



Strategies to Prepare for Meetings with the FDA

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Topics for Discussion

- Who Are We?
- How Do We Interact Internally?
- Why Are Meetings Important?
- How to Get the Most Out of Your Meeting
- What's New?

Who Are We?

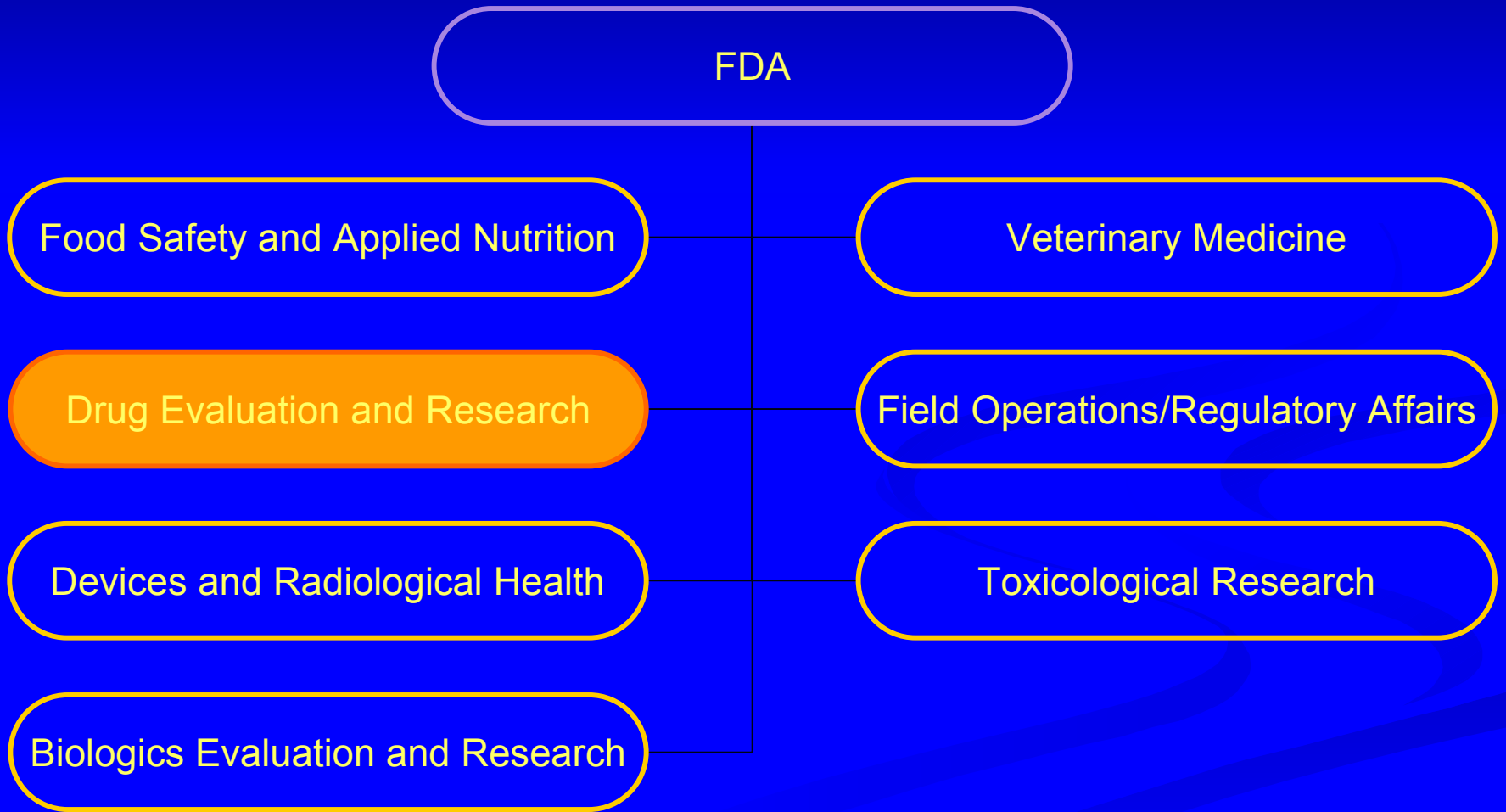
Shared Public Health Goal:

- “**Promote** the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner...also responsible for **advancing** the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable...”

