PROMETHERA
BIOSCIENCES

Watson & Crick Hill
Rue Granbonpré, 11
B-1435 Mont-Saint-Guibert
(Belgium)

Tél.: +32 (0)10 39 43 00
Fax: +32 (0)10 39 43 01

Monday, 26th September 2016

Dear Sir or Madam,

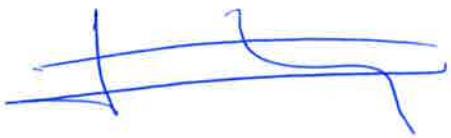
Promethera Biosciences is a clinical stage pharmaceutical company that develops innovative therapies for the treatment of liver diseases with no effective therapeutic cure.
Our mission is to discover, develop, and commercialize cell therapy products to treat liver diseases in an innovative way using allogenic progenitor cells harvested from healthy human livers.

Promethera Biosciences is registered as an SME in the EMA register. Promethera Biosciences is a member of Co-ACT, a platform grouping together advanced therapies companies based in Belgium, as well as a member of the global organisation ARM (Alliance for Regenerative Medicine).

Promethera Biosciences welcomes the initiative of the European Commission to launch its second public consultation on the document 'Good Manufacturing Practice for Advanced Therapy Medicinal Products'. In particular, we welcome the flexible approach taken by the Commission that takes into account the specific characteristics of advanced therapies and the clarifications how to meet the specific requirements for these products.

Promethera Biosciences has actively contributed to the response provided by the Alliance for Regenerative Medicine. We generally support it, including the request that this document should be incorporated as an annex in EudraLex Volume 4 rather than published as a separate document. We laud the efforts and the objective of the Commission to make this document as easy and relevant as possible for ATMP manufacturers but we believe that for the many aspects that are not different for ATMP and non-ATMPs (e.g. personnel, qualification and validation, etc.), the consultation document summarizes GMP requirements failing to incorporate all the details that can currently be found in Volume 4. We believe that this approach creates different standards between ATMPs and non-ATMPs for all the areas that are not specific to ATMP. Such difference is difficult to justify from a public health perspective. We therefore encourage the Commission to revisit this approach and welcome additional interactions between the industry, the Inspection Working Group and any other concerned stakeholders to address this issue.

Many thanks for your consideration and best regards,



Patrick Stragier
VP Operations