



ROSLIN CELLS LIMITED

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Unit D5 "Medicinal products – Authorisations, European Medicines Agency"
European Commission
DM24 02/133
B-1049 Brussels (Belgium)

12 November 2015

Dear Sir or Madam,

Feedback on GMP Advanced Therapy Medicinal Products Consultation Document

I am writing on behalf of Roslin Cells Ltd to provide feedback on the GMP Advanced Therapy Medicinal Products Consultation Document. Roslin Cells Ltd is a company registered in Scotland and falls within the EU definition of a small and medium sized enterprise.

The guidance proposals are good and is clear guidance in terms of flexibility and acknowledgement of the application of risk assessment depending on life cycle. It is not indicated however where the document would sit in with the rest of the EU GMP guidelines as there is no indicated reference to other Annexes or chapters.

If you require any further clarification please do not hesitate to contact me.

Yours sincerely

A handwritten signature in black ink, appearing to read "Janet Downie".

Mrs Janet Downie
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