Multimodal Therapies for Brain Disorders:
A FDA Medical Device Staff Perspective

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A Risk Based Approach for Medical Devices since 1976

Increasing Risk

Classification determines extent of regulatory control (Risk Based)

Class I
- General Controls

Class II
- General controls
- Special controls

Class III
- General controls
- Premarket approval (PMA)

General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

Special Controls (addressing Risk)
- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Performance testing, such as biocompatibility, engineering, animal, etc.
- Special Labeling

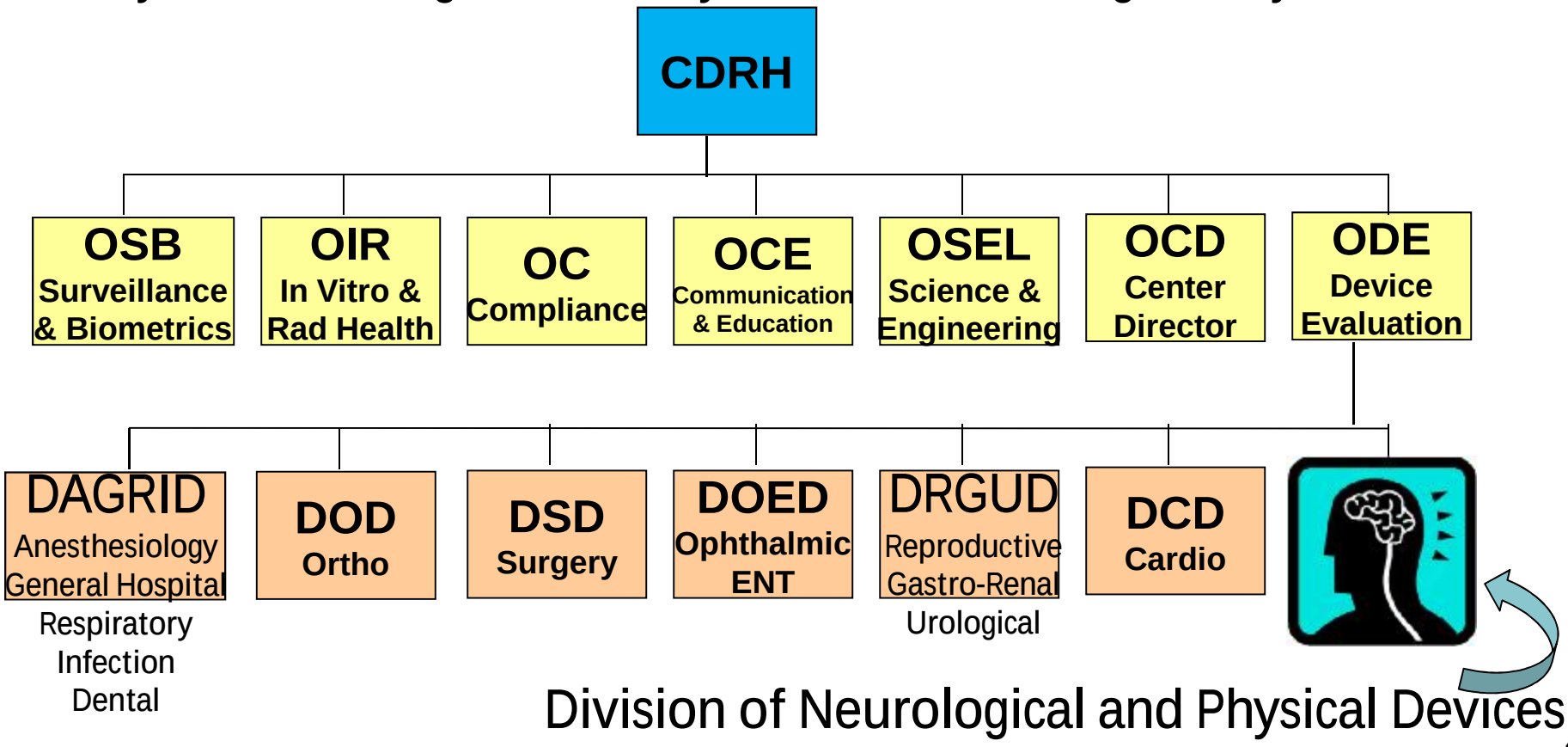
Points of Staff Exchange Across FDA
Advancing Products to Patients

- Submissions
- Advisory Committee Meetings
- Public Meetings and Workshops
- FDA Working Groups
- Domestic Conferences

Investing in Review-A New Division at FDA

Center for Devices and Radiological Health (CDRH) Organization

Pathway for Neurological and Physical Medicine Regulatory Submissions



Division of Neurological and Physical Devices

Pre-Submissions

<u>WHAT</u>: an opportunity to obtain FDA feedback prior to IDE or marketing submission

<u>Guidance Document</u>

"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff"

(Document issued on February 18, 2014)