



Interacting with FDA

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Division of Gastroenterology
Products

Overview

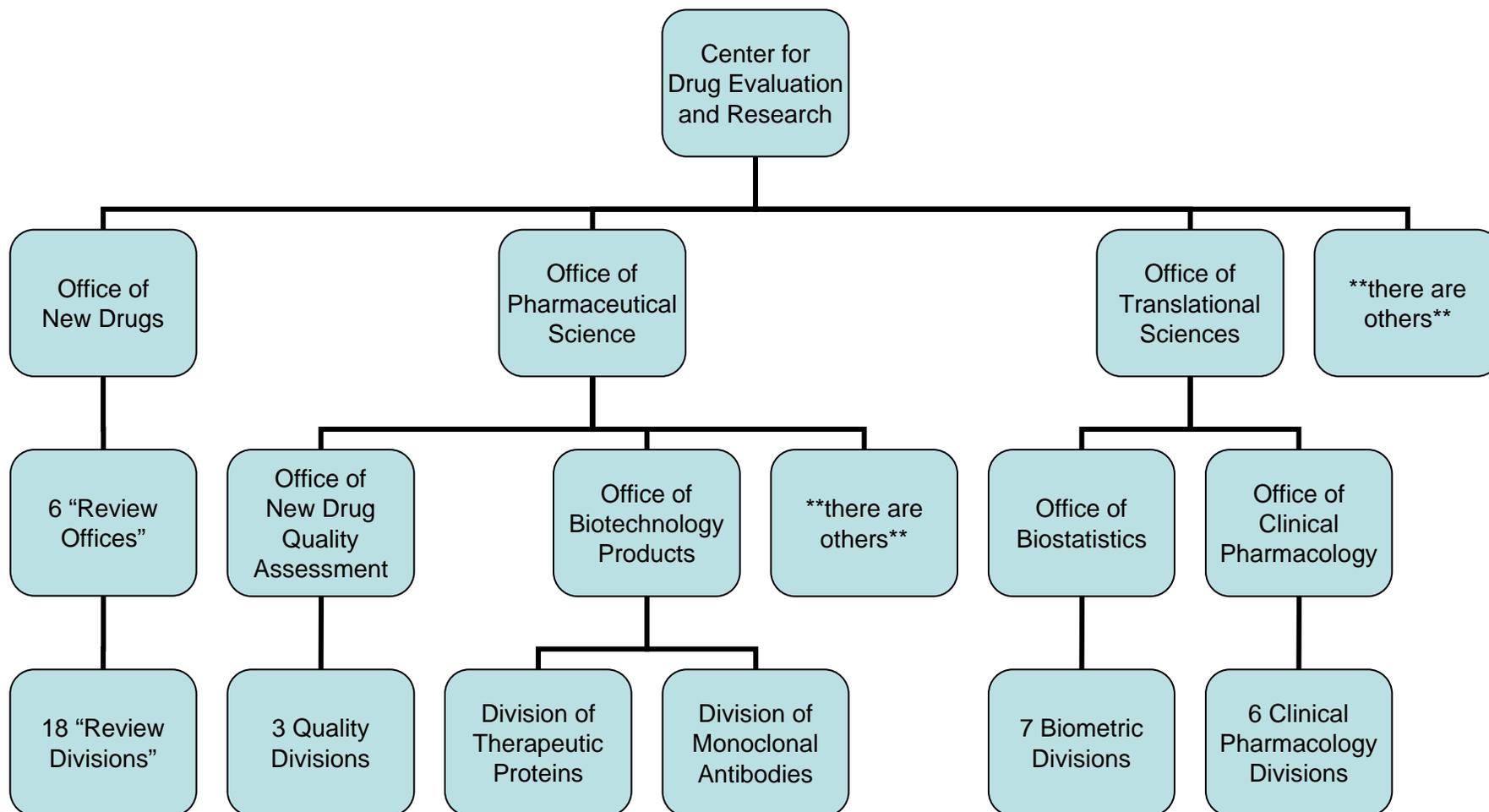
- Structures
 - Organizational
 - Team Dynamics
 - Statutory and Regulatory
- Processes
 - Pre-IND Submission Activities
 - IND Submission and Review
 - Post-Submission Activities and Responsibilities