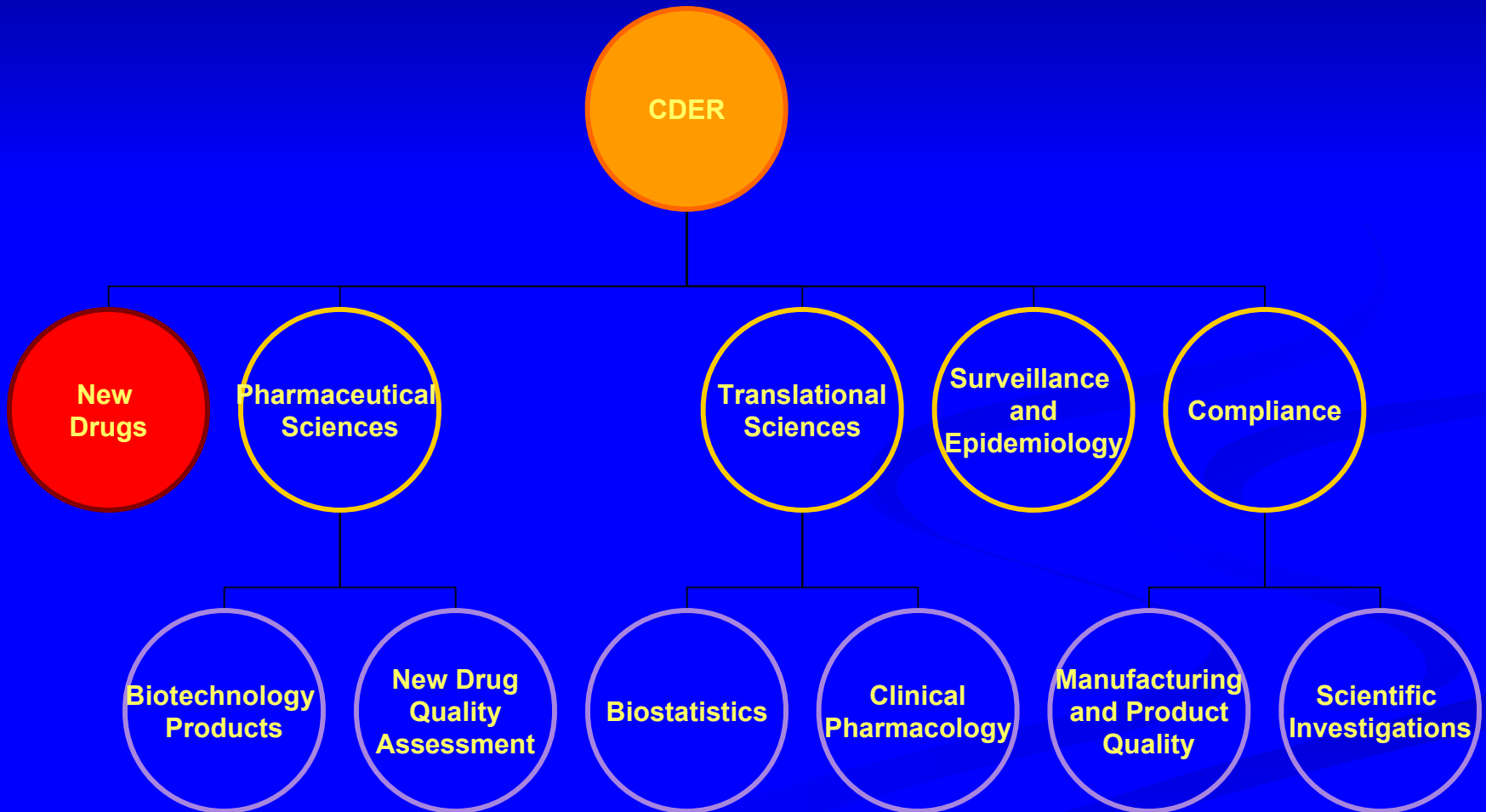
FDA's Mission Statement

www.fda.gov/opacom/morechoices/mission.html

Who Are We?



