



19 February, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-D-4644
Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base
Guidance for Industry

Dear Sir/Madam:

The International Society for Pharmaceutical Engineering (ISPE) appreciates the opportunity to comment on this Draft Guidance. ISPE applauds CDER's commitment to support and enable the modernization of pharmaceutical manufacturing as part of FDA's mission to protect and promote public health. We strongly agree with the agency that these efforts to facilitate companies' adoption of emerging technologies are the foundations of some of the long term solutions to addressing drug shortages.

Since 2013, ISPE has provided a key voice in drug shortage prevention discussions through several of our initiatives, including comprehensive research into the causes of drug shortages, releasing the freely available *ISPE Drug Shortages Prevention Plan*, and the development of a *Drug Shortages Assessment and Prevention* tool. We support the Agency's belief that encouraging the development of emerging manufacturing technology could lead to improved manufacturing, and therefore improved product quality and availability throughout a product's lifecycle.

ISPE is committed to providing a forum for industry and regulators to work toward effective implementation of emerging technologies, with the notable example of our *Continuous Manufacturing Conference* in April, 2016, where several speakers from FDA have been invited to participate.

We have the following comments on the Draft Guidance:

- To provide additional clarity, we recommend that FDA also consider within its internal procedures whether submissions not proposed under this program could be referred by the responsible reviewer to the Emerging Technology Team (ETT) to ensure consistency of approach and enhance overall internal communication.
- Considering that many of the issues involved here - and the aseptic processing example noted in the guidance in particular - are subject to inspection by field investigators and review by the Office of Compliance, we recommend that the ETT encompass both Office of Compliance personnel and Office of Regulatory Affairs participation, if not already considered. ISPE believes this interaction would further enhance the ongoing Program Alignment Group organizational activities. This also would take forward practical considerations of the ongoing discussions in ICH Q 12, *Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management* to understand those topics that are subject to established conditions and CMC review and those which are covered by the Pharmaceutical Quality System (PQS).

On behalf of ISPE, thank you again for the opportunity to provide feedback on this Draft Guidance. Please feel free to contact me if you have any questions.

Sincerely,

Dora Kourti, PhD
Senior Vice President for Global Regulatory Affairs
ISPE