



# **CDRH Office of Compliance Initiatives: The Case for Quality**

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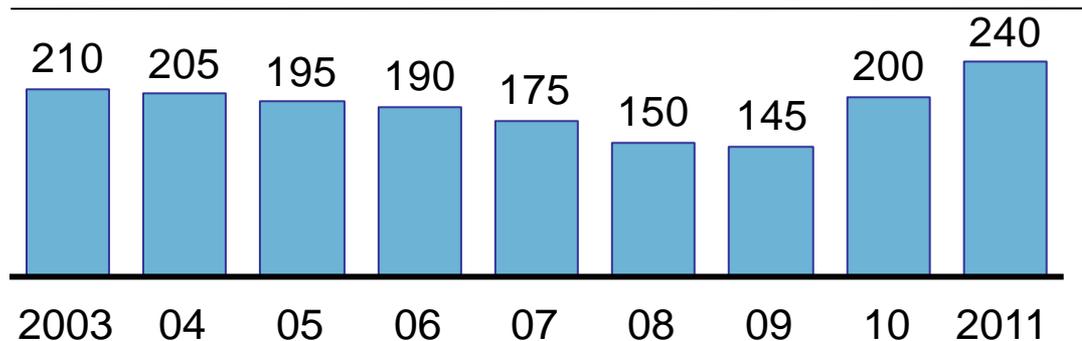


## **Key Questions:**

- **Why are we here?**
- **What's happened so far?**
- **What's next?**

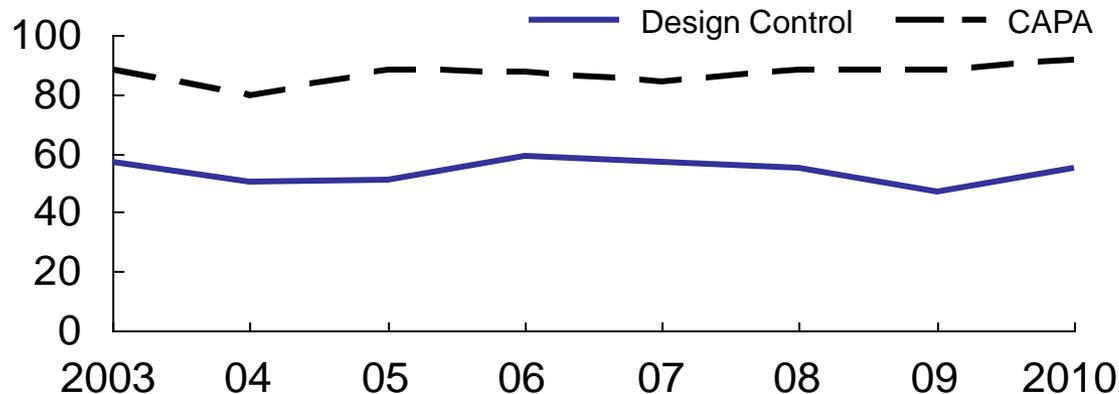
## The number of inspections with OAI outcomes has remained high, with frequent recurrences

Inspections with OAI outcomes over time



Percent Warning Letters with CAPA or DC citation

Percent of Warning Letters

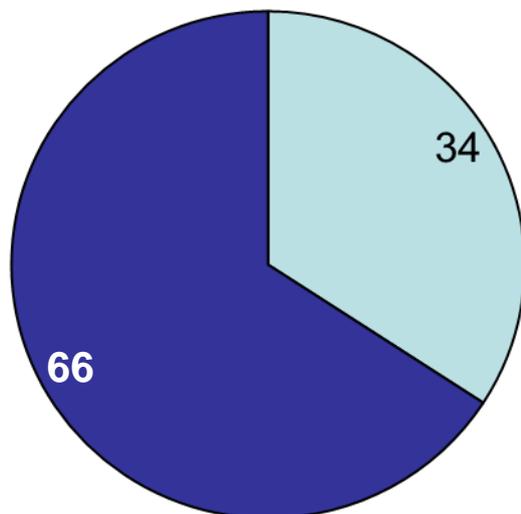


- We are consistently seeing a high volume of the same issues.
- Are we using the right methods to improve device quality?