Structures

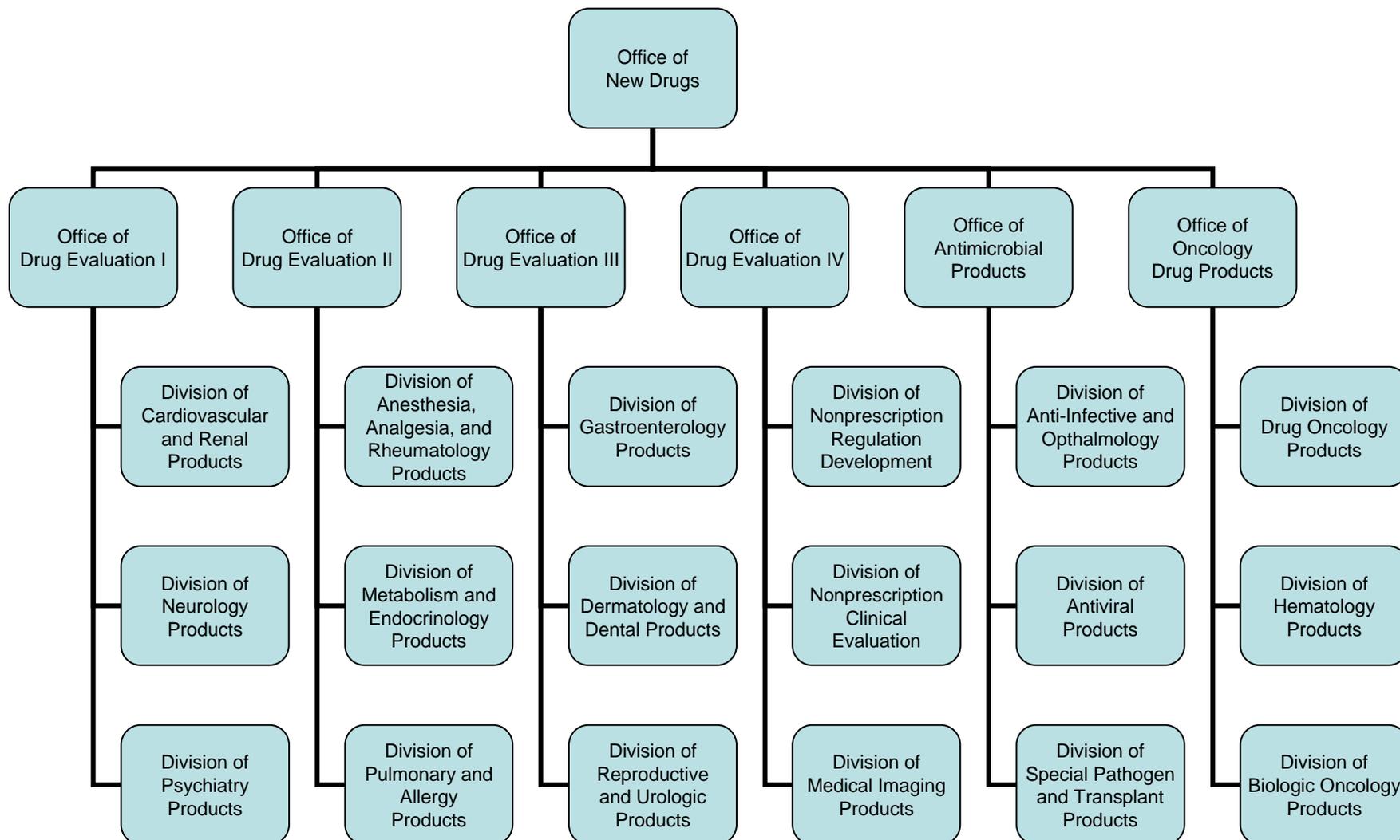
- **Organizational**
- Team Dynamics
- Statutory and Regulatory

