Comments on Consultation Document GMP for ATMPs

General comments

Current Volume 4 of the EU Good Manufacturing Practice Guidelines contains 9 Chapters with Basic Requirements for Medicinal Products, and Part II, III, and 19 Annexes with specific Requirements for Medicinal Products. To our opinion, these Guidelines provide proper guidance, a sufficient level of detail, but also possibilities to follow risk-based approaches in manufacturing of ATMPs. Therefore:

1. We do not recommend the replacement of any of the current EU GMP Guidelines by a separate GMP Guideline for ATMPs. Rather, relevant topics in current EU GMP Guidelines may be revised (such as Annex I and II) to include more specific guidance to ATMP manufacturing, to cover novel manufacturing methods (such as (semi-)closed production systems) and scientific insights. Many aspects covered in the Consultation Document are considered useful additions to current GMP Guidelines.

Although a major part of early ATMP research and development may be executed in not-for-profit institutes which do not aim for EMA marketing authorization, clinical ATMP trials should be designed to acquire information on safety and efficacy of high quality ATMPs. Treatment of patients with investigational ATMPs can only be justified when the level of ATMP manufacturing is appropriate to the stage of development, to build a proper ATMP dossier and work towards regular patient care. Collaboration between not-for-profit and commercial ATMP development teams and transfer of ATMP development from not-for-profit towards commercial ATMP manufacturers may be seriously hampered by implementation of different quality requirements for investigational and commercial ATMPs. Therefore:

2. We do not recommend to implement different GMP guidances for “investigational” ATMPs and “commercial” ATMPs. Rather, the risk-based approach which has been introduced for many aspects in current GMP Guidelines could be followed. To increase flexibility for manufacturing of investigational ATMPs we propose to add the risk-based approach items laid down in this Consultation Document to the appropriate sections of current GMP Guidelines. Furthermore, ATMP specific guidance in GMP Guidelines could be specified for the requirement to be consistent with the stage of ATMP development where appropriate.

These comments were submitted by our academic ATMP R&D and Manufacturing team:

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