Advanced Manufacturing Technologies Designation Program Frequently Asked Questions

The FDA established the **Advanced Manufacturing Technologies Designation Program (AMTDP)** to encourage the adoption of advanced manufacturing technologies (AMTs) that significantly improve drug and biological product production without compromising product quality. The following Frequently Asked Questions (FAQs) provide information about the program and its benefits, eligibility, participation processes, and other early engagement opportunities. For detailed program and participation information, refer to the Draft Guidance Document for AMTDP.

1. What are the potential benefits of the Advanced Manufacturing Technologies Designation Program?

The AMTDP enables persons or organizations who are the holders of or are using a designated AMT to engage with the FDA early to discuss potential regulatory and technical challenges related to use of the designated AMT in drug development or manufacturing.

Benefits of the program may also include earlier and more frequent applicant interactions with FDA to discuss the use of a designated AMT and assignment of a designated AMT lead to help facilitate communications and the application assessment process related to the use of a designated AMT.

2. What are the criteria for the Advanced Manufacturing Technologies Designation Program?

To qualify for designation under the AMTDP, a method(s) of manufacturing must incorporate a novel technology or use an established technology in a novel way that substantially improves drug manufacturing while maintaining or improving product quality.

Additionally, participants will need to provide data or information supporting the technology, showing it can reduce development time or increase or maintain the supply of a drug that is life-supporting, life-sustaining, of critical importance to providing health care, or in shortage. Participants may submit supporting data specific to a particular drug (if available) or a class of drugs, including development data and batch analysis data generated using a developmental candidate molecule or model (i.e., representative) drug.

More information is available in Section III-A of the AMTDP Draft Guidance Document.

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3. What is the process to participate in the Advanced Manufacturing Technologies Designation Program?

To participate in the AMTDP, submit a request as outlined in Section III-B of the AMTDP Draft Guidance Document. A submission should include:

- A description of the method(s) of manufacturing
- The context of the use of the AMT
- An explanation of how the method(s) of manufacturing meets eligibility criteria in a particular context of use, including:
  - Evidence intended to ensure equivalent or superior drug quality
  - Sufficient model drug or developmental candidate molecule data
- Any anticipated regulatory or technical challenges
- A drug development timeline
- Information on any previous engagements with relevant FDA teams

Send requests to AMT_designation_requests@fda.hhs.gov with the subject line "*REQUEST FOR AMT DESIGNATION,*" contact information, and if the request is specific to CDER, CBER, or both Centers.

4. Are there any opportunities for early engagement with the FDA prior to submitting my AMT Designation Request?

Where appropriate, the FDA encourages early engagement for interested parties with teams such as CDER's Emerging Technology Team (ETT) or the CBER Advanced Technologies Team (CATT) before submitting requests.