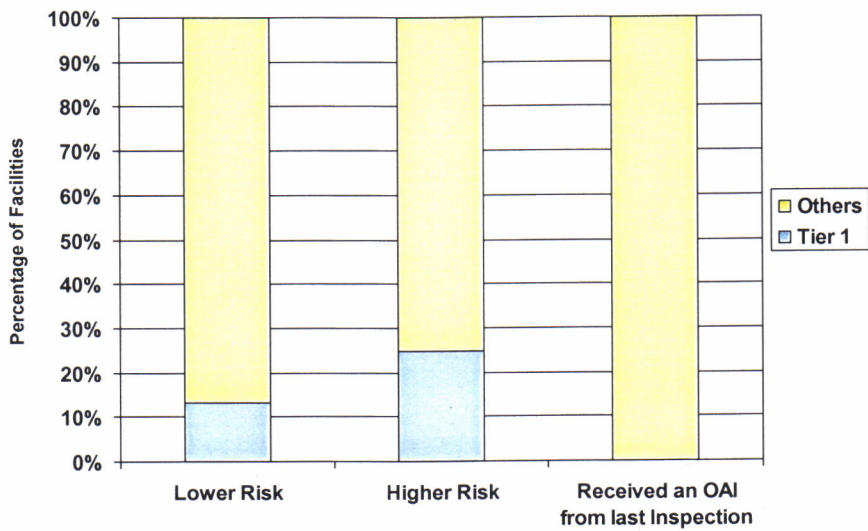
* FY2007

Facility - by Establishment Type



* FY2007

Facility - by last 3 Decisions

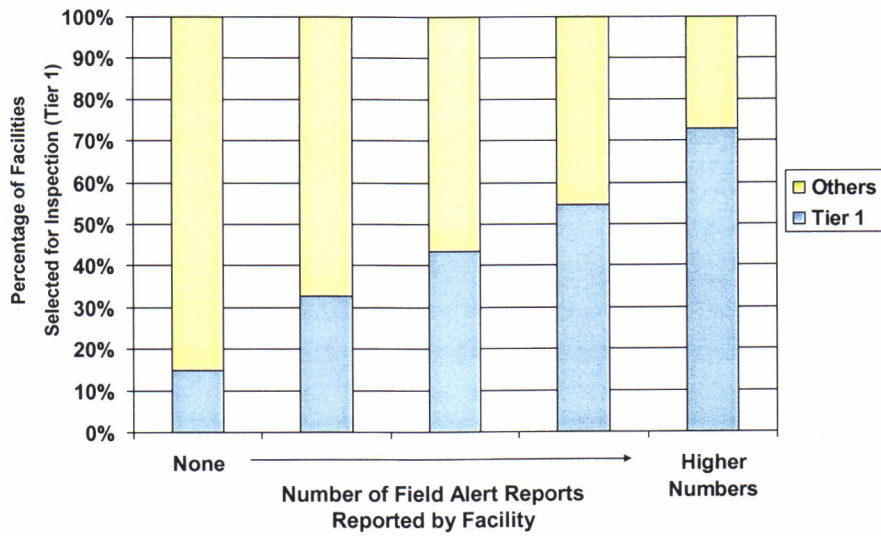


* FY2007

Comp Part 3 inspection

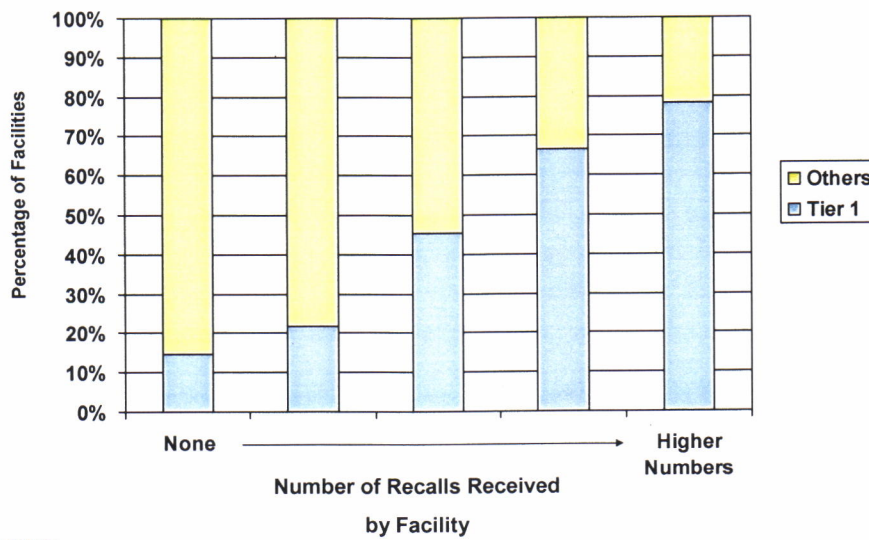
no action

Facility – by Number of Field Alert Reports



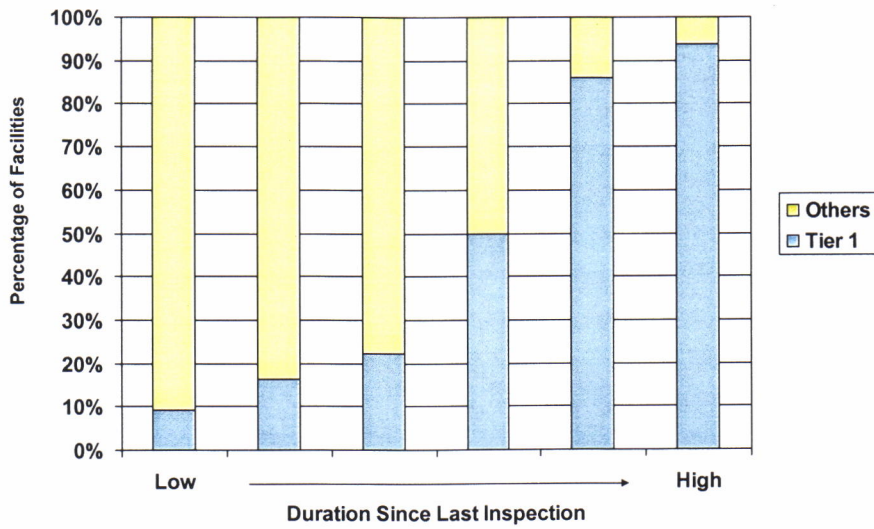
* FY2007

Facility – by Number of Recalls



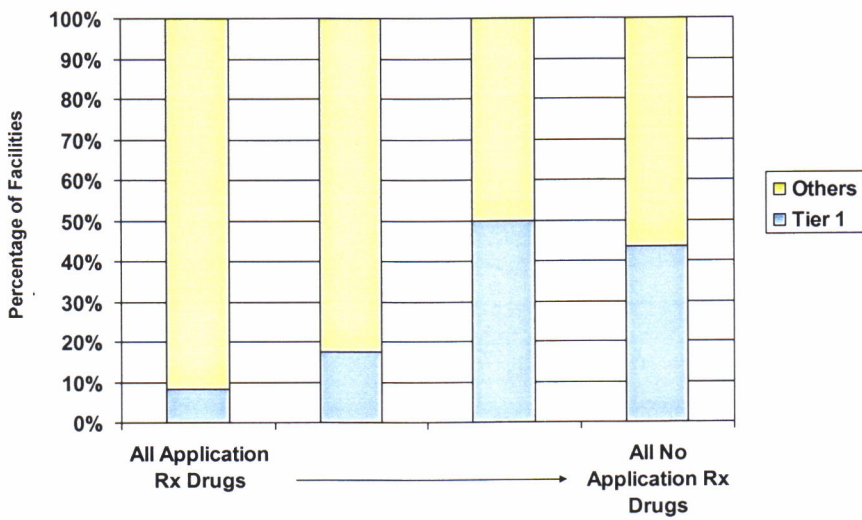