Who Are We?



Who Are We?



How Do We Interact Internally?

Review Teams: Multidisciplinary Experts

- Clinical
 - Including Microbiologists for Antimicrobials
- Chemistry / Manufacturing
 - Including Sterility, If Needed
- Non-clinical Pharmacology / Toxicology
- Clinical Pharmacology
- Statistics
- Regulatory (Project Manager)

Why Are Meetings Important?

- “Review team members generally consider open and frequent communication as having a high impact on the review process.”
- “EOP2 meetings have a positive impact on first-cycle approval rate....of the multiple-cycle applications...25% ...had the critical issue...identified at this meeting.”

*Independent Evaluation of FDA's First Cycle Review Performance
–Retrospective Analysis Final Report, Booz Allen Hamilton, Inc.
www.fda.gov/oc/pdufa*

Why Are Meetings Important?

*Meetings Are One Method of
Communication Between
the Agency and Industry
to Facilitate a Common Goal –
More Efficient Drug Development.*

How to Get the Most out of Your Meeting – the Request

First Ask Yourself – Do I Need a Meeting?

- Identify Your Questions *Before* You Request a Meeting (i.e., Know Why a Meeting is Needed and the Best Method of Communication)
- Written Feedback Can Be Provided Upon Request for Amendments to the IND (Not Always Provided)
- Regulatory and Procedural Advice Can Be Given Over the Phone or by e-mail

How to Get the Most out of Your Meeting – the Request

- Submit Request in Writing
 - Clearly Identify Your Submission as a “**Meeting Request**”
- Include Relevant Background in the Request
 - Objective / Expected Outcome
 - Draft Questions (With Paragraph of Explanation*)
 - Proposed Industry Attendees; Requested FDA Attendees

How to Get the Most out of Your Meeting – the Request

- Don't Ask Unanswerable Questions
- Select Attendees Based on Identified Issues – Scheduling Considerations
- Expect a Response to Your Request (Granted or Denied) Within 14 Calendar Days of Receipt

How to Get the Most out of Your Meeting – Types

- Type A: Stalled Development Program
 - Held Within 30 Days of Receipt
- Type B: “Milestone” Meeting (pre-IND, End of Phase 1 or 2, pre-NDA)
 - Held Within 60 Days of Receipt
- Type C: Any Other Request for Advice
 - Held Within 75 Days of Receipt

How to Get the Most out of Your Meeting – the Preparation

Background Package Submission

- Don't Be Late!
 - Type A: 2 Weeks Prior to Meeting
 - Type B/C: 4 Weeks Prior to Meeting (Type C Timeframe Was a Technical Fix in PDUFA III; Not Updated Yet in Guidance)
- Communicate With Your RPM Regarding Archival and Desk Copies

How to Get the Most out of Your Meeting – the Preparation

Background Package Organization

- Organize by Agenda Topics / Questions, Grouped by Technical Discipline
- Pagination, Table of Contents, Indices, Appendices, Cross-references, Tabs – Whatever Makes Your Package Easy to Navigate

How to Get the Most out of Your Meeting – the Preparation

Background Package Content

- Needs to Support Intended Objectives
- Relevant Summary Product Information
- Final List of Questions to be Addressed
- Supplementary Information to Address the Specific Issues / Questions
- If Data Has Already Been Submitted, Reference the Submission (Manage the Volume of Your Package)

How to Get the Most out of Your Meeting – What to Expect

- Internal CDER Pre-meeting Ideally 2-7 Days Prior to the Meeting
- Draft / Preliminary Responses to Questions Submitted in Background Package Sent 24-48 Hours Before Meeting
 - Increases Efficiency of Meeting by Eliminating Issues Not Requiring Further Discussion
 - Highlights Areas Needing More Information for Resolution
 - Alerts Sponsor to CDER's Issues of Concern

How to Get the Most out of Your Meeting – Conduct

- Skip the Presentation – Use the Time for Discussion
- Don't Hide Concerns – Share Them and Propose Solutions
- Stay Focused on the Agenda
- Minimize Surprises
- Never Assume – Be Clear

