GMP production of bacteriophages

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Facing the emergence of difficult-to-threat bacterial infections, the perspective of using the anti-bacterial potential of bacteriophages has re-gained a significant interest in many countries. In the European Union (EU), bacteriophages are not of common and widespread use, and, in turns, do not have a specific regulatory framework, for both the use and the production of the phages.
From a pharmaceutical classification point of view, phages fall in the categories of anti-infectious products and of biological products, given the intended use and their live nature. In addition, the compliance to the Good Manufacture Practices (GMP) is a requirement for any medicinal product.
The PhagoBurn's project is a EU-funded project, started in2013, with the aims of 1) producing two cocktails of lytic bacteriophages in compliance with the GMPs, 2) performing a phase I-II clinical trial on burn patients suffering from *E. coli* or *P. aeruginosa* infections, 3) preparing the required evolutions towards an appropriate regulatory pathway. Clean Cells has been involved as partner in PhagoBurn's consortium, in charge with the production of the cocktails.
The strategy for organizing the production steps was elaborated on the pre-existing basis of the viral vaccine for human use. After the validation of the quality control methods, and the validation of the process, each phage was individually produced, then controlled and used for assembling the cocktails in the GMP environment.
The resulting cocktails were authorized by the national authorities in 3 countries (France, Belgium, and Switzerland) and the clinical trial is in progress for safety and efficacy assessment. Among others, this work constitutes a contribution for the forthcoming evolutions of the regulatory pathway in the UE.

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