

NL comment on draft template for the qualified person's declaration concerning GMP compliance of investigational medicinal products manufactured in non-EU countries

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Reaction Netherlands Ministry of Health on draft template:

- Template could be very practical as a tool, however shouldn't be mandatory;
- Template focuses in our opinion too much on audits which is only *one* of the aspects the QP takes into account before releasing an IMP, as is described in Annex 16 Certification by a Qualified Person and Batch Release.

Questions Netherlands Ministry of Health would like to raise:

- In which way will the Ethical Committees use this form?
- From a more general viewpoint, for innovative products the approval of a study and the development of a product, notably ATMPs, is often in parallel. Could the use of such a template possibly form a hindrance to the development of products?

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