# Association for Molecular Pathology

***Promoting Clinical Practice, Translational Research, and Education in Molecular Pathology***

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Comments for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff (HFA-305 / Docket No. FDA-2013-D-0616)

The Association for Molecular Pathology (AMP) recognizes the importance of cybersecurity for electronic medical records, diagnostics instrumentation and test systems. AMP recommends that security standards be established to guide manufacturers in preparing premarket submissions in order to maintain patient information confidentiality and data integrity. Such standards should not prevent qualified professionals from utilizing, maintaining, and/or repairing the systems. In establishing such standards, AMP believes it is important to include experts from outside the agency, including those in cybersecurity; relevant medical and diagnostics manufacturers; relevant laboratory engineering, medical, and technical professionals; experts in other federal agencies such as the National Institute for Standards and Technology (NIST).