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

The Importance of CMC for Bringing Animal Health Phage Products to Market

The ability to produce a consistent, stable pharmaceutical product through a well-defined, robust manufacturing process is a key regulatory component. The Chemistry, Manufacturing, and Control (CMC) component of the regulatory dossier is essential for regulatory approval and eventual marketing of therapeutic agents including phage-based products. If the phage product is a cocktail, the CMC section will need to define the production specifications for each phage as well as the process for combining the phages to produce the final product. Early development of the CMC process is essential as regulatory agencies often require that pivotal studies be performed using product produced using the final process. The CMC section is also essential for establishing the final Cost of Goods (CoGs) for the product which will affect commercial viability. Given the potential for contamination of phages In both vaccine and pharmaceutical products, standalone GMP manufacturing facilities will be required for phage production. This is a substantial capital investment with costs generally in the 15-25M USD range. Moreover, capacity of those manufacturing facilities could be very large depending on the indication. For example, a poultry product would require a very large number of doses to treat a significant portion of the global poultry population (~14B). In conclusion, manufacturing considerations may be a considerable hurdle to the successful introduction of phage-based products. Fully understanding the market needs and cost structures may allow these hurdles to be overcome.