

# After The Inspection

## When and How to Meet With FDA

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**“Imagination Is  
A Poor Substitute  
For Experience”**

(Havelock Ellis)

# Agenda

- **FDA Meeting Lifecycle**
  - Stages of meeting development
  - Points to consider
- **Keys to Successful Meeting Management**
- **Discussion/Questions**

# The FDA Meeting Lifecycle

External

Factors that may affect the meeting:

- Organization's existing reputation or prior problems with FDA.
- Experiences of competitors
- Changes in laws or regulations
- Media interest in issues relating to organization's sector

Internal

Factors that may affect the company's ability to organize and manage the meeting:

- Past learning's applied to process and policy
- Culture
- Ability to identify, understand and act on issues
- Company business relationships
- Consultant advice

## Deciding to Meet With FDA

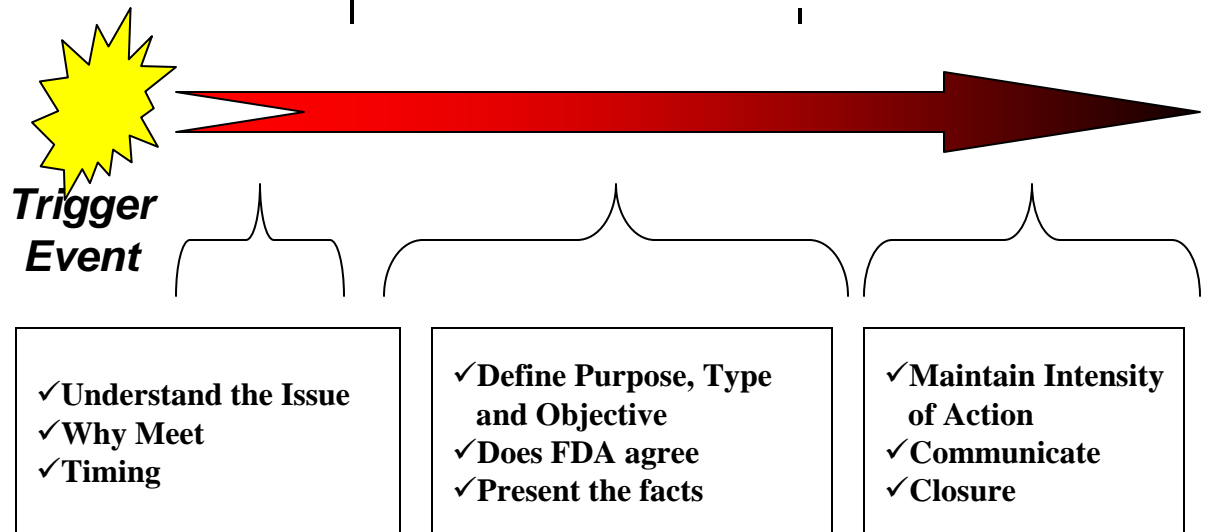
An event is the dominating issue

## Preparing for and Conducting the Meeting

Organizing the message and preparing the facts

## Follow up Actions and Closure

The memory lingers....  
Commitment is Key



# Anatomy of a Meeting

## *The Decision Stage*

### *The event is the dominating issue*

- Understand the problem
  - Get the facts, avoid denial
- Decide if a meeting is appropriate
  - Scope of the issue
  - Purpose, type and objectives
  - Who will attend (District, Center, Company members)
- Does FDA agree
  - Discuss the meeting request with FDA
  - What is FDA requirement for timing

# Anatomy of a Meeting

## *The Preparation Stage*

### *Organizing the message and preparing the facts*

- Know the Facts
  - Be accurate and straightforward
  - Understand the company commitments
- Identify potential questions
  - Prepare and practice

# Anatomy of a Meeting

## *The Preparation Stage*

### *Organizing the message and preparing the facts*

- Plan your message
  - Identify your team and roles
  - Appoint a spokesperson
  - Be consistent in the message – *maintain control*
  
- Address the issue
  - Be concise
  - Focus on systems not symptoms

# Anatomy of a Meeting

## *Follow Up, Commitment and Closure*

### *The Memory Lingers .....*

- Prepare meeting minutes
  - Identify the important points of the meeting
  - Document conclusions and action items
  - Attach a participant list
  - Provide meeting minutes to FDA
- Focus resources on meeting commitments
  - Communicate
  - If timing or plan changes – *let FDA know*



# Anatomy of a Meeting

## Points to Consider

- Have a plan
  - Identify the key concerns and actions
  - For updates, provide a brief status
  - Be consistent with past communications
- Understand the issues/gain agreement
  - Verify that FDA and Company have the same understanding of actions
  - Gain agreement that the important issues are being addressed
  - Are the actions appropriate
  - Identify any open issues

# Anatomy of a Meeting

## Points to Consider

- Know the message
  - Truthful
  - Accurate
  - Consistent
  - Do not speculate/assume
- Team membership
  - Roles and responsibilities
  - Limit participation
  - Consider having an independent person to observe and take notes
  - Verify everyone knows the facts
  - Identify FDA and company coordinators

# Anatomy of a Meeting

## Points to Consider

- Follow up
  - Company
    - Communicate decisions
    - Organizational commitment is key
  - FDA
    - Provide all information as agreed
    - Keep to timing
- Set achievable goals and targets
  - Assure there is a process for the company to stay on track.

# Anatomy of a Meeting

- Keys to Success

- Commitment at the top
- Understand the issues
- Consistency/clarity of message – know the facts, identify the action plan and don't waiver without reason.
- Stay within the boundaries of prior responses
- Correct the *system* not just *symptoms*
- Understand that meetings alone can not solve the issues at hand. Action is important and meetings are for clarity, timing and milestone communications.
- Adopt the lessons learned to the organization's operations.