Structures: Organizational (1)

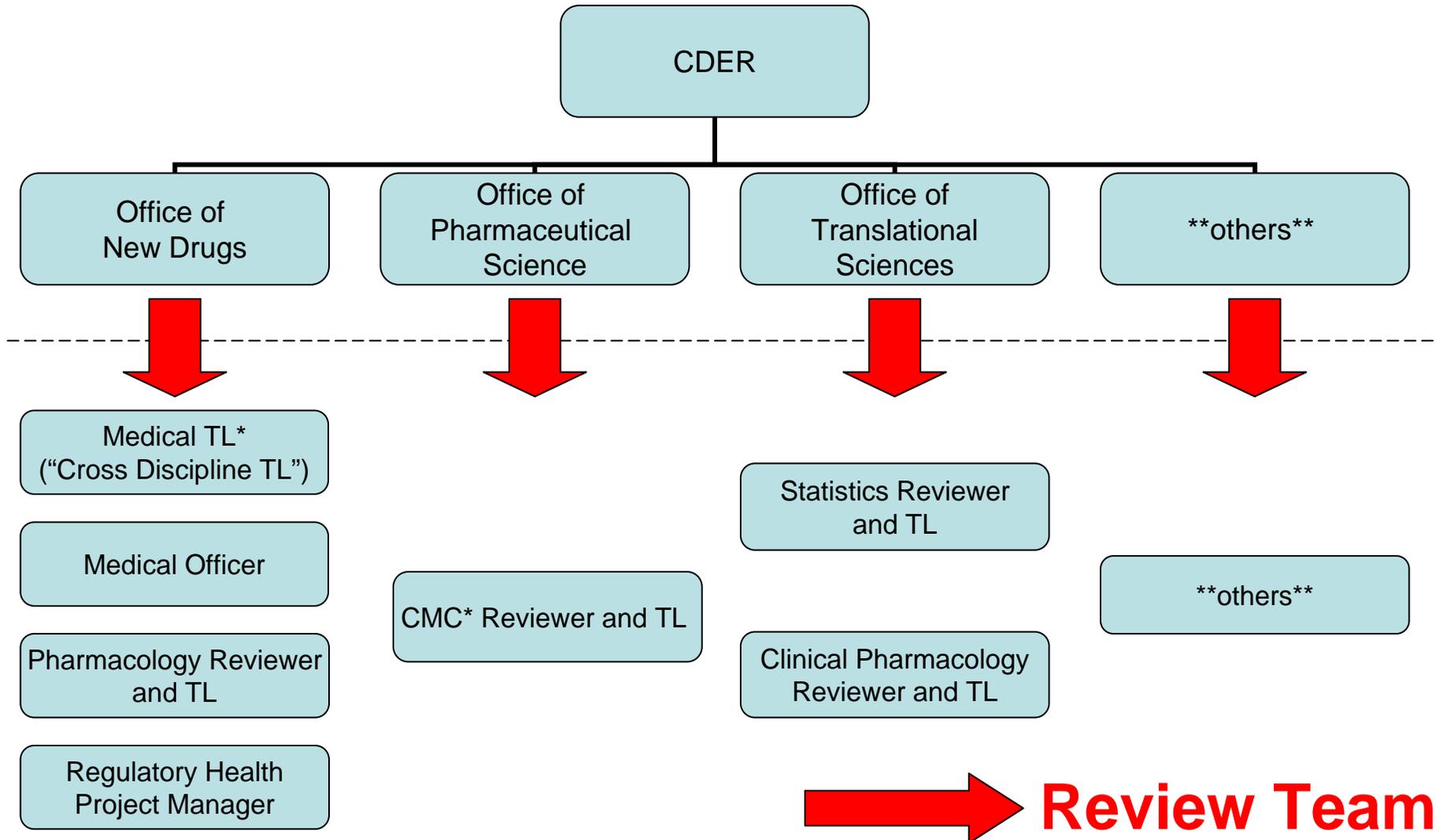


Note: This is a simplified organizational chart for presentation purposes and does not reflect all Offices/Division within CDER

