SANTE PHARMACEUTICALS D6

From: SANTE PHARMACEUTICALS D6
Subject: Comments on EudraLex - Volume 4 - Annex 15 - revised version

From: joao soares
Sent: Saturday, February 08, 2014 6:13 PM
To: ADM-GMDP@ema.europa.eu; SANCO PHARMACEUTICALS D6
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Dear Sirs,

My contribution concerns the potential use of Factory Acceptance Tests (FAT) / Site Acceptance Tests (SAT) and Commissioning Tests in the Qualifications activities, and the constraints due to the need to have pre-approval of IQ and OQ Protocols by the Quality Unit.

The experience shows me that in most occasions FAT / SAT / Commissioning activities take place before the approval by Quality Unit of IQ and OQ protocols. This often leads to wasteful repetition of the tests performed, without any added value.

One approach to deal with these constraints is the one expressed in the ISPE Guide: “Applied Risk Management for Commissioning and Qualification”. In this approach, IQ and OQ activities are considered essential engineering activities, and are addressed primarily through engineering generated documentation. The Quality Unit has the responsibility to approve the User Requirements, Quality Risk Assessments and associated list of Critical Aspects, Qualification Plan and final acceptance and release of the qualified equipment or system, but IQ and OQ protocols are managed by Engineering and relevant Subject Matter Experts (SME) - individuals with specific expertise on the area or field of the qualification.

This approach is in line with ASTM E2500-07 - Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment, , and with principles introduced in the FDA initiative, Pharmaceutical cGMPs for the 21st Century—A Risk-Based Approach.

In my opinion, organizations working in European Union would gain with a greater alignment between Annex 15 and ASTM E2500, and therefore reducing the level of formality in IQ and OQ protocols approval, and the costly repetition of tests, maximizing the use of FAT / SAT / Commissioning documentation, generated by Engineering and other SME, against a Quality Unit pre-approved set of requirements and acceptance criteria.

Kindly regards,

João Soares