2.1_ Introduction: Last sentence (page 5): Suggest the wording is changed to "This cooperation should be described in a technical agreement".

2.7.5_Labelling (page 11): Performing relabelling at a manufacturing site (preferably) is not referenced here as it is in Annex 13 Article 33)

2.9.iii (page 13): The QP's duties relating to imported comparator which does not have certs of analysis is not referenced (see Annex 13 Article 39(d). It will be difficult to ensure compliance with Art 63(3) Reg 536/2014 without further guidance. Furthermore the sponsor's responsibility to ensure that a supplier of a comparator has a recall procedure is not referenced. (Annex 13 Article 50)

2.10_Outsourcing (page 14): It is recommended that a section on Distribution is included to retain GMP expectations for sponsors as documented in the current version of Annex 13 under Shipping as follows: Articles 43, 44, 45, 46, 47. Please also consider adding the following requirement to this section: s "The manufacturer/importer is responsible for ensuring that the distribution of the products minimises any risk to their quality and takes account of the applicable principles of Good Distribution Practice in accordance with the pharmaceutical quality system requirements listed in EU GMP Guide Part I".