* FY2007

Outdated Information Score Duration since last Inspection



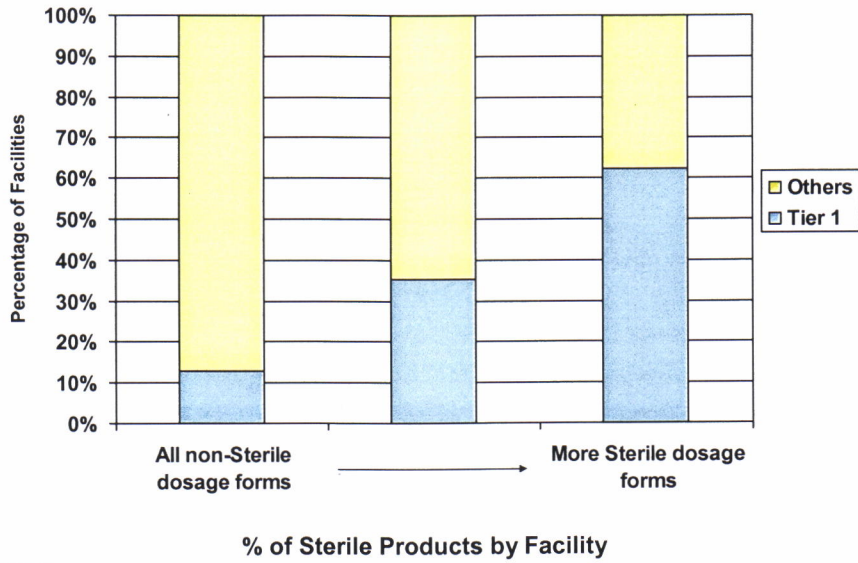
* FY2007

Product – by Non-Application Rx Products

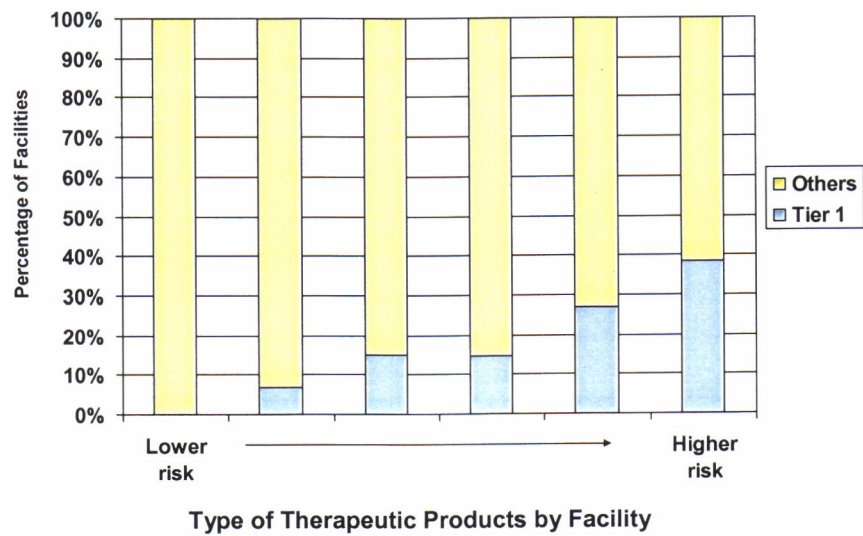


* FY2007

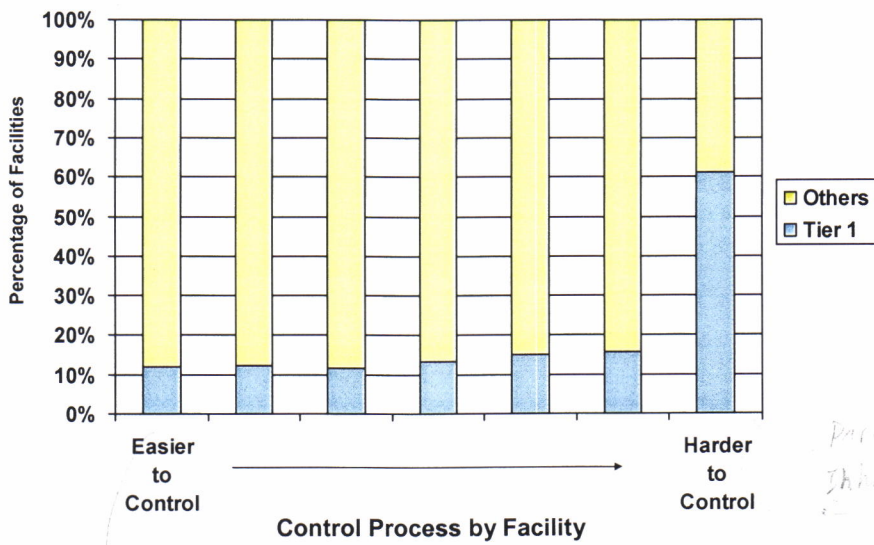
Product - by Sterility



Product - by Therapeutic Drug Class

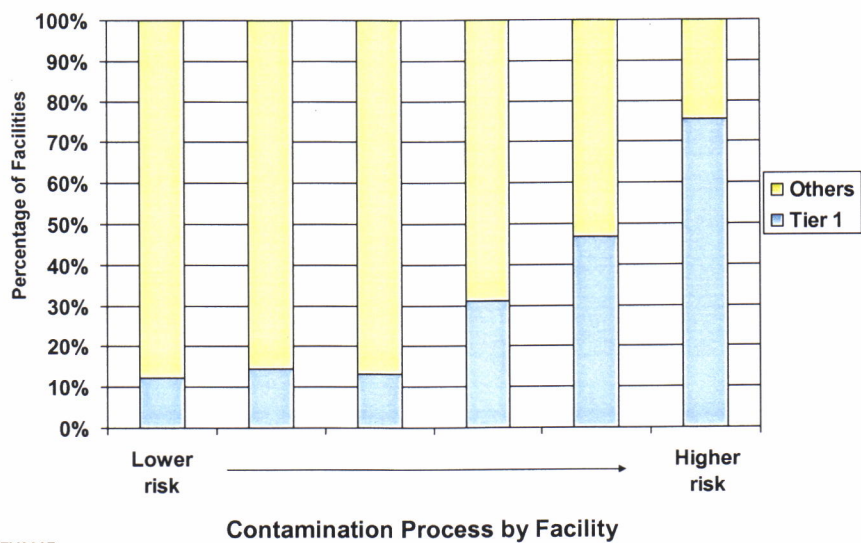


Process - by Difficulty to Control



