PDA Parenteral Drug Association

PDA Discussion Forum: Implementing Rapid Microbiology Methods

21 September 2009 - Frankfurt, Germany

Call for Questions

At the *PDA Rapid Microbiology Methods Conference 2009* held in Berlin emerged, that:

- Implementing Rapid Microbiology Methods (RMMs) is a complex regulatory scenario.
- It can become very costly, if Variations to Marketing Authorisations (MAs) are involved.
- Also, the time horizon to get approval for implementation might be unpredictable, especially if the product or products concerned possess heterogeneous MAs.
- Discussions with regulators on scientific and practical questions seem not to be endorsed before a formal application is submitted, leaving the risk of missing aspects crucial to the authorities and related delays to the applicant. In essence the process seems not well understood. The regulators agreed to dedicate a Discussion Forum to these very practical questions.

The meeting will develop around questions put forward but not limited to the following topics:

- **Variations and Rapid Microbiology Methods: Successful Ways to Implementation and Issues**

In this discussion, the regulators are willing to share their views and give examples of what will result in a transparent process, get timely approval as well as how to choose a **cost effective strategy.** New developments and existing options in the regulatory framework will be explained. Emphasis will be given to regulatory options available and the scientific basis to build on.

- **Scientific Advice**

Although FDA offers discussions on “comparability protocols” to enhance implementing RMMs, such an instrument does not exist in the jurisdiction of the EU. However, Regulators will highlight the regulatory support any interested organisation might be able to get from international as well as national Competent Authorities in Europe.

- **Issues on Validation, Transition, Use and Documentation of RMMs**

The focus will be on practical problems to implemented RMMs to enhance and/or substitute conventional **Environmental Monitoring, In-Process and Finished Product Testing**. It will be discussed how to demonstrate equivalence or superiority to traditional methods employed. Furthermore aspects of transition specifically for level/limit definitions, trending, data evaluation, release decisions and methods to be applied during stability studies or in case of dispute are discussed.

Send Your Questions in Advance

You are encouraged to participate and send in specific questions or issues, to make sure, the regulators can prepare for concise and to the point answers. There are no limitations to the topics to be asked for in the context of RMMs. PDA guarantees anonymity and confidentiality, if case studies or other sensitive data is put forward to be discussed.

Please send your questions, comments or concerns to eck@pda.org.

[redacted]

PDA Discussion Forum

Implementing Rapid Microbiology Methods

21 September 2009 | Frankfurt – Offenbach, Germany

Agenda (Draft)

9:00 Welcome and Introduction

9:15 Implementing Rapid Microbiology Methods: Experiences and Expectations from Regulatory Authorities

Riccardo Luigetti ***(EMEA)***

Gustavo Marco ***(Assessor, MHRA)***

Paul Hargreaves ***(Inspector, MHRA)***

(Content of the regulatory and compendial framework and requests to the industry)

10:45 Industry Perspective: What Needs to be Done to Simplify Implementation

(examples of current practice, experiences from USA and EU, wishes to regulators)

11:15 Break

11:45 Questions, Answers and Discussion on:

- Changes and Variations to Marketing Authorisations
- Environmental Monitoring, In-Process and other testing
- Product end-testing

(This will also reflect the questions collected in advance by the committee and from the audience)

12:30 Lunch

14:00 Continue Questions, Answers and Discussion (Coffee Break in-between)

17:00 Summary and Close of the Meeting

Registration Form

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3 WAYS TO REGISTER **FAX: +49 33056 23 77 77 EMAIL: petzholdt@pda.org**
MAIL: PDA Europe, Adalbertstr. 9, 16548 Glienicke/Berlin, Germany

1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

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Name (Last, First, MI)

Job Title

Company Department

Mailing Address

City Postal Code

Country Email

Business Phone Fax

☐ Subsituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

2 Forum Registration

All fees given in Euro and excluding VAT (7%)

PDA Member	☐	**695**
Nonmember	☐	**950***
Government/Health Authority/Academic	☐	**350***
Committee Member	☐	**300**

* Registration fee includes a one-year PDA membership. If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies). ☐

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