



International Alliance for
Biological Standardization

Avoiding Antimicrobial Resistance: Veterinary Use of Phages for Prevention, Therapy and Control of Bacterial Infections

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Virtual Meeting

Quality Control of Therapeutic Phages in Belgium

The greatest hurdle to the introduction of phage therapy in Western medicine remains the lack of an appropriate legal and regulatory framework. Since 2018, Belgium is implementing a pragmatic phage therapy framework that centers on the unlicensed ad hoc tailor-made phage medicines in magistral preparations. Central to this approach is a two-step quality control of phage active pharmaceutical ingredients (APIs) effectuated by Sciensano. This API QC consists of the construction of a genetic passport which contains information of phages lifestyle, genome size and content, and its capacity for horizontal gene transfer. Secondly, each production lot is checked for identity, potency, microbial contamination, endotoxin levels and pH, using either official Pharmacopeia or in-house protocol. I will briefly discuss the QC pipeline, and relevant aspects in the dedicated Ph. Eur working group.