# FDA can only inspect a portion of firms

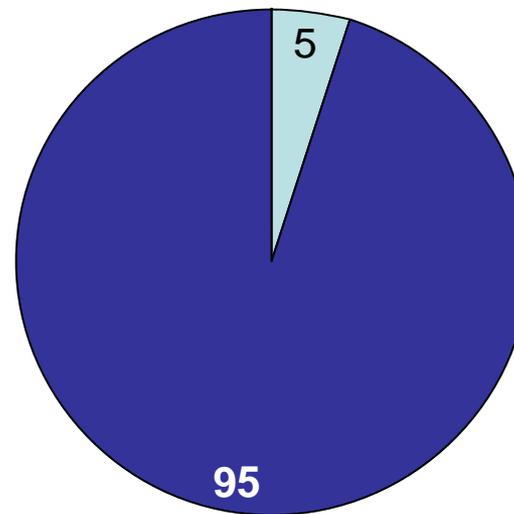
**Percent of firms inspected**

Domestic; Annual



**Percent of firms inspected**

Foreign; Annual



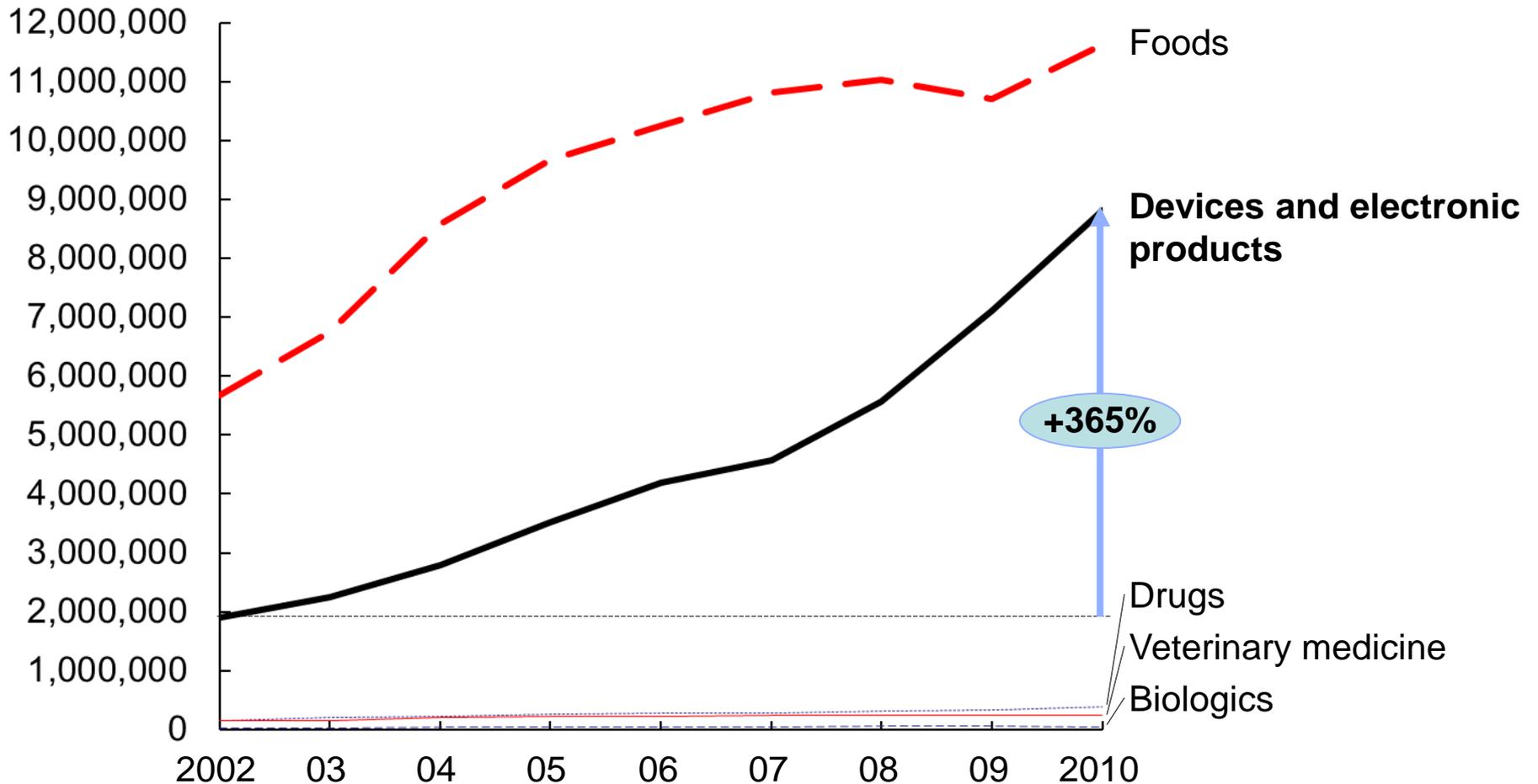
- Inspected
- Not inspected

**91** Warning Letters were issued in the 2011 fiscal year – 3% of total investigations<sup>1</sup> resulted in a Warning Letter

<sup>1</sup> Counts both domestic and foreign investigations

# Imports of devices have risen dramatically

Import lines per center



## The Case for Quality

- **Support and ownership of quality go beyond quality/compliance units**
- **A culture of quality yields benefits:**
  - Enhanced process stability
  - Cross-functional skills and collaboration
  - Reduced compliance risks and costs
  - Fewer complaints and investigations
- **Recent trends highlight the importance of quality:**
  - Rapid growth of the U.S. device industry
  - Adverse event reports outpace market growth
  - Risks are unevenly distributed across product types
  - Design failures consistently account for about ½ of all recalls

## Barriers to quality

- **Increasing complexity of devices and use environments with static quality practices**
- **Historically more focus on compliance than quality**
- **Historically underutilized comparative quality information**

## Quality has a strong impact on firms' market position

- **Quality issues can impair or enhance market reputation**
- **Quality failures or failure prevention efforts affect costs**
- **The impact of quality on customer satisfaction can alter revenues**

## What's next: The Case for Quality Implementation Plan

- **Initiative 1:** Focus on quality
