Dear Stefan, we met at the APIC conference last November, where I have discussed a presentation on Italian requirements for API importers.
Nice to know that I can address comments to your attention.

1. After discussion with Renato Massimi, who is in charge of the Manufacturing Authorization Office at AIFA, we would like give some comments on the concept paper Sanco.ddg1.d.6(2012)73176.
   We agree that directive 2001/94 should be revised to extend the scope to the GMP for active substances. Nevertheless, in the document is pointed out that the concept of "qualified person" does not apply to active substances, making references to several points of the directive 2001/83/EC.

   We wish to express our concerns about this position; from one side it can be accepted that the qualified person for API manufacturer and finished product manufacturer may have different qualification grades, but according to our opinion the API manufacturer must have a responsible person, qualified for the tasks to be accomplished. In fact, the API manufacturers put on the market APIs which must have been manufactured in accordance with EU quality standards and EU GMP Part II and this should be endorsed by a responsible person. As a conclusion we would like that art. 48 of the directive 2001/ 83 is applied also to the manufacturers of API located in EU.

   In addition, consideration should be given on the fact that companies performing importation must be able to evaluate the quality and compliance of the original extra-EU countries manufacturer; this implies that also for importer there is a need of qualified people which are able to evaluate the compliance to the quality and regulatory requirements.

2. Regarding the written confirmation format (SANCO/D6/(2012) ddg1.d6.517666we would like to comment that from our point of view, it is important that the last inspection dates are stated in the document since it is a relevant information.

Thank you for your attention and don't hesitate to contact me for any further clarification

Kind Regards

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