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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Reference: [Docket No. 00D-1538] "FDA Draft Guidance for Industry 21 CFR Part 11;
Electronic Records; Electronic Signatures; Validation"**

Dear Sir or Madam:

Merck & Co., Inc. is a leading worldwide human health product company with a corporate strategy to discover new medicines through breakthrough research. Through a combination of the best science and state-of-the-art medicine, Merck's R&D pipeline has produced many important pharmaceutical and biological products on the market today.

In fulfilling this strategy, Merck's operations use computer systems subject to this regulation, and as such Merck is interested in commenting on the FDA Draft Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures; Validation. This guidance is consistent with past guidance documents and our comments are intended to seek clarification to assure a common understanding.

Validation Plan

The Validation Plan, described in Section 5.2.1, defines validation activities and this is further described in Section 5.6. The concept of scalability of validation activity based on system complexity and risk, introduced in Section 5.6, should also be described in Section 5.2.1 where the Validation Plan is first defined.

Key Testing Considerations

In Section 5.4.1 on "Key Testing Considerations", the sentence starting "Live, user-site tests...", needs to be clarified we suggest the following for your consideration:

"Live, user-site tests: these tests are performed in the end user's computing environment using the system as it will be used for actual production, but not while product is being produced."

Testing a system during the time when it is being used to produce saleable product (i.e. under actual operating conditions and standard staffing levels) would not provide an adequate environment for detailed automation testing.

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Software Structural Integrity

In Section 6.1.2 on Software Structural Integrity, at the second bullet reference is made to "contemporary standards". We find this term to be ambiguous and recommend this sentence be clarified as follows:

*"Evaluating the supplier's software development activities to determine **the supplier's conformance to established industry software development standards at the time of software development.**"*

Functional Testing of Software

In Section 6.1.3 on Functional Testing of Software, the final sentence suggests that for Commercial Off-the-Shelf software some unspecified activity is required to ensure adequacy. However, we believe those necessary activities are defined in the other parts of Section 6, and to help the reader understand what those elements are, we suggest this final sentence should be modified as follows:

*"Note, however, functional testing alone is not sufficient to establish software adequacy **and needs to be supplemented with the other elements described in this section.**"*

We appreciate the FDA's effort to provide guidance on 21 CFR Part 11, and look forward to additional opportunities to comment on new guidance documents on this topic.

Sincerely,

Handwritten signature in cursive script that reads "Bonnie J. Goldmann FOR".

Bonnie J. Goldmann, M.D.
Vice President Regulatory Affairs

Federal Express