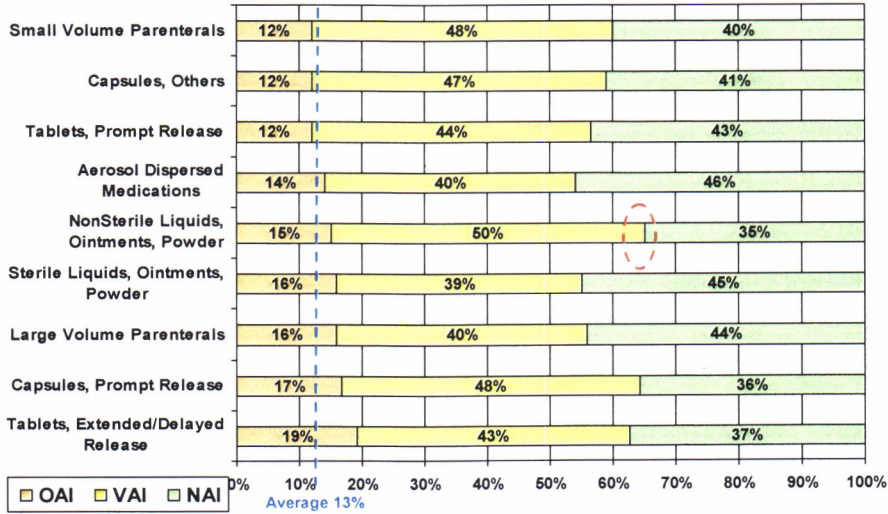
* FY2007

Process - by Risk of Cross Contamination

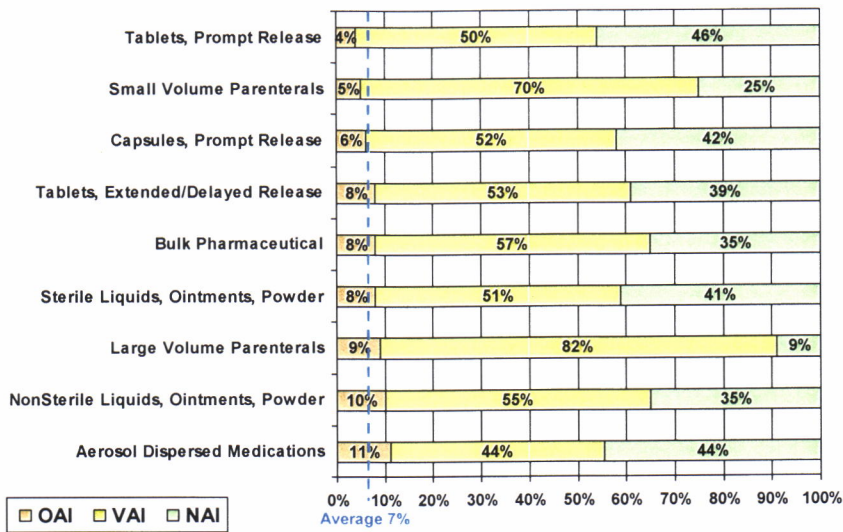


* FY2007

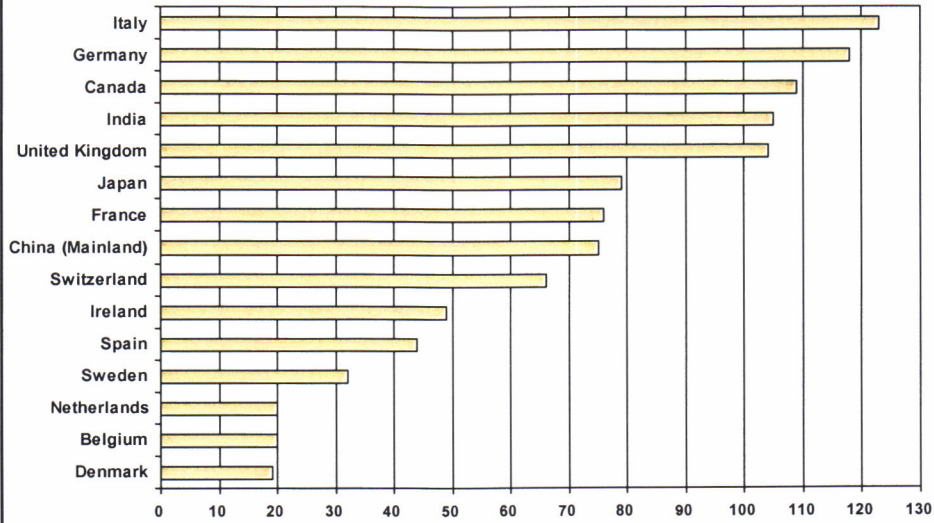
Domestic cGMP Compliance Rates by Process Indicator Code FY00 – FY06



Foreign cGMP Compliance Rates by Process Indicator Code FY00 – FY06

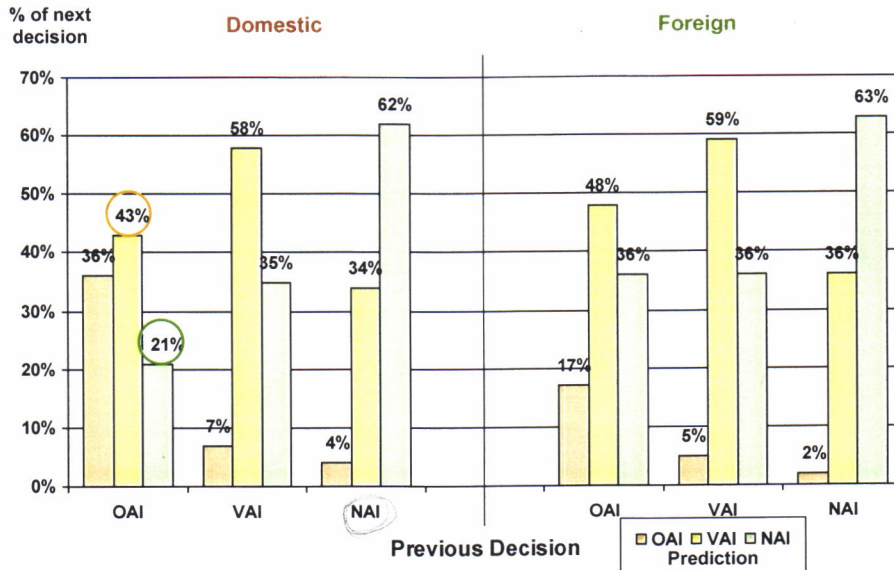


Number of Foreign cGMP Inspections by Top 15 Country FY00 – FY06



By Visit.

Percentage of Next Decision FY00-FY06



前回
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次回

Number of Visits* per Site by Fiscal Year (Domestic)

- In FY2000, 9% of the sites were visited more than once.
- In FY2005 and later, only 3% of sites were visited more than once in the same fiscal year.
- This appears to be the result of application of risk-based model.

* cGMP inspections, one visit defines as by the start date of each inspection

Summary

- The Risk-Based Model has been Implemented since FY2005 for conducting Systematic and Risk-Based cGMP Inspections.
- Model Seeks to ~~Establish Risk~~ *Pick site* for Surveillance Decision.
- Applying the Model for Inspections Reduced the Number of Revisits to a Site.

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brenda.wang@fda.hhs.gov