- **Initiative 2:** Enhanced transparency
- **Initiative 3:** Stakeholder engagement

## Focus on quality

- **Focus on quality**
  - Enhance focus on quality while maintaining compliance
  - Promote a root-cause approach to quality challenges
- **Enhanced transparency**
- **Stakeholder engagement**

## Good quality practices, not just compliance

### What is the focus on quality effort?

- Focus on good company practices that lead to quality outcomes
- Regulatory emphasis on preventive quality practices
- Encouraging companies to view compliance as one part of achieving quality, not the ultimate goal
- Focus on identifying and addressing causes of quality failures

## Informal survey of FDA investigators

### Why we initiated survey

- **Stakeholder and industry concerns** about the mindsets of FDA employees towards issues of quality and compliance, e.g., that employees may:
  - Focus on non-systemic remediation
  - Focus on additional resources as the primary means to achieve quality goals
- **We conducted an informal survey** to understand internal mindsets

### What we found – investigator beliefs

- Firms that spend more resources on quality experience fewer compliance issues (majority belief)
- Frequently, firms focus on remediating 483 issues rather than making systematic corrections (majority belief)
- Suggestions from investigators on how to improve device quality

## FDA placing greater emphasis on quality

### Current state

- FDA assesses firms' quality practices against the Quality System Regulation (QSRreg)
- FDA's interaction with firms is mainly focused on compliance
- Some firms focus on FDA observations rather than focus on underlying causes

