Deutsche Post DHL

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Sanco-pharmaceuticals-d6@ec.europa.eu
Unit SANCO/D/6
DM24 02/050
BE-1049 Brussels

DPDHL comments on the REVISED COMMISSION GUIDELINES ON THE PRINCIPLES OF GOOD DISTRIBUTION PRACTICES FOR ACTIVE SUBSTANCES FOR MEDICINAL PRODUCTS FOR HUMAN USE

Dear Madam, Sir,

Deutsche Post DHL is the world's leading mail and logistics services group.

The Deutsche Post and DHL corporate brands represent a one-of-a-kind portfolio of logistics (DHL) and communications (Deutsche Post) services. The Group provides its customers with both easy to use standardized products as well as innovative and tailored solutions ranging from dialog marketing to industrial supply chains. About 470,000 employees in more than 220 countries and territories form a global network focused on service, quality and sustainability. With programs in the areas of climate protection, disaster relief and education, the Group is committed to social responsibility. In 2011, Deutsche Post DHL generated revenues of € 53 billion.

DPDHL is in the EU Transparency Register under the following number: **48544465107-88**

DPDHL has reviewed the revised Commission guidelines on the principles of good distribution practices for active substances for medicinal products for human use and is pleased to offer the following comments:

Paragraph/Section	DPDHL Comments
General Observations	1. DHL Life Sciences operates over 150 dedicated facilities around the globe operating to over 30 different types of Good Distribution Practices so a Reference section would be useful to understand which Guidelines are covered ie WHO, ICH, PIC/s, PDA, USP, IPEC etc 2. The guidelines should be aligned with EU GMP Part II Section 10, PIC/s PE009-10 GMP Part II Section 10 dated Jan 2013 and ICH Q7 GMP Practice for API - Section 10 - Storage and Distribution 3. As new EU GDP Guidelines for medicinal products are now aligned with the Chapters of EU GMP Part I it would seem logical to follow the same format of these GDPs to be aligned with EU GMP Part II – it does in part under para 9 Documentation and para 32 4. A Glossary would be helpful as some international guidelines use APIs – as per Section 20 EU GMP Part II 5. Time-limits are generally not specified
Scope 1- 2	1. Are Excipients in scope - as they play a role in preserving efficacy and stability? 2. Paragraph 2 would suggest re-labeling activities would fall under EU GMP requirements – would this apply to all labeling activities eg where quarantine, released or damage, rejected, expired labels are applied as some label activities

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	will apply under GDP processes
Quality System 3	Consider reference to QRM and ICH Q9 as per GDP for Medicinal Products
Personnel 6	A number of titles are used in the industry eg QPs, RPs and MRs - Manager representative is a term used in medical devices – should we use "Responsible Person" as sites which are licensed to handle licensed finished products could be used to store and distribute active substances
Personnel 6-8	No mention of hygiene requirements or that personnel need to be trained in GDP as per other GDP Guidelines
Procedures 11	Consider including principles of Good Documentation Practices are followed
Receipt 15	No mention of the need for managing the status of products ie product being received into quarantine until released and process for segregation
Storage 18-23	Does not appear to mention the control and status of active substances from receipt (33 refers to quarantine of returns and should be identified) – one would expect a secure area for quarantine, released products and areas for Returns, Recall and product awaiting destruction etc as referred at Section 10.11 of EU GMP Part II.
Storage 22 (destruction)	Distributors who do not have title would need to clear this with their customer/manufacturer. This process needs to be controlled to avoid products entering the supply chain as SSFFC – with documents specifying batches, quantities to allow traceability from dated receipts from the destruction company
Returns 35	1. Need to be a link to the customer/manufacturer before returning any stock. There should be reference to products that have been in strict temperature regimes – as it is not normal to accept returns because the cold chain may be broken while the product was not in their hands. 2. 35 d) This would normally be the QP?
Returns 38	Clarify if process requires the over labeling of a Release label over a Returns label for traceability
Complaints 41	Complaints records minimum retention time is not specified in this section.

I would be pleased to provide any additional information you may require.

Yours faithfully

M Meakin
Vice President – Global Quality, Regulatory & Compliance
DHL Life Sciences & Healthcare
Newnham Drive
Heartlands Business Park
Daventry
NN11 8YG
United Kingdom