Structure: Organizational (2)



Structures: Organizational (3)



***CMC** = **C**hemistry, **M**anufacturing and **C**ontrols

***TL** = **T**eam **L**eaders

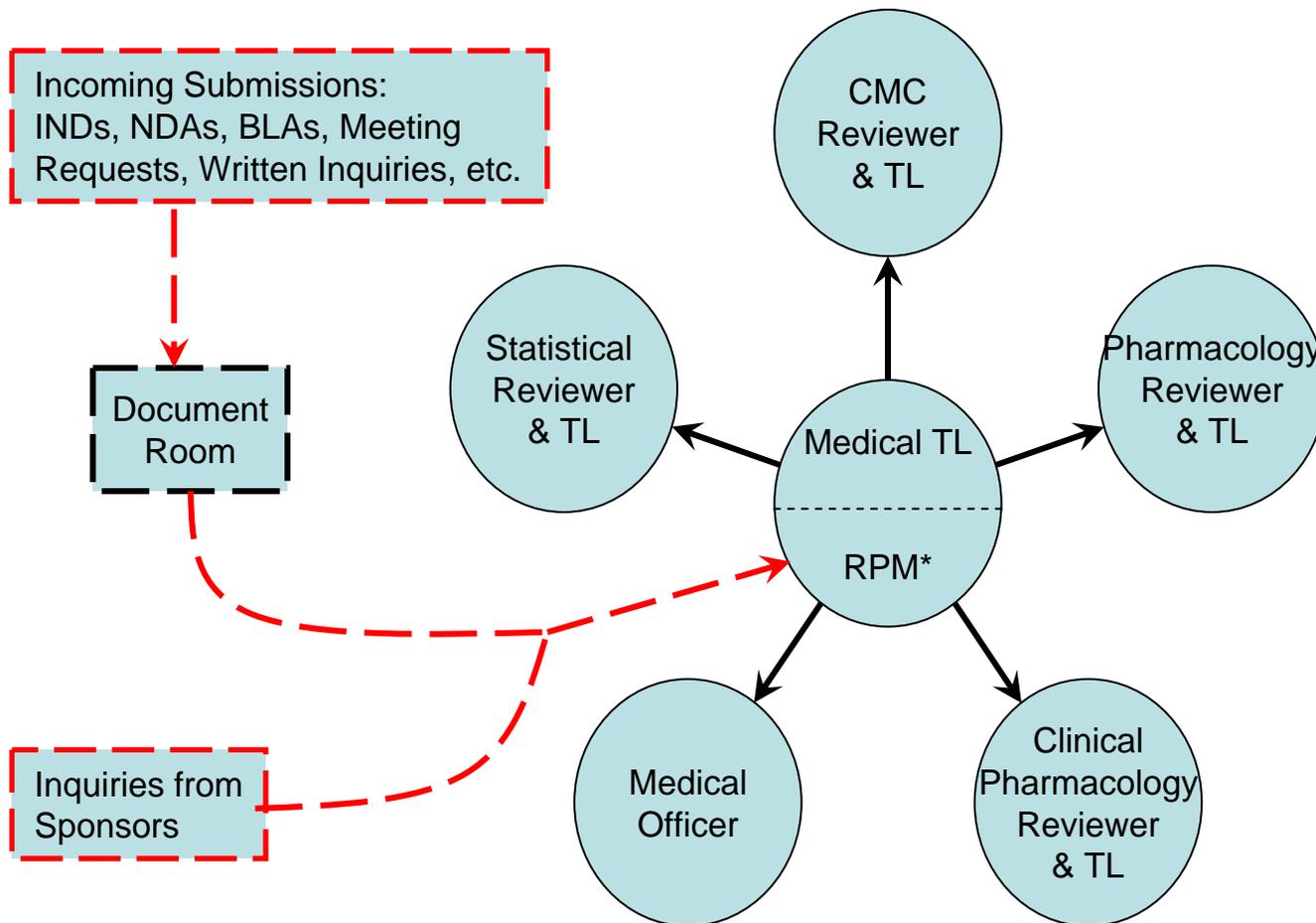
Structures

- Organizational
- **Team Dynamics**
- Statutory and Regulatory

Structures: Team Dynamics (1)

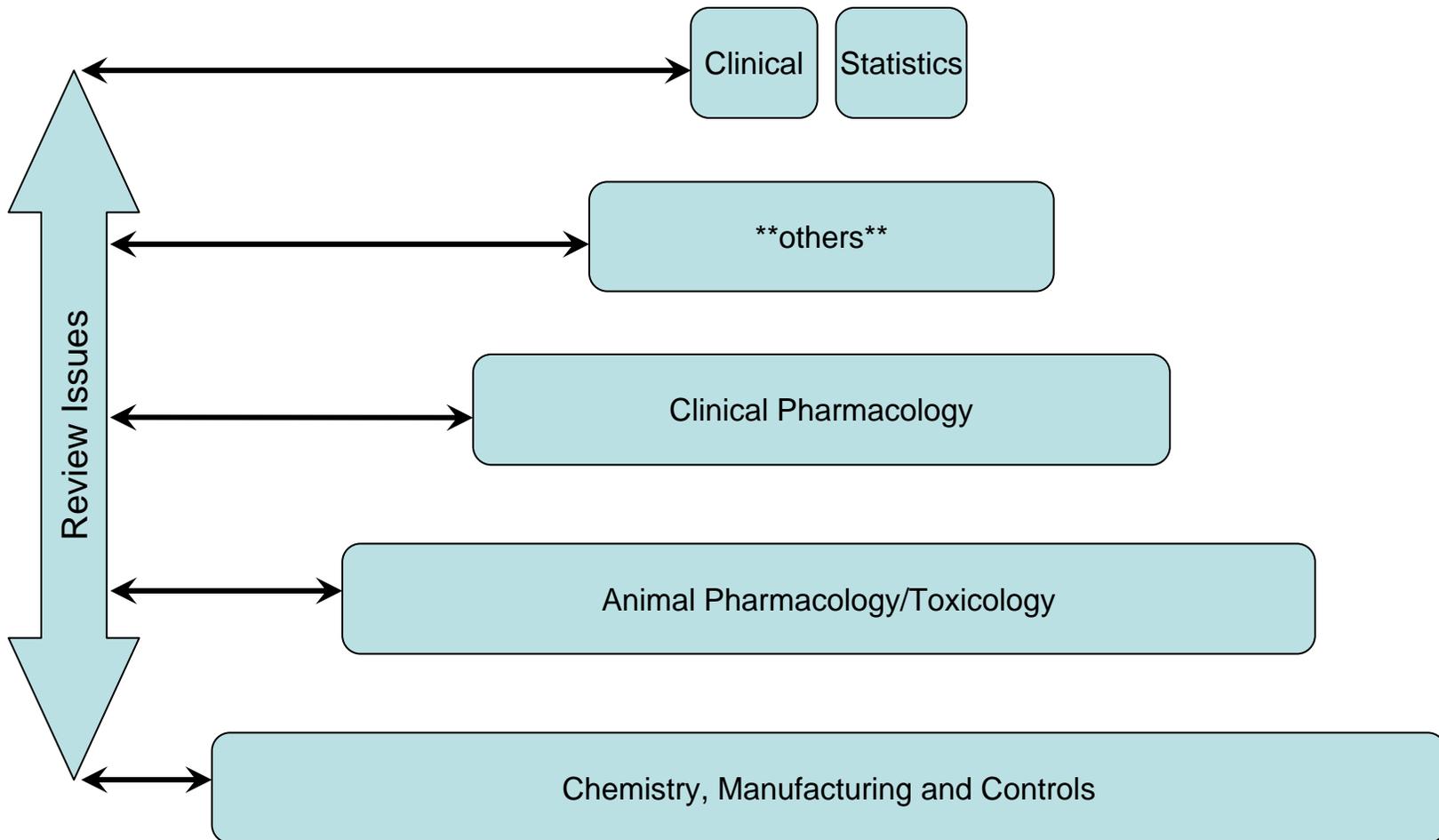
Regulatory Health Project Manager	= BSN, MSN, PharmD, RPh, MS, MPH, BS
Medical Team Leader ("Cross Discipline TL")	= MD, PhD, MPH
Medical Officer	= MD, PhD, MPH
Statistics Reviewer	= PhD, MS
Clinical Pharmacology Reviewer	= PhD, PharmD
Pharmacology Reviewer	= PhD
Chemistry, Manufacturing and Controls Reviewer	= PhD, MS

