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Subject: Comments to Annex 16 from GE Healthcare

Comments from GE Healthcare Life Sciences:

As the abbreviations in the Draft Annex 16 document are similar, and to avoid any potential for confusion about responsibilities, we would recommend to write the terms "Manufacturing and Importation Authorisation" and "Marketing Authorisation" in full each time they are used in the document rather than using the abbreviations MIA and MA. We note that already in the document the full term is used more often than the abbreviation.

We consider that the content and requirements of the document are appropriate and note some areas which could be further clarified:

1. Although the use of a checklist to document batch certification activities by the QP is not specifically mentioned, we consider that the language of the document is leaning towards this practice. Is this the intention?
2. Section 3.5.3. We discussed the meaning of "register or equivalent document". In some companies it is common practice to certify batches by signing a page of the batch record; whereas in others the QP has a "stand alone" register which they use to certify batches. We believe that the first practice (signing the batch record) is acceptable and particularly so if it is justified in the batch release procedure (SOP) that this is the official batch certification. This should be clarified in the final text.
3. Section 5: We note that planned changes are now not included, whereas Section 8.1d of the current version does include 'planned changes'.

Kind regards,

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