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Human Medicines Development and Evaluation

Expert workshop on process validation for the manufacture of biotechnology-derived active substances

9th April 2013, 9:00 – 17:00 (GMT)

European Medicines Agency

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK

Abstract

In May 2011, the CHMP Biologics Working Party (BWP) issued a concept paper that stipulates the need for a guideline on process validation for the manufacture of biotechnology-derived active substances. This request is based on the lack of detailed guidance on this topic and the need to provide practical recommendations on data requirements in the context of an initial Marketing Authorisation Application (MAA) for a biotech product.

In order to assist the BWP in drafting this guideline, a one-day stakeholder workshop on biotech manufacturing process validation will be held at the EMA offices on April 9, 2013. The aim of the workshop is to address key questions concerning specific evaluation/ validation data which are essentially required to confirm the reproducibility and robustness of the process steps and ultimately guarantee a product of consistent high quality at the time of evaluation of the MAA.

In line with the various approaches currently followed in biopharmaceutical industry to demonstrate process validation, the workshop will have a main session focused on the tools and strategy followed in a “traditional” validation approach and a second session dealing with the “enhanced / QbD” validation approach.

The morning session on the traditional validation approach will first address the upstream manufacturing process (i.e., cell culture) to discuss process parameters and quality attributes to be tested during inoculation, expansion, harvest and pooling. The second part of the first session will deal with the downstream process: parameters/ attributes to be tested during purification (columns/resins/membranes), pooling, holding time/storage and reprocessing. In both parts, a discussion on specific cases of multi facility production and scale down models is intended.

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The second session in the afternoon will cover the additional tools that could be used to demonstrate process validation in an enhanced/QbD approach. Discussions could address scale down models, PAT tools, expectations on continuous process verification.

Each part of the workshop will comprise a presentation from a regulator and likely two presentations from industry with the intention of fostering a discussion on these issues and to clarify the expectations from different stakeholders. The event is intended to bring together experts in the area and draw upon the experience of the participants during the discussions. It is expected that the output from the workshop will provide useful reference for the future EMA guideline on process validation for the manufacture of biotechnology-derived active substances.