Structures: Team Dynamics (2)

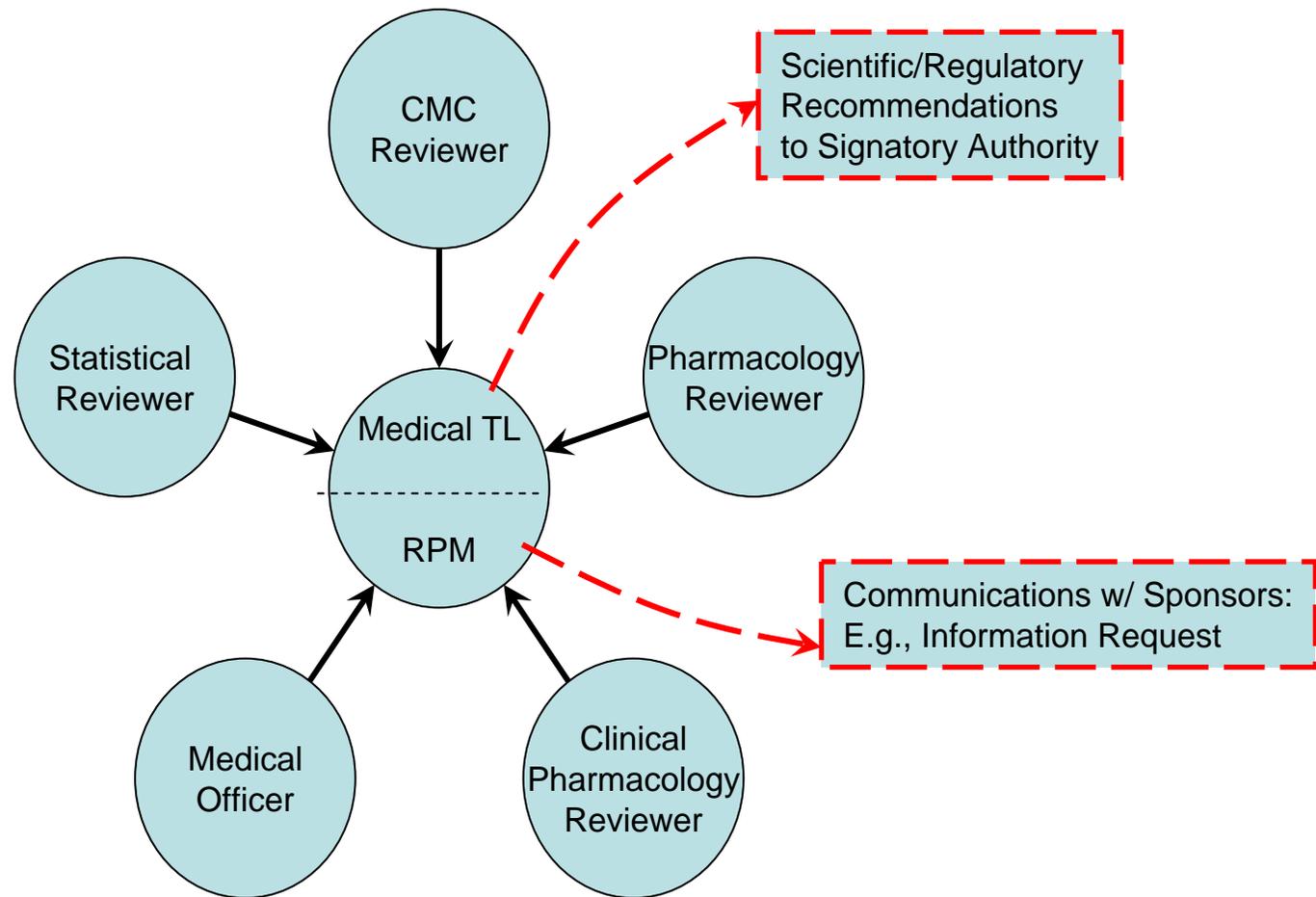


*RPM = Regulatory Health Project Manager

