



Microbiological Best Laboratory Practices, USP <1117> Value and Recent Changes to a Guidance of Quality Laboratory Practices

Scott Sutton¹, Ph.D, and Donald Singer²

¹President, Microbiology Network

²Global Lead Manager, Microbiology & QC, GlaxoSmithKline

The field of pharmaceutical microbiology is responsible for many key objectives in ensuring patient safety and product quality. Quality control, method development, process and product design, and product stability are a few of the objectives. The United States Pharmacopoeia (USP), other global pharmacopoeias and some parallel industry specific compendia offer some standardized test methodologies and material specifications relating to microbiological quality and control. However these test methods assume significant operational knowledge on the part of the laboratory practitioner and significant operational capabilities of the laboratory itself. It is imperative to have some basic knowledge, experience and infrastructure that can support consistent use of these methods. The USP informational chapter <1117> Microbiology Best Laboratory Practices was developed to serve a part of this purpose.

The proposed general information chapter about Microbiological Best Lab Practices was first published in 2003 (USP 2003) in the *Pharmacopoeial Forum*, following the long standing USP Revision process of development and writing standards by experts along with public comment. After comments and further revision of the draft chapter (USP 2004), it was first published as an official USP Informational chapter in USP 29, 3 years later (USP 2006).

The intent of the chapter was to address a perceived lack of clarity on the parts of both industry and the regulators on the basic requirements of infrastructure needed to support mandatory microbiological criteria and tests in the USP. Chemistry had a lot of guidance and information, but there was very little guidance for microbiological testing.

The question of laboratory variability was central to this concern. Microbiologists work every-day with variability in the detection, recovery and growth of microbiological species. This variability can be thought of in two categories, "avoidable" variability (variability due to poor practice) and inherently unavoidable variability (variability due to limitations of the methods and the vagaries of dealing with biological samples - see Jarvis, 1989). The goal of "best practices" would then, be to minimize "avoidable" microbiological error.

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Sabine Zange

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