From: [redacted]
Sent: 25 November 2015 23:02
To: SANTE-D6-GL-GMP-IMP
Cc:
Subject: GL on GMP for IMP. position to the consultation document, Guidelines on Good Manufacturing Practice for Investigational Medicinal Products for Human Use

Please publish the . contribution as B

position to the consultation document
. Guidelines on Good Manufacturing Practice for Investigational Medicinal Products for Human Use

Regarding second subparagraph of Article 63(1) of Regulation (EU) No. 536/2014 -

section 2.9 'Release of batches' (line 485-486); finds that the QP should be responsible for all release except extension of shelf life on clinical centers, hospitals etc.

. support the Distribution concerns from MHRA, has already equivalent GDP requirements for IMP and commercial products. We support the MHRA position to GDP, however if other control mechanisms could replace the two-step release could be in favor for such a change.

have following comment to GDP of IMP A requirement for a wholesaler/storage authorization for the distribution of IMP would be the logical mean to assure harmonized implementation of GDP for IMP.

support the Recalls and returns and Destruction concerns from MPA,

Kind regards,

[redacted]