

SANTE PHARMACEUTICALS D6

Subject: FW: Annex - 15

From: V K BHALLA
Sent: Monday, June 16, 2014 2:25 PM
To: ADM-GMDP@ema.europa.eu; SANCO PHARMACEUTICALS D6
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Dear Sir,

Your guidelines under annexure 15 are too General in nature and are subjective. My suggestion is to cross-link requirement to detailed guidelines elsewhere.

Further the CLEANING VALIDATION does not address the cleaning validation requirements in a dedicated facility / equipments. APIC guidelines on cleaning validation is quite exhaustive. What is regulatory status of APIC guidelines. Can one adopt them?

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DR. V.K. Bhalla