



AbbVie
Amgen
Baxter
Bayer
Biogen

Boehringer Ingelheim
Bristol-Myers Squibb
Eli Lilly & Co.
Genentech
GlaxoSmithKline
Merck & Co.
Pfizer



AbbVie
Agios

Alexion Pharmaceuticals

Alkermes
Allergan
Amgen

Astellas Pharma US LLC

AstraZeneca Pharmaceuticals

Baxter
Bayer
Biogen

Blueprint Medicines

Boehringer Ingelheim

Bristol-Myers Squibb

Celgene Corporation

Concert Pharmaceuticals

Daiichi Sankyo

Eisai, Inc.

Eli Lilly & Co.

EMD Serono

Endo Pharmaceuticals

Genentech

Gilead Sciences

GlaxoSmithKline

Incyte Corporation

Infinity Pharmaceuticals

Johnson & Johnson

Merck & Co.

Novartis

Otsuka Pharmaceutical Co.

Pfizer

Pierre Fabre Laboratories

Roche
sanofi

Seattle Genetics

Sunovion

Takeda

Teva Pharmaceutical

Theravance Biopharma

UCB Pharma

Vertex

Comments from Allotrope Foundation and the IQ Consortium on the FDA Draft Guidance for Industry:

“Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base Guidance for Industry”

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm478821.pdf>

Docket No: FDA-2015-D-4644

Federal Register Notice: <https://federalregister.gov/a/2015-32316>

We are pleased to offer the following comments, prepared by the members of Allotrope Foundation and the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ Consortium).

Allotrope Foundation is an international consortium of pharmaceutical and biopharmaceutical companies with a common vision to develop innovative new standards and technology for handling data in R&D, with an initial focus on analytical chemistry. The Allotrope Framework is comprised of the Allotrope Data Format (ADF), taxonomies to provide a controlled vocabulary for metadata and a software toolkit. The ADF is a vendor agnostic format that stores datasets of unlimited size in a single file, organized as n-dimensional arrays in a data cube, and stores metadata describing the context of the equipment, process, materials, and results. The Framework enables cross-platform data transfer, data sharing, and vastly increases the ease of its use. This effort is fully funded by the members of Allotrope Foundation and is rapidly progressing on our common goals to reduce wasted effort, improve data integrity and allow us to realize the full value of our analytical data.

The IQ Consortium is a technically-focused organization of pharmaceutical and biotechnology companies with a mission of advancing science and technology to augment the capability of member companies to develop transformational solutions that benefit patients, regulators and the broader R&D community. IQ provides a sustained forum for the exchange of ideas within and across technical disciplines in these industries. The Consortium is leading initiatives in the areas of chemistry, manufacturing and control (CMC); preclinical safety; drug metabolism; clinical pharmacology; quality; and the reduction, refinement, and replacement of animal testing. As part of these initiatives, which are managed by Leadership Groups and Working Groups, members lead and participate in collaborative research, industry surveys and benchmarking exercises. IQ is also partnering with governmental bodies, other trade groups, and academic researchers. Through publications, scientific conferences, workshops and roundtables, the Consortium shares the results of its work and facilitates constructive scientific exchange.

These comments are organized into the following sections:

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Comment Tracking Number: **TBD**

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Introduction

Allotrope Foundation and the IQ Consortium appreciate the opportunity to comment on the FDA Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base Guidance for Industry [Docket No. FDA-2015-D-4644]. This document provides comments and recommendations compiled from member companies participating in Allotrope Foundation and the IQ Consortium.

The response is organized into two sections. The first section contains General Comments pertaining to the criteria for accessing the Emerging Technologies Team to facilitate review of innovative technologies being developed or in use by in the pharmaceutical industry. The second section provides specific comments on individual sections and lines of the guidance in a tabular format. Within the specific comments section, proposed changes, recommendations and requests for clarification begin with bolded text. Furthermore, comments deemed of highest priority have been noted as “**Priority**” in the table.

