SANTE PHARMACEUTICALS D6

Subject: FW: Comments to EudraLex GMP Annex 15

From: Riitta.Laine
Sent: Friday, May 30, 2014 10:54 AM
To: ADM-GMDP@ema.europa.eu; SANCO PHARMACEUTICALS D6
Cc: Subject: Comments to EudraLex GMP Annex 15

To whom it may concern,

Please find below our company's comments to EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines draft Feb 2014 Annex 15 on Qualification and Validation.

To Chapter 4 Process validation, point 4.4

> For the site transfer of legacy products, the manufacturing process and controls should comply with the Marketing Authorisation and meet current expected licensing standards for that product type. If necessary, variations to the Marketing Authorisation should be submitted.

we have the following comment:
The highlighted requirement should be defined in detail, which guidelines or regulations need to be followed, so that the variation applicant and the assessor of the variation will have a common understanding without need for additional questions and unnecessary additional variations.

Regards,

Riitta Laine, M.Sc. (Chem.)
Orion Corporation