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Comment on Draft EU GDP Guide by the European QP Association Expert Panel

The European Qualified Person Association (EQPA) expert panel have reviewed the draft GDP guideline and provide the attached comments for your consideration.

Reasons for review

- The new EU Directive 2011/62/EU, describes the responsibilities of the QP in the supply chain
- The revised EU GMP Chapter 1, defines QP involvement in the supply chain
- QP's are required to approve 3rd party logistic service providers (3PL) and ensure a quality agreement between their company and the 3PL is in place to maintain product security in the supply chain
- The manufacturers are required to comply with the requirements stated in the GDP documentation for distribution of their products

The review team has categorised their comments on the document into:

- Technical comments
- Requests for clarification
- Request for addition of information
- Editorial comments

In general, we found the document very user friendly, and easy to understand with many clear guidelines for requirements; however, we believe some areas require further clarification. The main areas for concern include:

- The RP qualification requirements seem excessive for the role; we do not believe there is a need for an RP to be a pharmacist. A life science degree is sufficient for this role (similar to the QP qualification requirements), with more emphasis on the experience and knowledge.
- The document states any hub used must be audited and approved prior to use. We estimate that over 1000 hubs across Europe are currently in use by various pharmaceutical manufacturers and wholesalers. In view of the low level of risk such hubs can have on the products in the distribution network (maximum 24hours storage allowed), we propose that audits are managed through a risk based approach with possible documentation review e.g. questionnaires, and not necessarily site based audits.
- The document states that contract giver must audit the contract acceptor before beginning of the outsourced activities and afterwards audits should be done periodically; again a risk based approach to such audits is recommended (Section 7.2).
- The requirement for validation of transportation of medicinal products is not possible as transportation is not a fully controlled operation; we suggest qualification of transportation.

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- We believe the implementation timeline suggested (six months) in the draft document is very aggressive which may result in non compliance across the whole industry. We propose an 18 month implementation period, where each site must have an implementation plan in place within 6 months of issue of the document.
  There is no mention of the application of on the guideline to the storage and distribution of IMPs and clinical trial materials.

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