

Dear Sirs,

You have asked for comments and responses to the 'DRAFT Guidelines on the GDP for APIs':

The company QueMaCo Limited is a small sized enterprise with less than EUR50M turnover and fewer than 250 employees.

QueMaCo was set up as a Commercial Agent representing the interests of various overseas manufacturers of APIs. We adopted the European model of AGENT rather than the UK model of DISTRIBUTOR. Nevertheless we have AGENT business which pays commissions and we have DISTRIBUTOR business which requires that we buy and resell the goods.

As a rule we have never tested the quality of any materials. Why is this necessary? The draft guidelines appear to indicate the need for a Quality System which requires that that we set in section 3 the responsibilities, processes and risk management principles; and in section 4 that the quality system should be adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities. If so this appears to indicate the need to test the materials before their onward despatch to the client. If not, why would we require premises, equipment and facilities? Taking samples requires that the drums could be opened. If so this likely to introduce a breach of cGMP. We have never done so and consider that this is completely unnecessary. The manufacturer has tested and packed the material. Why introduce potential risks into the process? Our task as an agent or distributor is to ensure only that they are delivered safely to the client.

Moreover we rarely see the goods. We do not have warehousing facilities and do not see the need to have such. All of our large deliveries are delivered directly to the client from the manufacturer. In most cases they are delivered directly to the client as per our instructions. Our involvement is merely to organise the trans-shipment from manufacturer to the client.

Accordingly we find the phrasing of points 3-5 to lack clarity. What exactly is required?

I would appreciate your clarification of the above concerns.

Best Regards,
Graham Ewing, Director

QueMaCo Limited, Mulberry House, 6 Vine Farm Close, Cotgrave, Nottingham, United Kingdom NG12 3TU

Tel: 0115-9899618/9890288/fax 9899826/mob 07885-755847

email: graham.ewing@quemaco.co.uk

Skype: quemaco1

Company registered in England & Wales no 2645888