Roundtable Session 1 – Table 14: Focus on FDA's Plans for Advanced Manufacturing and Platform Technology Designations

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Abstract:

The Food and Drug Omnibus Reform Act of 2022 provided for two "designation" programs to be developed by the FDA: the platform technology designation and the advanced manufacturing technology designation. A platform technology is defined broadly as a well-understood and reproducible technology that can be used by more than one product sharing common structural elements and is meant to promote technologies that may facilitate the manufacture or development of more than one product through a standardized approach. This technology must be approved for use in one product before a designation can be requested. Likewise, the Advanced Manufacturing Technology Designation is meant to facilitate the development or manufacturing of multiple products. The Advanced Manufacturing Technology may be a novel technology, or an older technology used in a novel way. This designation can be requested early in development and does not need to be a technology that is already approved for use by a product. Obtaining either of the Designations allows for closer cooperation with FDA reviewers and either Designation can be cross-referenced in support of other products thus streamlining the review process. Draft guidance associated with each of these Designations is expected by the end of 2023 and should provide additional clarity on FDA expectations for requesting and implementing these new programs. Discussion at this roundtable will include both Designations and explore details provided in the pending draft guidance documents.

Notes:

Draft guidance: Advanced Manufacturing Technologies Designation Program (fda.gov)

Statute for AMT designation: BILLS-117hr2617enr.pdf (congress.gov) page 1368

Statute on Platform Technologies, start page 222: BILLS-117s3799is.pdf (congress.gov)

(no guidance yet)

Guidance on engaging with ETT: Advancement of Emerging Technology Applications for Pharmaceutical Innovation and (fda.gov)

Discussion on the Designation programs

Advanced Manufacturing Technology designation:

What is Novel? Novel to a company /firm versus novel to the whole industry

See section V, Q1 – A firm may need to submit "blindly" without knowledge of what some other firm may have already used and approved.

Firms essentially must first go through ETT or CATT regardless, so that process should inform whether or not something is novel.

The word “limited” in the guidance allows for flexibility.

Also an older technology used in a novel way would still be in scope.

What are the advantages to having a designation?

Expedited review? By how much (no timeframe)? FDA is directed that they must expedite, but no timeframe is given.

Suggest that firms will need to be clear and directive in the engagement they want.

Reminder that the statute is written by Congress, not FDA.

Going through ETT and CATT leverages relevant teams that are already in place at FDA.

The designation request review itself is given 180 days - - that seems long or could it become a bottleneck?

Let’s say that you have gotten an Advanced Technology designation, and you have benefitted from accelerated review, and then a product is licensed with that designation, then does the “graduation” mean that all that follows loses the benefit ?

How can an AMT designation apply to a post-approval supplement?

Will FDA have specific reviewers tagged to reviewing products that use a technology with an AMT designation? How will that interface with ETT and CATT?

Understanding what happens as something graduates from AMT designation and knowledge transfer from the “special” AMT reviewers (from ETT or CATT?) and transitions to “regular” reviewers.

Key benefit is early interaction with applicants “as resources permit”.

A meeting with ETT is a Type C meeting request, follows the timelines of a Type C meeting.

60 days after the Type C meeting, there is notice of acceptance (or not) into program.

If this is so critical that there is a drug shortage, but it still needs to go through ETT or CATT, is this going to make this faster? Or does this slow things down (eg. in the case of what will be an ANDA / generic?)?

Expect that firms will have to work in parallel. Firms will submit INDs in parallel with going to ETT / CATT and the AMT designation request.

Will firms consider parallel development, where they do development using a conventional technology but in parallel, go through AMT designation to facilitate accelerated introduction of the new technology with ETT/CATT counsel, as risk mitigation (in case the new technology fails)? Or to make it easier to introduce the AMT into a post-approval supplement?

A CDMO or technology developer would be motivated to apply for AMT designation to facilitate adoption. But the guidance assumes that there is a product involved, not just a technology, so the pathway is unclear in the absence of a specific product or the sponsor who will apply for the IND or BLA.

Does FDA expect to grant the AMT designation to multiple applicants for the same technology?

Eg. if multiple firms are simultaneously developing what is essentially the same technology and all apply simultaneously for AMT designation, will only one be granted?

Can firms work together if the technology is of general benefit, eg. rapid micro methods for adventitious agent detection? Can a consortium of firms then submit a single application together for the technology? Can it then graduate to platform designation?

Platforms

Expect that platform technology designation should be applicable to analytical methods as well as “modalities” and manufacturing processes.

(platforms were extensively discussed through a CMC Forum workshop and many other sessions within WCBP, so given this and the absence of the draft guidance, table discussion focused mostly on the AMT designation guidance)