

BQP Qualification Program Cover Letter

Date:

Subject: DDT QUALIFICATION SUBMISSION

DDT Type: Biomarker Qualification

ATTN: CDER-Biomarker Qualification Program

C/O CDER Document Room: Upon receipt notify:

CDER-BiomarkerQualificationProgram@fda.hhs.gov

Biomarker DDT Tracking Number: (in bold print), if previously assigned

Check Here	Submission Type
	Letter of Intent
	Qualification Plan
	Full Qualification Package
	Update of Above (Check two, this box and one above)
	Other (please specify):

Biomarker Name(s): (in bold print) Identify the specific biomarker by name that is submitted for the specified stage of qualification.

Context of Use: Describe the intended drug development use for the biomarker named above (1 to 2 sentences, see the graphic below for how to write the context of use.)

A COU is generally written to be consistent with the following structure: [BEST biomarker category] to [drug development use].
--

Contact Information: Complete contact information including name(s), affiliation, mailing address, email address, phone and fax numbers.

Purpose Statement: Describe the purpose of the submission in 3-5 sentences.

Submission Statement: Include a statement in the cover letter that: "The physical media submission is virus free with a description of the software (name, version and company) used to check the files for viruses."

Additional Instructions for LOI/QP/FQP¹ submissions: For every electronic submission, a comprehensive table of contents should be submitted containing three or four levels of detail, with the appropriate bookmarks to key referenced sections in the document.

¹ LOI: Letter of Intent; QP: Qualification Plan; FQP: Full Qualification Plan