Please find below a comment from **GE Healthcare, Medical Diagnostics** on the draft “GUIDELINES ON THE FORMALISED RISK ASSESSMENT FOR ASCERTAINING THE APPROPRIATE GOOD MANUFACTURING PRACTICE FOR EXCIPIENTS OF MEDICINAL PRODUCTS FOR HUMAN USE” which were submitted for public comment earlier this year.

Our comment to the draft text is as follows:

“The responsibility for implementing the guideline is very clearly assigned to the Manufacturing Authorisation holder. Many companies rely solely on contract manufacturing operations, which might give some conflict. The activities described in Section 3 can be seen as part of the vendor management process. Although the manufacturing site must take responsibility for qualification of their vendors, the Marketing Authorisation holder may still have a responsibility regarding some elements of risk assessment . Therefore some clarification of the respective responsibilities of the Marketing Authorisation holder and the manufacturer when these are not the same organisation, could be useful for industry.”

Kind regards,

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