### Future state

- FDA will continue to assess firms' compliance with the QSRreg
- Both FDA and industry emphasize that good quality practices drive better products and protect public health
- FDA focuses with firms on root cause analysis, designing quality into the product, and optimizing corrective actions

## Initial Activities

### Preliminary ideas

### Description

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**Communicate  
FDA's Focus on  
Quality**

- Communicate FDA focus on good quality practices, not just compliance
    - Ongoing conversation with industry and other stakeholders to help drive implementation – including forums, interviews, and surveys
  - FDA outreach to change perception that investigators use a checklist approach to inspections
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**More focus on  
effectiveness and  
building in quality**

- Update compliance approach to focus on the effectiveness of corrective actions
  - Shift FDA compliance focus away from quantity of QA resources to quality in product development
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**Promoting root-  
cause approach**

- Promote a focus at FDA on root-cause analysis in compliance situations
- Unify approach at FDA: develop internal FDA root-cause training and develop common language and approach

## Comparative quality transparency

- **Focus on quality**
- **Enhanced transparency**
  - **Data transparency:**
    - Drive quality by **improving ease of access to information**
    - Provide **one integrated data source** that affords maximum flexibility
  - **Improved analyses:**
    - **Leverage wealth of Agency data** to refine FDA's initiatives
    - Provide **consistent and regular publically available analyses** that will guide compliance and quality discussion
- **Stakeholder engagement**

## Problem Statement



- **How can FDA act to help ensure that stakeholders (*industry, agencies, device purchasers, patients, and payers*) incorporate differentiating quality data into their decisions?**

# Transparency initiative will support data-driven decisions

## Current state

- **Data transparency:** Through query interfaces, FDA shares pre-market, adverse event, registration and listing, recall, and inspection information
- **Ad hoc analyses provided:** FDA provides infrequent and varying analyses and FY compliance activities

## Future state

- **Enhanced data transparency:** FDA provides a flexible, comprehensive, daily updated database structured for analysis
- **Improved analyses provided:** FDA provides consistent, predictable analyses of compliance data to support device quality improvements

## Overview of Transparency efforts

- We will encourage stakeholders to conduct analyses of medical device availability, quality, and safety through one integrated data base
- FDA will leverage the internal CDRH Data Warehouse
- FDA will use the CDRH Data Warehouse to improve analysis

### Description

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#### What will change

- Improved **ease of access and flexibility**
- Consistent access to FDA databases
- **Enhanced FDA analyses**
- **Expected increase in third party analyses** based on more accessible data

#### What will NOT change

- The data itself will not change significantly
- FDA will continue to provide device and quality system analyses and will not generally provide manufacturer specific perspectives

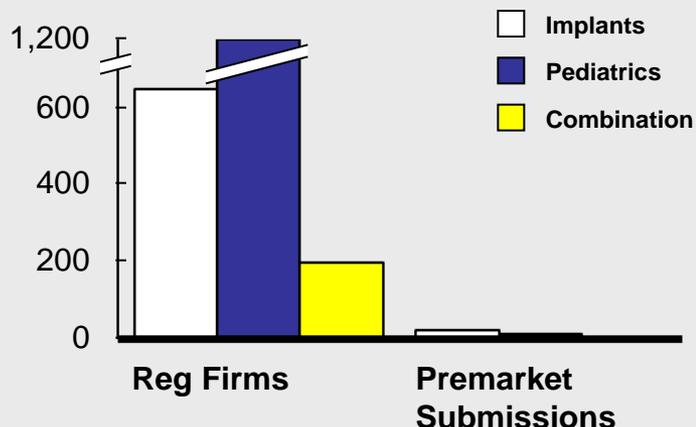
## Overview of future public reporting engine and support

