PHARMIG
Verband der pharmazeutischen Industrie Österreichs

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PHARMIG response to the European Commission Draft: Template for the Qualified Person's Declaration Concerning GMP Compliance of Investigational Medicinal Products Manufactured in Non-EU Countries

PHARMIG, the association of the Austrian pharmaceutical industry, would like to thank the European Commission for the opportunity to comment on the **Draft Template for the Qualified Person's Declaration Concerning GMP Compliance of Investigational Medicinal Products Manufactured in Non-EU Countries**.

Please find following our comments.

Part B in the current Draft version of the template might be interpreted in a way that the audit, which has to verify the GMP compliance, has to be conducted by a QP, either employed by the Manufacturing Authorisation holder (MAH) or by a third party. Audits of course do not mandatorily have to be performed by a QP. Furthermore it is common and agreed practice that audits are conducted by a suitably trained and experienced person. This person of course does not obligatorily have to be a QP.

We therefore recommend amending Part B as stated on the following page.

Part B

I confirm that I am a QP and am authorised to make this declaration.

I declare that compliance with GMP at least equivalent to EU GMP has been verified on the basis of:

(i) ~~Personal audit~~ **Audit conducted by the Manufacturing Authorisation Holder (MAH)**

Manufacturing site(s) (Name and address of site where the activity is performed)	Date of last audit (completion) *

* expected to be within the last 3 years

(ii) Audit conducted by third party ~~(including another QP employed by the importer)~~

Manufacturing site(s) (Name and address of site where the activity is performed)	Third party	Date of audit (completion) *

* expected to be within the last 3 years

(iii) If an audit of the site has not been performed **by the Manufacturing Authorisation Holder or a third party** ~~or on behalf of the QP~~, please provide a brief justification and explanation on how the QP knows that standards at least equivalent to EU GMP are being followed at the site.

Manufacturing site	Justification