



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Communication with Regulatory Agencies
SOP Number: 24300
Revision: 05

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1. PURPOSE

The purpose of this SOP is to define the procedure for Biopharmaceutical Development Program (BDP) communication with the FDA and other Regulatory Agencies and to build and maintain a positive rapport with them. Purposeful communication with Regulatory Agencies can expedite the workflow of submissions.

2. SCOPE

This SOP applies to BDP correspondences and verbal communications with the FDA and other Regulatory Agencies as directed by the BDP or NCI-Frederick.

Communication with Regulatory Agencies includes formal meetings, correspondences, telephone conversations, teleconferences, faxes, e-mails, and any other means of communication. Also included are short conversations at off-site meetings or seminars regarding BDP products.

3. RESPONSIBILITIES

3.1 The Associate Director of Regulatory Affairs (RA), Director of Regulatory Compliance, Biopharmaceutical Quality Assurance (BQA), or the BQA/RA designee

- Initiates communications (via telephone, e-mail, fax, etc.) with FDA or other Regulatory Agencies regarding BDP submissions or questions.
- Channels any response or inquiry of a particular individual from BDP, NCI or from any Regulatory Agencies to appropriate BDP and NCI staff.

3.2 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight.

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4. PROCEDURE

- 4.1 When a communication is received by any individual at the BDP from a Regulatory Agency, the communication has to be directed to the Associate Director of RA, Director of Regulatory Compliance/BQA, and/or the RA/BQA designee. If no one is available, a message will be taken, and the call will be returned as soon as possible.
- 4.2 If the inquiry from the Regulatory Agency is regarding a specific issue, the responsible person for that project (for example, NCI Project Manager, Project Scientist, BDP Technical Director), or his/her designee may be requested to provide the response, review a response, or to participate in a conference call that includes the Associate Director of RA, Director of Regulatory Compliance/BQA, and/or RA/BQA designee.
- 4.3 When a BDP individual has a particular inquiry to be made to a Regulatory Agency, he or she must inform the Associate Director of RA, Director of Regulatory Compliance/BQA, and/or the RA/BQA designee regarding the subject matter to be discussed with that agency prior to initiating communication. The NCI/Biological Resources Branch (BRB) Project Manager should also be included in discussions with the FDA, when appropriate. Some projects may require Cancer Therapy Evaluation Program (CTEP/NCI) individuals to communicate BDP inquiries. The Regulatory Compliance/BQA Director or RA Associate Director can provide guidance to determine which communications may need to be conducted by CTEP/NCI individuals. The Regulatory Compliance/BQA Director or RA Associate Director initiates and manages Regulatory Agency contacts when CTEP is not involved as requested by the NCI/BRB.
- 4.4 Under urgent situations, in the absence of the Associate Director of RA, Director of Regulatory Compliance/BQA or the RA/BQA designee, the BRB Project Manager and/or the BDP Program and Technical Director is the backup person if communication needs to be made with a Regulatory Agency. The Associate Director of RA and the Director of Regulatory Compliance/BQA should be informed of the communication as soon as possible and copied on all correspondence, if possible.
- 4.5 Notes are taken during contact with Regulatory Agencies. After contacts with regulatory agencies, a contact report must be prepared from the notes taken, using the Regulatory Agency Contact Report (Form 24300-01). The Contact Report should be initiated within 24 hours of the contact or as soon as possible. Printouts of e-mails and faxes should be attached to the Contact Report form with the specific details filled in.



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- 4.6 The contact report is initiated and finalized by the Associate Director of RA, Director of Regulatory Compliance/BQA, or the RA/BQA designee. The contact report may be routed to other BDP or NCI participants to ensure the completeness and accuracy of the content. Pertinent BDP staff should be included in the distribution list if the issue involves a specific project.
- 4.7 The completed contact report is filed with the corresponding project.

5. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
24300-01	Regulatory Agency Contact Report