How to Get the Most out of Your Meeting – Conduct

- Stay Professional
- Listen Closely and Strongly Consider What Is Being Recommended
- At the End of the Meeting, or After Each Agenda Topic / Question: FDA Will Ask Sponsors to Summarize What Was Heard, Outcomes and Any Action Items

How to Get the Most out of Your Meeting – Post-meeting Activities

- Meeting Minutes Will Be Provided Within 30 Days
 - Meeting Summary, Not a Transcript
 - FDA Version is the Official Version: Submit Disagreements in Writing
- Follow-up on Action Items
 - Effective Communication Now Will Improve Your Path Later

How to Get the Most out of Your Meeting – Other Considerations

- Communications Should Not Be Limited to “Milestone” Meetings – Advice Should Be Requested as *Needed*
- Guidance Meetings Can be Held at Request of Sponsor or FDA to Discuss Any Issues
- General Principles for Meeting Management Apply to All Interactions – Teleconferences and Videoconferences Are Meetings Too!

How to Get the Most out of Your Meeting – Specific Meetings

Pre-IND Meeting

- Not Necessary For Every IND
- Focus on Pre-clinical Studies and Design of Initial Clinical Protocol
- Opportunity to Discuss Uniqueness of Molecular Entity, Studies or Indications
- Pre-IND Meeting \neq No Clinical Hold
- Remember - Advice Given is Based on Information Provided

How to Get the Most out of Your Meeting – Specific Meetings

End-of-Phase 1 / End-of-Phase 2

- Discuss and Reach Agreement on Clinical Studies That Will Provide Definitive Support for Efficacy and Safety
- Most Important Meeting During Development!
- Consider a Mock-up a Label (Target Product Profile) so We Can Help Ensure That Your Trial Design Supports Your Labeling Goals
- End-of-Phase 1: Designated for Fast-track Products Where Phase 2 Trials May Provide Sufficient Data on Safety and Effectiveness to Support Approval

How to Get the Most out of Your Meeting – Specific Meetings

End-of-Phase 2A

- *Pilot Program* – Limited by Available Resources
- 1st in Class New Molecular Entities, Fast Track Products, and / or Drugs With a Well Understood Mechanism of Action
- Intended to Improve Efficiency of Drug Development by Early Discussion of Exposure-Response
- Contact Office of Clinical Pharmacology *Before* Submitting a Formal Meeting Request

How to Get the Most out of Your Meeting – Specific Meetings

Pre-NDA / BLA

- Request When All Studies Designed to Support the Desired Claims of Safety and Efficacy Have Been Completed
- Discuss Whether Evidence of Effectiveness Was Seen in the Phase 3 Trials, the Need for Risk Management, Technical Aspects (Format), Plans to Address Potential Problem Areas
- Address All Previous Advice Not Taken, and Unresolved Issues
- Be Honest – Are You Really Ready to Submit?

How to Get the Most out of Your Meeting – Specific Meetings

End-of-Review Conference

- Following Approval as a Lessons Learned Exercise
- Following Non-approval With the Signatory Authority to Ensure Clear Understanding of Deficiencies and Information Needed to Resolve Them
- Required First Step Prior to Formal Dispute Resolution

What's New?

Good Meeting Management Principles

- Outcome of OND Process Improvement Team on Meeting Management
- Implements Consistent Processes and Best Practices Across of All OND Review Divisions
- Many Processes Already Put Into Place; Additional Guidance Will Include Discipline Specific Advice on Background Packages for Milestone Meetings
- Draft Guidance to Publish Soon...

“I’m From the Government, and I’m Here to Help...”

- Guidance for Industry
- Use (Not Abuse!) Your Regulatory Project Manager
 - Keep in Touch With the Regulatory Project Manager on an Informal Basis – Provide Updates, “Heads Up!”, etc.
- Follow Chain of Command When Issues Cannot Be Resolved
 - Scientific, Regulatory and / or Procedural Disputes Follow Formal Dispute Resolution
- Utilize the Ombudsman’s Office

In Summary...

- Meetings Are a Critical Component of the Way We (Industry and FDA) Do Business
- Extensive Framework Around Meeting Process and Procedures Enhance Predictability
- Efficient Use of Meetings Facilitates Our Shared Public Health Goal