Dear Sirs,

I am writing on behalf of Genus Pharmaceuticals Ltd in the UK. Our organisation has less than 250 employees and have an annual turnover of >€50 million.

We hold a UK Manufacturer's/Importer's Authorisation but operate a virtual business subcontracting all manufacture and testing within and outside the EU.

We have started to work with our suppliers on producing an excipient risk assessment for our products based on the draft guidance including clause 5:

"5. Importers of medicinal products must have the risk assessment/management documentation for appropriate GMP for excipients available on site."

Many of our manufacturers have responded positively to our request to populate such a risk assessment but have stated that they are unable to send it to us due to the confidentiality conflicts with other clients where many excipients are used in more than one type of product. We would however be able to review this risk assessment during a periodic GMP audit of their facilitates (as is performed for other topics such as cleaning validation, equipment qualification etc.).

We therefore are concerned about compliance to the statement stating that we must have this document on site. We would propose the following change:

"5. Importers of medicinal products must have access to the risk assessment/management documentation for appropriate GMP for excipients"

If you have any questions or requests then please let me know.

Kind regards,

Dan Pearce

QA Manager

Genus Pharmaceuticals

Park View House
65 London Road
Newbury
Berkshire
RG14 1JN

Mobile: +44 (0) 7789 792955

Landline: +44 (0) 1635 568406