Updated: 11/01/13

Animal Model Qualification Program

Procedures for Submitting Animal Model Qualification Correspondence and Documents

Format of Electronic Submissions

Animal Model Qualification Program (AMQP) correspondence and documents should be transferred to either a compact disc (CD) or optical disc storage media (e.g., DVD) and accompanied by a paper copy Cover Letter (see Cover Letter elements below).

The Cover letter should also be included in the electronic media. The paper copy Cover Letter and electronic media should be submitted to:

CDER Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266
Attention: **ANIMAL MODEL QUALIFICATION PROGRAM**
Office of Counter-Terrorism and Emergency Coordination/CDER/FDA

Submitters are strongly encouraged to consider the use of relevant data standards (e.g., CDISC) in submitting these data for review. For submission and review purposes, these electronic data should conform to the requirements described in the *Study Data Specifications* document, July 18, 2012, version 2.0 (http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM312964.pdf).

- Physical media
  For the most recent information on submitting physical media (e.g., CD-ROMs), see http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163567.pdf

- Data Standards
  CDER strongly encourages submitters to consider the use of data standards, starting as early as possible in the product development lifecycle, so that they are incorporated into the design, conduct, and analysis of studies. Study data standards for submissions to CDER can be found at the following location: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm248635.htm

The Cover Letter should contain the following elements:

1. Date:

2. Subject: (in bold print) **DDT QUALIFICATION SUBMISSION**

3. DDT Type: (in bold print), **ANIMAL MODEL**

4. DDT Tracking Record Number: (in bold print), if previously assigned

5. Submission Type: (in bold print)
   - **INITIATION REQUEST**
   - **LETTER OF INTENT**
   - **INITIAL BRIEFING PACKAGE**
   - **CORRESPONDENCE**
   - **SUPPORTING DOCUMENT(S) FOR CONSULTATION AND ADVICE STAGE**
   - **FULL QUALIFICATION PACKAGE**

6. DDT Name(s): (in bold print): Identify the specific Animal Model (by name) that is being submitted

7. Context of Use: Describe the intended use of the Animal Model (1 to 2 sentences)

8. Complete submitter contact information including name(s), affiliation, mailing address, email address, phone and fax numbers

9. For every electronic submission, a comprehensive table of contents should be submitted containing three or four levels of detail, with the appropriate hypertext links to key referenced sections

10. Statement in the cover letter that the submission is virus free with a description of the software (name, version, and company) used to check the files for viruses