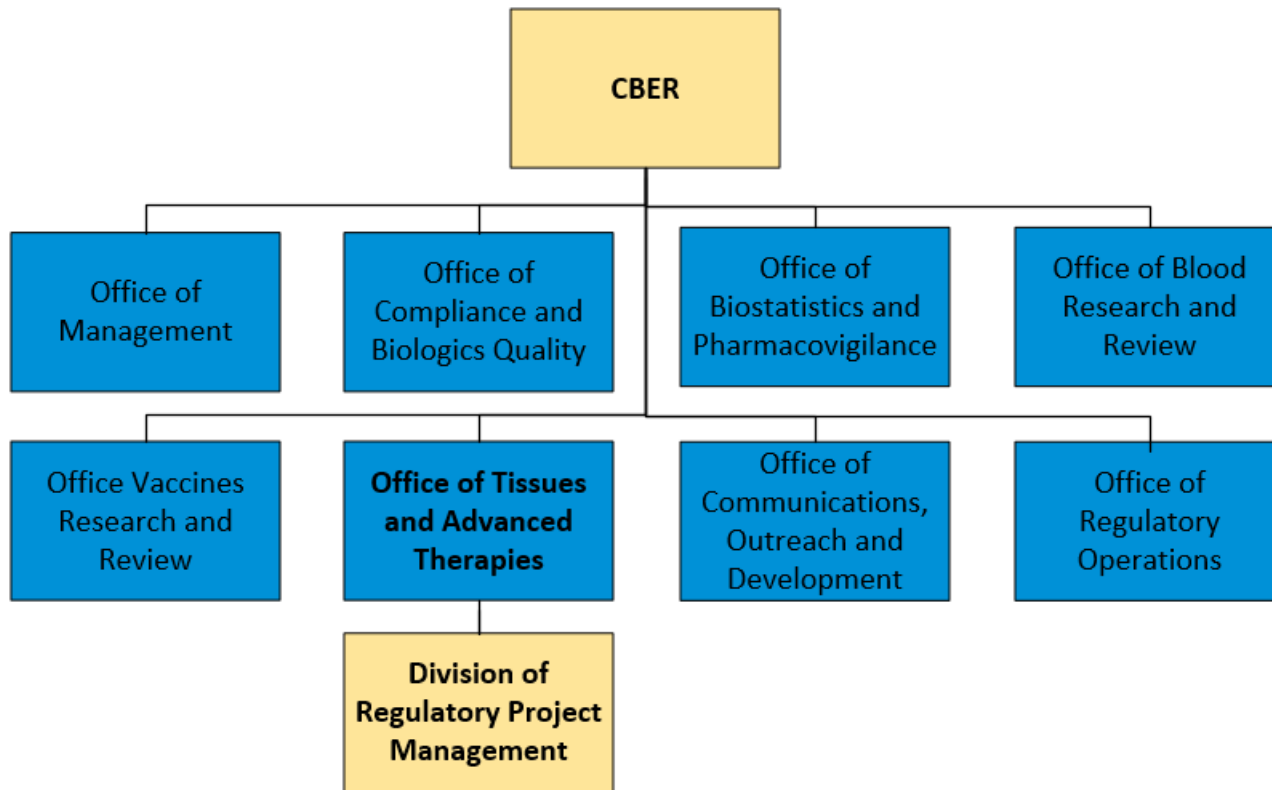


Communication Best Practices – Interacting with Regulatory Project Managers in OTAT

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CBER/DRPM Organizational Chart



Presentation Overview



- To increase familiarity with the Division of Regulatory Project Management (DRPM) in the Office of Tissues and Advanced Therapies (OTAT).
- To learn best practices that may improve the interaction with CBER/ OTAT RPMs.

OTAT RPMs: Introduction

- Serve as primary liaison between Industry and the Review Team
- Serve as a regulatory expert and project manager for:
 - Investigational New Drug Applications (IND)
 - Investigational Device Exemptions (IDE)
 - Biologics License Applications (BLA)
 - New Drug Applications (NDA)
 - Premarket Notification Submissions (510(k))
 - Premarket Approval Applications (PMA)
 - Humanitarian Device Exemptions (HDE) and
 - Related submissions (including supplements), including all pre- and post-submission communications, and internal and industry meetings.