- **More than just flat html display**
- **Support on-site analysis**
- **Provide canned reports for public use**
  - Allow CDRH control over and creation of reports
  - Engagement with stakeholders on what data and reports will be of value
- **In addition, we propose supplementary explanation of available data fields**
  - This will help to minimize data pitfalls (e.g., interpretation of nomenclature, explanation of data fields)
  - We will assist the public in understanding the data, thereby encouraging accurate analysis

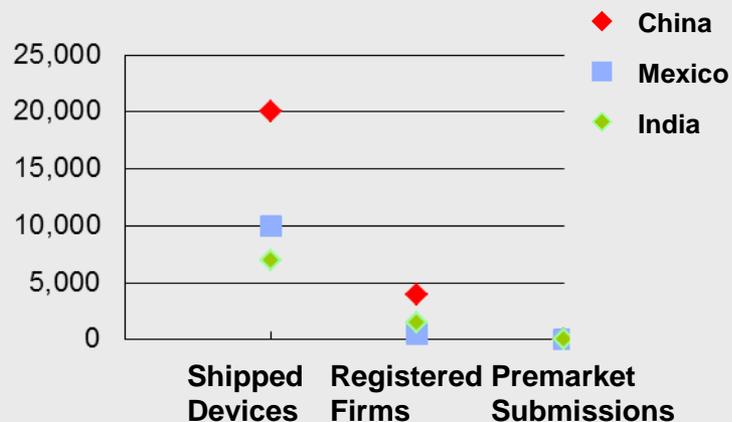
# One focus: program baselines and trending analysis

## Example analyses:

Registered firms and Premarket submissions by industry



Import information by market of origin



### Example areas for exploration:

- Quarterly automated device analysis
- Cover “device groups”
- Include Total Product Life Cycle data
  - Premarket data
  - Recall root causes
  - MDRs
- Center activity snapshot by device group
  - Where the action is
  - Where there might be an overarching issue
- Provide level conclusion on the state of overall device quality

## Another focus: comprehensive characterization analysis – “state of the device”

- **Device selected through risk-benefit analysis or signals from other systems (e.g., PREDICT)**
- **Detailed review of premarket submissions, recall documentation, epidemiological resources, publications, and EIRs**
- **Market and D&B Information**
- **Results of analysis**
  - For clinicians, patients, users, manufacturer/distributors
  - Recommendations based on quality data
  - Suggestions/recommendations focusing on design, manufacturing, training, reminders, etc.
  - Good reference for public health notifications
- **Timelines by specific product code or manufacturer**
  - Chronological representation of pre- and post-market data

## Stakeholder engagement

- **Focus on quality**
- **Enhanced Transparency**
- **Stakeholder engagement**
  - Forums to explore with stakeholders issues that will arise during our transition to a more quality-focused approach
  - We will collaborate beyond these forums

**FDA is undertaking an initiative to enhance communication among stakeholders. This will include:**

- Developing multiple engagement touchpoints between FDA, Industry, and other stakeholders to:
  - More effectively communicate expectations
  - Solicit input on necessary changes and improvements
- Conducting a change-management program to promote optimal quality practices
- Developing a project management structure to support this initiative and monitor its impact

## FDA is looking for input on stakeholder engagement

### Initial questions we would like to have input on:

- How could FDA, industry, and other stakeholders work together to systemically advance quality and identify gaps?
- What support from FDA would be required or would act as an accelerator to address these gaps?
- What collaborative models could be developed between industry, FDA, and other stakeholders that you envision as helpful?