Structures: Team Dynamics (3)



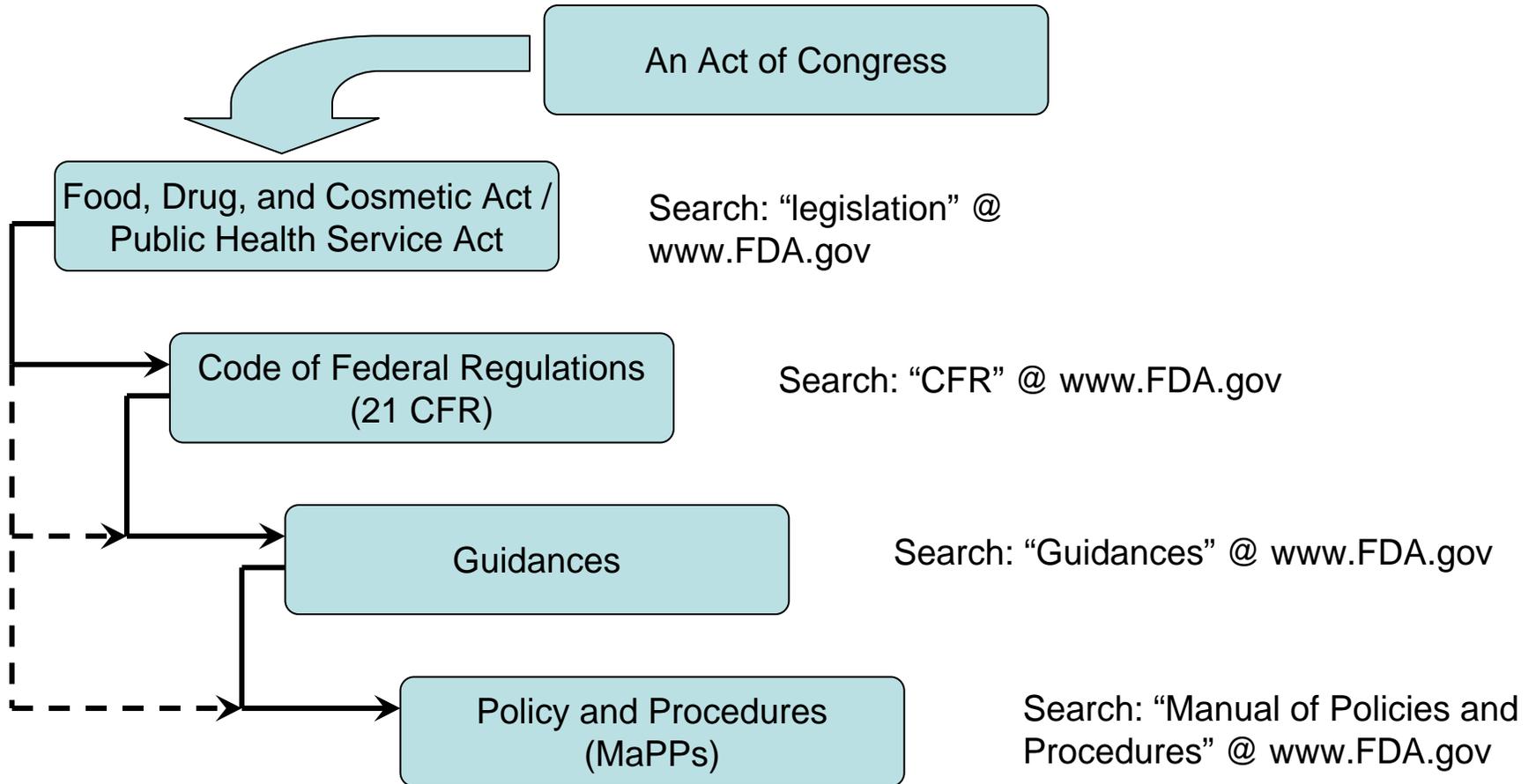
Structures: Team Dynamics (4)