OTAT RPMs: Responsibilities

- Regulatory Review and Guidance
 - Serve as the review team's subject matter expert for regulatory and process-related questions.
 - Ensure regulatory advice and outgoing communication is accurate and consistent with federal regulations, CBER policies, and guidance documents.
- Project Management
 - Ensure review continues throughout the review cycle and monitors status on ongoing concurrent activities
 - Ensure that key decisions and milestones are met
- Communication & Meeting Management
 - Draft and issue all regulatory communications
 - Schedule, coordinate, manage and facilitate informal and formal meetings between Industry and the Review Team



Communication Best Practices



- What to include when communicating with RPMs?
 - Name and Company
 - Application Type and Number
 - Reason for call or email
 - Time sensitivity
 - If you call, consider following up with an email
- Helps RPMs prioritize and organize their large portfolios



Communication Best Practices

- Develop and maintain good working relationship with RPM
- Keep each other informed
- Communicate clearly
- Follow through
- Establish a flexible, mutually agreeable communication strategy
 - email vs. phone
 - frequency of communications
 - RPMs acknowledge requests within 2 business days



Communication Best Practices



- Provide alternate regulatory contacts
- Respond to information requests in a timely manner
 - Acknowledge receipt of information requests
 - Keep RPM informed of delays
- Prior to contacting RPM, seek answers to questions from available resources
 - FDA.gov
 - Guidance Documents
 - CBER Standard Operating Policies and Procedures (SOPPs)



Communication Best Practices

Secure E-mail



- Establish a secure email with FDA
- Required for outgoing emails containing regulatory information
- For any questions, please submit your request to secureemail@fda.hhs.gov.



Communication Best Practices

Email Best Practices



- Include topic and application details in subject line
- Retain the subject line when responding to RPM emails
- Only include information pertinent to the referenced application or a related precursor submission (e.g. PIND, MF)
- Emails for new topics should not contain previous email strings





Communication Best Practices

Cover Letters

- Cover letters should provide details of the submission
 - Application type, submission date, product title, and indication for use
 - Information on any previous OTAT interactions
 - Any related STNs (e.g., Master Files)
 - Important submission or communication content
 - Contact information (mailing address, phone number, email address)

- Facilitates triage, routing, and reviewer assignment

Communication Best Practices

Points To Consider



- Provide a clear cover letter that outlines your inquiries that are contained within the submission.
- Please don't ask us to pre-review a proposed submission before you submit it, 'just to check'
- Communicate with OTAT through the RPMs, not the reviewers
- Ensure secure email is established prior to first submission
 - Questions can be sent to SecureEmail@fda.hhs.gov
- Consider the RPM's large portfolio and be realistic with expectations
- Acknowledge receipt of communication with RPM
- Have 1-2 backup authorized contacts to ensure a representative is always available during the review process.
 - FDA will not discuss any information regarding your submission with non-authorized contact



Resources

- **Guidance for Industry:** [Best Practices for Communication Between IND Sponsors and FDA During Drug Development](#)
- **Guidance for Industry:** [Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products](#)
- **Guidance for Industry:** [Providing Regulatory Submissions in Electronic Format](#)
- **CBER SOPP 8110:** [Submission of Regulatory Applications—Exempt from eCTD Requirements](#)
- **List of gene and cell therapy guidance documents:** <https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/cellular-gene-therapy-guidances>
- **OTAT Learn:** [Webinar Series](#)

Challenge Question #1

- Which of the following statements is NOT true?
 - A. RPMs are your main points of contact in OTAT
 - B. CBER staff can only send outgoing emails, containing regulatory information, through secure email
 - C. You should always contact the reviewers directly when you have a question about your submission
 - D. Be specific and clear in all communications and submissions

Challenge Question #2

- Division of Regulatory Project Management (DRPM) for OTAT is located under-----
 - A. Center for Biologic Evaluation and Research (CBER)
 - B. Center for Drug Evaluation and Research (CDER)
 - C. A&B
 - D. None of the above

OTAT Contacts



Contact OTATRPMS@fda.hhs.gov

Thank you!