# FDA proposes a set of stakeholder engagement forums

## Preliminary ideas

### Central forum

## Description

- Cadence of CDRH / ORA interactions with leaders of medical device companies and other stakeholders
- Objective is to
  - More effectively communicate expectations
  - Solicit input on necessary changes and improvements

### Field forums

- Cadence of ORA district office interactions with leaders of medical device companies and other stakeholders
- Objective is to
  - More effectively communicate expectations
  - Solicit input on necessary changes and improvements

### Current practices sharing platform

- Platform to share FDA and device company experience on recent quality practices
- Data collaboration will inform these discussions

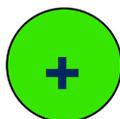
# Stakeholder engagement forums could be led by FDA, industry, or others

## Options for leadership

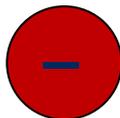


## Description

- | Options for leadership | FDA  | Industry professional group  | Industry user-group  | University   |
|------------------------|--|--|--|--|
| <b>Description</b>     | <ul style="list-style-type: none"> <li>FDA (CDRH or the ORA districts) leads and organizes industry – FDA forum, and commits to organizing these on regular basis</li> </ul> | <ul style="list-style-type: none"> <li>Industry professional group leads industry – FDA forum and commits to organizing these on regular basis</li> <li>Examples: AdvaMed, RAPS, MDMA</li> </ul> | <ul style="list-style-type: none"> <li>Group of industry players who decide to create user-group that will organize these forums on regular basis</li> </ul> | <ul style="list-style-type: none"> <li>University leads industry – FDA forum, and commits to organizing these on regular basis</li> <li>Example: University of Georgia conference</li> </ul> |



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|--|---|---|---|
| <ul style="list-style-type: none"> <li>FDA would                             <ul style="list-style-type: none"> <li>– Be motivated to do this</li> <li>– Have agenda that is aligned with stakeholder engagement initiative</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>Industry or professional group may be                             <ul style="list-style-type: none"> <li>– Motivated to do this</li> <li>– Capable based on experience to organize these meetings</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>Industry user-group would                             <ul style="list-style-type: none"> <li>– Be motivated to do this</li> <li>– Be capable to organize these meetings</li> <li>– Have agenda that is aligned with stakeholder engagement initiative</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>University is independent partner</li> </ul> |
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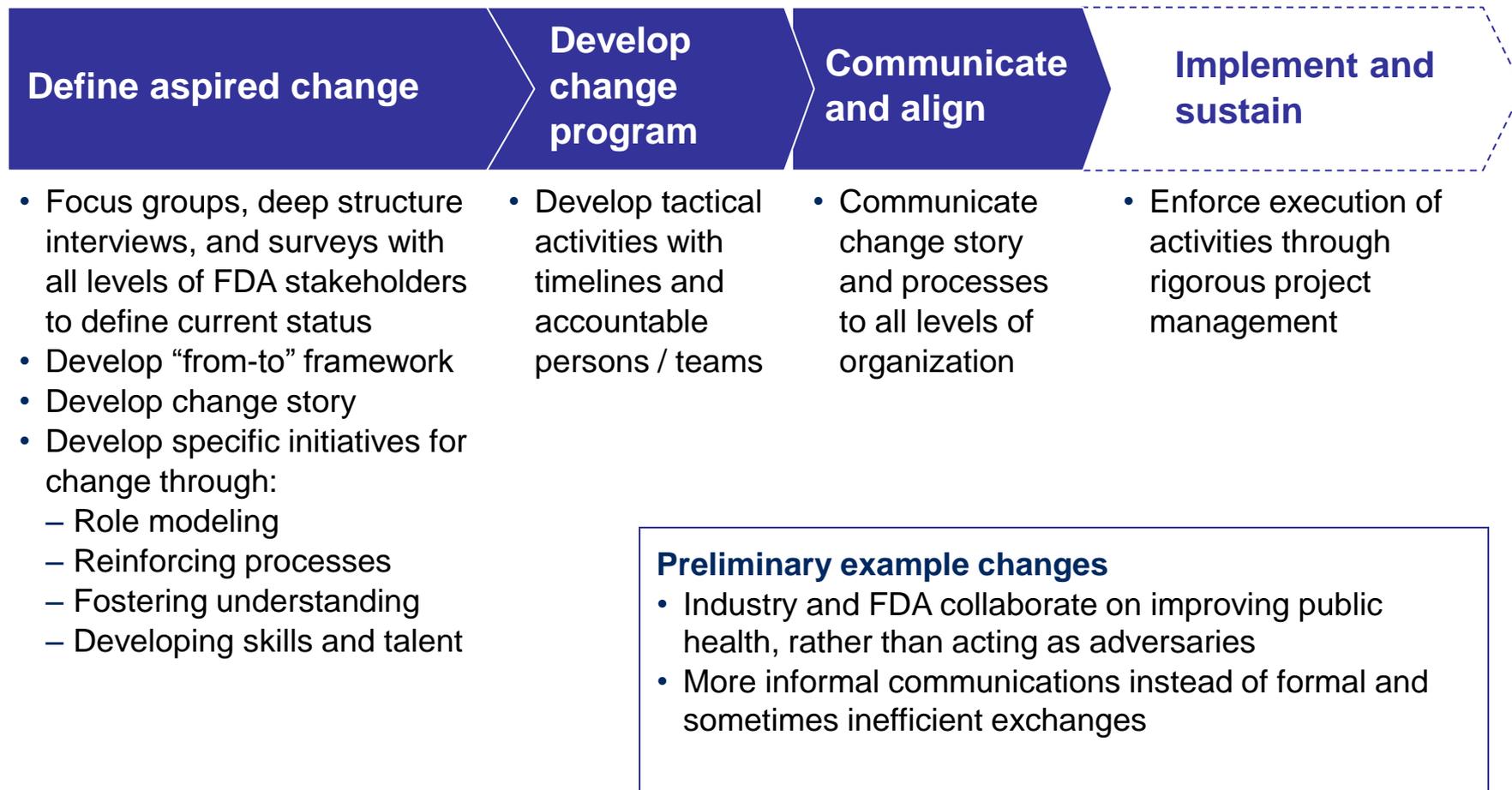


