From: [redacted]@aefi.org>
Sent: 24 November 2015 15:18
To: SANTE-D6-DA-GMP-IMP
Subject: CONSULTATION ON Commission Delegated Act on Principles and Guidelines on GMP for investigational medicinal products (AEFI)

Dear Sirs,

The *Spanish Association of Pharmacists in Industry* (AEFI), as a representative organism of pharmacists and other professionals that serve in Industry, would like to send you the following comment on the Consultation Document,

Commission Delegated Act on Principles and Guidelines on good manufacturing practice for investigational medicinal products for human use and inspection procedures, pursuant to the first subparagraph of Article 63 (1) of Regulation (EU) N 536/2014

Question 1a: Would a requirement for a product specification file (a reference file containing, or referring to files containing, all the information necessary to draft the detailed written instructions on processing, packaging, quality control testing, batch release and shipping of an investigational medicinal product) be useful to be introduced? **It would be very useful.**

Yours faithfully,

blog AEFI: www.aefi.org.es