Connecting a World of Pharmaceutical Knowledge

12 September 2013

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

RE: **Docket ID: FDA-2011-D-0790 - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices**

Dear Sir or Madam,

ISPE is pleased to have the opportunity to provide comments to FDA on the draft guideline referenced above. The draft guideline was reviewed by ISPE's technical sub-committee known as the GAMP Community of Practice, which is compromised of individuals from pharmaceutical companies, suppliers, and consultants. The draft was warmly received by the GAMP COP. ISPE has no comments on the draft guidance other than to commend FDA on the production of this well written guide.

The International Society for Pharmaceutical Engineering (ISPE) is an individual membership Society of more than 20,000 professionals involved in the manufacture of pharmaceuticals and related products. All scientific and technical areas of the pharmaceutical manufacturing industry are represented among the ISPE Membership. ISPE is committed to creating a forum for uniting the world's pharmaceutical manufacturing community and regulators.

Thank you for the opportunity to comment.

Yours sincerely,

Nancy S. Berg
President/CEO, ISPE

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