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|--|--|---|--|
| <ul style="list-style-type: none"> <li>FDA leadership may support false perception that FDA will not collaborate with other stakeholders</li> <li>Logistically challenging given formal processes to announce public meetings</li> </ul> | <ul style="list-style-type: none"> <li>Industry or professional group may have misaligned incentives / own agenda</li> </ul> | <ul style="list-style-type: none"> <li>Change in group membership could lead to planning uncertainty</li> <li>Priorities could shift</li> </ul> | <ul style="list-style-type: none"> <li>Universities may have little incentive to do this</li> <li>Universities may not have resources</li> </ul> |
|--|--|---|--|

## A wide range of topics could be within scope of these forums

- Good / acceptable quality practices observed by FDA and industry
- Good / acceptable quality practices observed by other regulatory agencies and other industries
- Innovative quality approaches that FDA encourages
- Quality-enhancing practices employed by other regulatory agencies and other industries, and potential leanings for FDA
- Touch points outside traditional inspections to drive quality outcomes
- Need for safe ways to object / react to 483 findings and best practices in engaging FDA while addressing 483 findings
- Need for more and better data collection on quality
- Existing data gaps and solutions in capturing or analyzing quality data

## The Need for a FDA / Industry Change Program



# FDA will track progress and apply impact measures

## Description

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### Program metrics

- Evaluation of the progress towards finalizing ongoing activities

### Impact metrics

- Evaluation of impact for each finalized activity by assessing the objective and the resulting impact

### Qualitative input on progress

- Set of qualitative statements that show whether sufficient progress has been made towards end goal of stakeholder engagement

## The initiative will start as soon as possible and specific goals have been established

### Short term goals (by end of 2012):

- Pilot versions of forums and, for at least one forum, regular interaction cadence ongoing
- Clear definition and baseline of performance metrics and time-based targets for long term goals

### Long term goals (by end of 2015)

- Engagement forums have created open communication between stakeholders, producing better quality outcomes
- Effective communication between industry, FDA, and other stakeholders increases FDA's openness to innovation and enhanced transparency
- FDA and stakeholders ensure that this effort is sustainable and reaches its goal of improved quality outcomes