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08 November 2011

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Center for Drug Evaluation and Research
Office of Pharmaceutical Science
10903 New Hampshire Avenue, Bldg 51, Rm 4160
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RE: Recommendations for Communicating IMD-A Validation Activities with FDA

Dr. Bryan Riley:

During BioVigilant's IMD Consortium meeting held in October 2011, you offered valuable guidance on the validation of microbial Environmental Monitoring (EM) Rapid Microbiological Methods (RMMs) like the IMD-A system. Among the guidance provided was clarity on the communication strategy suggested by the Agency for handling IMD-A validation plans and implementation. FDA does not approve EM methods nor EM action and alert limits, so formal submission to FDA regarding IMD-A validation is not needed. Validation should alternatively be addressed within a facility's internal GMP quality system and change control process.

How then does FDA become aware of a facility's use of the IMD-A system?

In the recent conversation we had with you to help answer the above question, we discussed options for customers to consider so that FDA is alerted of IMD-A validation efforts. Below is a summary of one option that was proposed.

PRIMARY COMMUNICATION: Pre Validation Type C Meeting with FDA

A Type C meeting may be a preferred route for the first few IMD-A validators and/or for those who would like to encompass multiple drug products in a single validation exercise.

What would the purpose and benefits be in holding a Type C Meeting?

1) Share the facility's IMD-A validation plans with FDA.
2) Receive responses from FDA on specific questions posed by the facility in regards to IMD-A test plans and implementation.

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3) Generate formal meeting minutes for the facility's internal IMD-A validation files.
4) Provide a means for initiating FDA review of BioVigilant's Drug Master File (DMF).

How is a Type C Meeting with FDA initiated?

1) Follow instructions provided in FDA's *Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants*, May 2009.

   General contents of the meeting request package include (taken from FDA's Guidance noted above):

   a. Product name
   b. Application number (if applicable)
   c. Chemical name and structure
   d. Proposed indication(s) or context of product development
   e. Type of meeting requested, i.e., Type C
   f. A brief statement of the purpose and objectives of the meeting. It also can include a brief summary of completed or planned studies…or data that the sponsor or applicant intends to discuss at the meeting
   g. A proposed agenda
   h. A list of proposed questions, grouped by discipline. For each question there should be a brief explanation of the context and purpose of the question
   i. A list of all individuals with their titles and affiliations who will attend the requested meeting from the sponsor's or applicant's organization and consultants
   j. A list of FDA staff, if known, or disciplines asked to participate in the requested meeting
   k. Suggested dates and times for the meeting (within 75 days of request)
   l. The format of the meeting (e.g., face to face, teleconference, or videoconference)

   Additionally include a copy of the **Letter of Authorization to refer to BioVigilant's DMF** (request a copy of this letter from BioVigilant).

   Once received, the FDA will respond to the request within 21 days and will include the answers to the questions posed. Customers then have the option to cancel the meeting if their questions have been addressed sufficiently or continue with the meeting on the scheduled date and time.

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SECONDARY COMMUNICATION: Post Validation, Pre-operational Visit

Once a facility has completed validation testing and is ready to implement the IMD-A system in its intended application, one recommendation is to contact FDA to arrange a site visit by the members of the PAT team (ORA, DMPQ, and Micro Reviewer). This is an informal interaction, not an inspection. The visit would be an opportunity to share validation results with FDA and obtain their feedback. The facility would receive a letter from FDA following the visit to summarize their evaluation of the IMD-A validation test results and identify concerns, if any exist.

FDA evaluation letters will be filed in the Office of Compliance Facility database and OPS databases for future reference. ORA will monitor cGMP compliance and the Center will assist in further scientific assessment of IMD-A matters, if needed.

Sincerely,

Carrene Plummer

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BioVigilant Systems, Inc.

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