SANTE PHARMACEUTICALS D6

Subject: FW: Revision to Annex 15

From: Bob Hayes [mailto:
Sent: Wednesday, May 28, 2014 3:21 PM
To: ADM-GMDP@ema.europa.eu; SANCO PHARMACEUTICALS D6
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Dear Sirs,

Having spent over 30 years in the pharmaceutical industry, I feel able to submit my comments on the proposed revision to Annex 15. I am Vice-Chair of the Pharmaceuticals Committee at the Institution of Mechanical Engineers (London). The views below are mine, not that of the IMechE, the Pharma Committee or its members.

I support the use of both a risk-based and lifecycle approach and the inclusion of CPV.

I do not support the inclusion of the traditional approach to validation. Pharma has been very slow to adopt modern quality systems thinking; allowing existing ways of working to continue to be used will not move the industry forward. For the most part, mainstream pharma quality systems are around 35 years behind leading manufacturing sectors.

Conceptually, URS, DQ, FAT, SAT, IQ, OQ, PQ are all necessary activities that should be carried out and concluded to support validation. Their goal, through full and proper understanding of the critical parameters and controls within the process and their effect on output, should be to design and install a process that works reliably and repeatably with minimal variation. Presently, these steps are often carried out in isolation of each other, which doesn't lead to good overall process understanding and control. Arguably, all the steps up to and including Performance Qualification are effective process design Good Engineering Practice.

With reference to 4.18, I cannot support the idea that three batches (minimum) is effective validation. Whilst I accept that the word "minimum" has been included and that there is a reference back to 4.17, this statement will, again, lead to many working towards getting three consecutive batches to fall within specification (often with a lot of extra effort to ensure success), then saying validation is complete. This approach leads to companies doing the bare minimum to develop data that is not statistically sound – would you get on an aircraft that had been validated by a pharma company using the traditional approach?

To summarise, this is an excellent document, save for the references to "old" ways of working.

I have also spotted a few typographical errors:

- In "Principle", 3rd line, the word "manufacturer's" has been used to express the plural, so should not have an apostrophe.
- 4.20 e) includes a break to the next bullet that clearly shouldn't be there.
- 4.27 has "ongoing" written as two words, not one.
- 9.5 has "carryover" written as two words, not one.

Yours,

Eur Ing Robert J Hayes, BSc, CEng, FIMechE, FIET