Structures

- Organizational
- Team Dynamics
- **Statutory and Regulatory**

Structures: Statutory/Regulatory (1)



Structures: Statutory/Regulatory (2)

Investigational New Drug Application (IND)

- 21 CFR Part 312

New Drug Application (NDA)

- 21 CFR Part 314

Biologics Licensing Application (BLA)

- 21 CFR 600's

Process: What you can expect

- **Pre-IND Submission Activities**
- IND Submission and Review
- Post-Submission Activities and Responsibilities

Process: Pre-IND Submission Activities

- Pre-IND Meeting
 - Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants
 - Search: “Formal Meetings” @ www.FDA.gov
 - Tracked Timeframe: Type B
 - Meeting date: ~60 days from date of request
 - Formal meeting request required
 - Background package: due to FDA 4 weeks prior to meeting date
 - Pre-IND file created

Process: Pre-IND Submission Activities

- Other Formal Meetings to Plan For:
 - Certain End-of-Phase 1 Meetings (Type B)
 - End-of-Phase 2 Meetings (Type B)
 - Pre-NDA/Pre-BLA Meetings (Type B)
 - Others (Type C)
- Other Correspondence

Process: What you can expect

- Pre-IND Submission Activities
- **IND Submission and Review**
- Post-Submission Activities and Responsibilities

Process: IND Submission/Review (1)

- IND Content and Format (21 CFR 312.23)
- Notify FDA
- Submit one original and two copies to:

Food and Drug Administration
Center for Drug Evaluation and Research

Division of _____
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research

HFM-99, Room 200N
1401 Rockville Pike
Rockville, MD 20852-1448

Process: IND Submission/Review (2)

- 30-day review “clock”
 - RPM will generally communicate the “30-day review date”
- Reviewers are assigned upon receipt
 - Document Room processing time
- Studies can not start until 30-days following FDA receipt of a new IND

Process: IND Submission/Review (3)

- Frequency and timing of communications between sponsor and FDA
- Clinical holds
 - Defined by 21 CFR 312.42
 - Teleconferences: *be available to discuss potential hold issues*
 - “Complete Response to Clinical Hold”

Process: What you can expect

- Pre-IND Submission Activities
- IND Submission and Review
- **Post-Submission Activities and Responsibilities**

Process: Post-Submission

- Safety reporting
 - 21 CFR 312.32
- Annual reports
 - 21 CFR 312.33
- IND withdrawal
 - 21 CFR 312.38
- Other Responsibilities
 - 21 CFR 312.50 through 312.70

