From: Stahl, Elke [mailto:Elke.Stahl@bfarm.de]
Sent: Tuesday, March 26, 2013 5:13 PM
To: SANCO PHARMACEUTICALS D6
Subject: public sonsultation of QPD template concerning GMP

Dear Madame or Sir:

We would like to comment the

Template for the qualified person's declaration concerning GMP compliance of investigational medicinal products manufactured in non-EU countries - draft submitted for public consultation

At the declaration template it needs to be clearly stated the name of the company to which the QP belongs, the 'Manufacturing and Importation Authorisation (MIA) number under which this declaration is made: ___' is not regarded as sufficient since not all Member States issue such 'ID-numbers', at least Gemany does not. Therefore an additional naming is essential.

Kind regards,

Elke Stahl

On behalf of BfArM

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