Biologicals Quality Monitoring Expert Working Group

Chairperson: Dr. Koji Oishi (JMAFF)

Paris, June 2010

Introduction

The Biologicals Quality Monitoring Expert Working Group (BQM EWG) was established in February 1999. It has met 8 times, with a total of 32 days. The last meeting was held in September 2003. Its objective is to establish comprehensive, scientifically correct, effective, proven and practical VICH guidelines (GLs) for harmonized quality assays of veterinary biologics and biological origin components thereof.

The EWG has adopted 2 GLs and is working on 2 other guidelines.

EWG Composition

K. Oishi - Chair (JMAFF, g) 	J. Hogan (AHI, i) 	R. Hyde (USDA, g) 	P. Thomas (AHI, g) 
W. Hesselink (IFAH-Europe, i) 	N. Yuasa (JPVA, i) 	H. Draayer (AHI, i)	J-C Rouby (EU, g)
R. Henderson (AHI, i)	O. Yarosh (Canada, g)		

Guidelines adopted

The BQM EWG completed Residual Moisture and Residual Formaldehyde Guidelines in 3 meetings. The folowing final GLs were adopted in May 2003:

- *Testing of residual formaldehyde (VICH GL25)*
- **Testing of residual moisture (VICH GL26)**

Guidelines under development

The BQM EWG continues work with two GL's: *Mycoplasma Detection* and *Extraneous Virus Testing*. Five mycoplasma test reference strain candidates have been made and are under study. The issue of full extraneous virus testing of final batches in addition to upstream seed, cell and component remains unresolved, but the test methodology and scope have been developed.

Key scientific issues to be resolved

- Mycoplasma media, reference and product interference collaborative study.
- Mycoplasma reference distribution chain and validation.
- Mycoplasma reference working stock (≤15 subcultures) guidelines.
- Extraneous virus test approach (i.e., Upstream (seed, cell, raw material, intermediate product) vs. Downstream (final batch).
- Extraneous virus test reagent availability.
- Master seed dilution provision to allow extraneous virus tests of high titer (i.e., non-neutralizable) or low volume MS's.
- Update extraneous virus agent list as applicable.
- Update Mycoplasma and Extraneous Virus test method technologies, as applicable.

Key benefits of the harmonised guidelines

- To consumers, patients, users: Assurance of safe and pure veterinary vaccines, uniformly tested to global standards for extraneous deleterious biological and chemical agents. Improved product availability and food chain safety.
- To authorities: Standardized guidelines and references. Centralized reference material preparation and distribution.
- To industry: Elimination of duplicate testing for product release in other regions. Expedite new product registration and batch release. Participation in evaluation and validation of new guidelines and references.
- To animal welfare: Reduced in vivo procedures. Prevention of vaccine related epizootics.

New topics

A topic regarding to Target Animal Batch Safety Test has been proposed by the EU. Additionally, potential new topics discussed at meetings 6 and 7 included Seed Lot Test (Japan), Stability Test (Japan) and Inactivation Test (AHI).