From: Prateek Goyal <prateekgoyal@lupin.com>
Sent: 19 November 2015 13:38
To: SANTE PHARMACEUTICALS D6
Cc: ADM-GMDP@ema.europa.eu
Subject: Comments on Annex 17

Dear Support

This is a nice initiative taken by EC. Generally pharmaceutical manufacturing involves laboratory testing on product sampled at the end of the manufacturing process to assure the product quality as part of the product release. This draft guideline provides another acceptable approach used to assure the quality product prior to release. It is good to see the references of other annexure covered under various points.

Following points need to be relooked:

1. Application of RTRT to any stage in the manufacturing process and to any type of FPs, including APIs and intermediates can be incorporated in reason for revision.
2. Evaluation of risk against non CQAs can be considered.
3. Historical data evaluation can be elaborated.
4. Point 3.11 is not very clearly understandable, details can be added for more clarity.
5. Point on interaction with regulatory body shall be elaborated.

These review comments have been provided by me as an individual not as an organization representative. My contribution can be directly published with my personal information (I consent to publication of all information in my contribution in whole or in part including my name and I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication).

Thanks and Regards

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