General Comments

Proposal

Allotrope and IQ are pleased to see a new guidance providing the opportunity to facilitate and promote the use of emerging technologies to improve the integrity, quality and efficiency of the manufacturing process, enabling the pharmaceutical industry to meet our patients need efficiently. However, the guidance defines access to the Emerging Technologies Team only in the context of a regulatory application (IND, NDA, ANDA, BLA) by a pharmaceutical company. We propose the FDA establish a process to allow scientific consortia who are developing emerging technologies the opportunity to work with the Emerging Technologies Team to seek the following support:

- Identify and help facilitate regulatory review of a new manufacturing technology in accordance with existing legal and regulatory standards, guidance, and Agency policy related to quality assessment.
- Identify and capture resolution to policy issues that may inform FDA approaches and recommendations regarding future submissions that involve the same technology.

Benefits

Expanding eligibility for participation to scientific consortia in the Emerging Technologies program is an opportunity for FDA to guide the development of novel technologies prior to its use. Early guidance from the FDA would provide the following benefits for the pharmaceutical industry:

- Provide consortia and pharmaceutical companies with feedback to aid in development of innovative technologies;
- Promote alignment with FDA strategies for accelerating reviews of regulatory submissions;
- Ultimately, allow the industry to get products to the patients faster.

Additionally, expanding the scope of the emerging technologies program will allow the agency to familiarize themselves with new technologies that may be used by multiple pharmaceutical companies and aid in the regulatory review process.

Criteria

To avoid over burden of FDA resources with requests not directly associated with a new drug submission, we recommend that the criteria for ETT evaluation must demonstrate potential benefits across multiple areas of the pharmaceutical industry.

Specific Comments

Line	Section Title	Specific Comments by Section and Line
15	I. INTRODUCTION	
32-34		<p>Line 32-34 states: “For example, contemporary aseptic manufacturing facilities that are highly automated and use isolators and other modern separation technologies have the potential to decrease the risk of contamination from the processing line.”</p> <p>Proposed Change: Consider providing additional examples of “emerging technologies”, specifically related to innovative data management tools or software that enhance manufacturing efficiency and/or data integrity”</p>
43-45	Priority	<p>Line 43. Consider expanding the scope of the emerging technologies program to industry consortia. “The ETT will serve as the primary point of contact for companies that are interested in implementing emerging manufacturing technology in the manufacture of their drug products”</p> <p>Proposed Change: Add industry consortia to line 43 so it reads "The ETT will serve as the primary point of contact for companies <u>and industry consortia</u> that are interested in implementing emerging manufacturing technology in the manufacture of their drug products"</p>
102	III. DISCUSSION	
116-118	Priority	<p>Lines 116 to 118 read - “Acceptance of a request to participate in this CDER program will depend on the applicant’s proposed plan for submission of an IND or original or supplemental ANDA, BLA, or NDA, based on the criteria described below.”</p> <p>Proposed change: Add verbiage to expand the scope to include emerging technologies with the potential to impact across multiple products or Pharmaceutical Companies “Acceptance of a request to participate in this CDER program will depend on the applicant’s proposed plan for submission of an IND or original or supplemental ANDA, BLA, or NDA, <u>OR potential impact across multiple pharmaceutical companies or products</u> based on the criteria described below.”</p>

122-124		<p>Lines 122 to 124 read- “Examples of such elements include an innovative or novel: (1) product manufacturing technology, such as the dosage form; (2) manufacturing process (e.g., design, scale-up, and/or commercial scale); and/or (3) testing technology.”</p> <p>Recommendation: add the following “...manufacturing process (e.g., design, scale-up, and/or commercial scale); (3) testing technology and/or (4) data integrity enhancing technology.”</p>
158	Priority	<p>Line 158 reads. (5) A timeline for a submission (IND, ANDA, BLA, IND, NDA, original or supplemental).</p> <p>Recommendation: Add the following, “... OR A timeline for implementation of the new technology, including impact to pharmaceutical companies and/or products.”</p>