Inventors of Instantaneous Microbial Detection
Know Now. Act Now.

AZBIL BIOVIGILANT
REGULATORY MEMORANDUM

In 2004, the FDA had published both the Pharmaceutical cGMPs for the 21st Century and the PAT Guidance for Industry for the Pharmaceutical Industry, where emphasis was placed on the knowledge and understanding of a firm's processes within a pharmaceutical operation. Since then, the implementation of such GMPs and PAT systems within industry has allowed an improved operational excellence in pharmaceutical manufacturing; specifically in the area of microbiological evaluation, there have been many advances which allow for more rapid microbiological testing methods. These methods, collectively known as Rapid Microbiological Methods (or RMMs), have drastically improved the process understanding of the pharmaceutical and medical device manufacturing environment, and launched the industry in the direction of Quality by Design (QbD). More recently, the FDA released its Strategic Plan for the advancement of Regulatory Science, which supports which supports new innovative approaches in support of QbD initiatives.

Azbil BioVigilant, Inc. is a manufacturer of a real-time environmental monitoring technology, termed IMD-A, that allows a user to evaluate the air in a controlled environment for the presence of microbial particulate quantitatively, and then report this data to the user. Where microbial tests have previously taken 3-5 days for a full incubation and analysis of data, results can now be visualized instantaneously using an advanced optical interrogation technology. This innovative technology will help to advance QbD at firms that choose to implement this system.

In support of the implementation of this technology, Azbil BioVigilant has embarked on a mission to inform and educate regulators on the science behind this technology, so that regulators who may witness the use of this instrument in the field have a clear understanding of the instrument use and application. Azbil BioVigilant has begun this mission by engaging Dr. Bryan Riley, CDER Senior Review Microbiologist in the Office of Pharmaceutical Science at the FDA, and others.

Most recently, Azbil BioVigilant held an IMD Consortium meeting on October 16, 2011 at the Bethesda North Marriott Hotel, a day prior to PDA's 6th Annual Global Conference on Pharmaceutical Microbiology. The meeting was attended by several Azbil BioVigilant IMD-A customers and Dr. Bryan Riley. The purpose of the IMD Consortium meeting was to share specifics of IMD-A 300 and 350 validation activities conducted by Azbil BioVigilant to meet USP <1223> and EP 5.1.6 and other applications related testing. Dr. Bryan Riley's participation offered customers a rare opportunity to obtain direct and immediate regulatory guidance on their IMD-A validation and implementation strategies.

In an effort to broaden the awareness of IMD-A technology by regulatory authorities and continually seek guidance to facilitate customer implementations, Azbil BioVigilant aims to maintain constant dialogue with FDA and other agencies. One such FDA communication occurred on November 18th, 2011 and was prompted by the IMD Consortium meeting.

Dr. Bryan Riley recognized the value of sharing the IMD-A validation material with other regulators who may be exposed to the technology during site visits or other occasions where the technology may be subject to review. The November 18th communication via WebEx was, therefore, coordinated to present IMD-A USP <1223> / EP 5.1.6 testing and results to a broader FDA audience, including individuals from CDER Office of Pharmaceutical Science, CBER Office of Compliance and Biologics Quality, CDER Office of Compliance, CDER Office of Generic Drugs, CVM Office of New Animal Drug Evaluation, and ORA.

The three hour long meeting covered the following:

- Azbil BioVigilant and IMD-A Technology Introductions
- IMD-A Validation Strategy and Statistics
- USP <1223> Test Chamber and Laboratory
- IMD-A Validation Data and Analysis
- Specificity Testing

The attendees of this meeting were:

Name	**Center/Office**
Hyesuk Kong, PhD	CBER/OCBQ
Jian-Jiang Hao, PhD	CBER/OCBQ
Josephine Wulu	CBER/OCBQ
Seema Parveen, PhD	CBER/OCBQ
Selwyn DavidWilson, PhD	CBER/OCBQ
Elena Semenova, PhD	CBER/OCBQ
Neetu Raghav	CBER/OCBQ
Bryan Riley, PhD	CDER/OPS
John Metcalfe	CDER/OPS
Jessica Cole	CDER/OPS
Stephen Langille	CDER/OPS
Denise Miller	CDER/OPS
Brenda Uratani	CDER/OC
Don Obenhuber	CDER/OC
Steve Fong	CDER/OC
Eric Adeeku	CDER/OGD
Scott Steffen	CDER/OGD
Nandini Bhattacharya	CDER/OGD
Lynne Ensor	CDER/OGD
Neal Sweeney	CDER/OGD
Mai Huynh	CVM/ONADE
Greg Hunter	CVM/ONADE
Jason Rossi	CVM/ONADE
Mark Skasko	CVM/ONADE
Dennis Guilfoyle	ORA/NERL