PDA
Parenteral Drug Association

Connecting People, Science and Regulation®

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Dr. Ofra Axelrod
General Manager

Mrs. Rachel Shimonovitz
National Inspector of GMP

The Institute for Standardization and Control of Pharmaceuticals
Eliav Street 9, Jerusalem Israel
Reference: Israel MOH Draft QP SOP, # EX-017/01

Dear Dr. Axelrod and Mrs. Shimonovitz:

The Parenteral Drug Association is a non-profit, international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing, science and quality.

We appreciate the opportunity to submit this response in support of comments made by the local affiliate of PDA, the (non-profit) organization for the furtherment of Pharmaceutical Science and Technology in Israel, on the recent draft QP SOP. PDA's mission is connecting people, science and regulation and providing input and comment to global health authority draft publications is a central to achieving this goal and important to our members. In general, PDA would like to recommend the following points be addressed in the SOP:

- Provide clarity on the criteria for a delegate QP and how it differs from the QP and connection to alleviating the shortage of QPs in Israel.
- Specify the expectations on training of a QP
- Clearly define roles and responsibilities of the QP in two scenarios: (a) if there is a manufacturing step performed in Israel or (b) if the product is imported.

More details of the PDA response are attached below.

The PDA comments detailed in the attachment have been endorsed by the PDA Board of Directors and the Regulatory Affairs and Quality Advisory Board made of up of industry experts from around the world. PDA is also available to share information on how a QP-type role is implemented in other jurisdictions.

If there are any questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson
President, PDA

Cc: Professor Eyal Shwartzberg, Ministry of Health; Denyse Baker, PDA

העמותה לקידום המדע והטכנולוגיה הפרמצבטית בישראל

The (non-profit) organization for the furtherment of Pharmaceutical Science and Technology in Israel

#	Comment	Alternative Suggestion
1	There is no structured academic or other training pathway for a QP. In the absence of objective requirements for the training, the draft does not provide acceptance / rejection criteria for a candidate submitted to be added / or as a replacement QP on the Manufacturers / Importers license. The requirements in Appendix 3 are rather broad and there are no objective criteria such as an exam, for assessing the candidate's conformance or not.	To fix minimum, objective requirements for the role of QP, where it is the responsibility of the company to train and verify the candidate's suitability and competence as for any other position defined under the law. Thereafter, notification only to the Ministry of Health regarding the appointment, by means of updating the Manufacturers / Importers License. The functioning / failure to function in accordance with the requirements, will be verified in the framework of the GMP inspections
2	There is no definition of the QP in the SOP and it is not explained that in Israel the term QP is equivalent to Responsible Pharmacist	Proposed Definition The QP / Responsible Pharmacist is the person in company, with the responsibility and authority to release or rejects batches of medicinal products, in accordance with the Pharmacist Regulations (GMP for Products) 2008
3	The title of the SOP does not reflect its content. For clarity, it is desirable the name emphasize that the SOP discusses submission of a request to add / replace a QP on the Manufacturers / Importers License	Replace the name of the SOP as follow: SOP for Submission of a Request to Add and / or Replace a QP on the Manufacturers / Importers License
4	We support the concept of a delegate QP, which we understand is intended to solve the acute shortage of QPs in Israel. The definition in the SOP is narrow and doesn't allow training delegate QPs with relevant experience and skills unless they already meet the requirements of the QP himself. As we understand it, the only difference is that the delegate need not be added to the Manufacturers / Importers License. As such, the SOP reinforces the existing shortage of Pharmacists / QPs.	We propose giving authority to a delegate QP who meets objective criteria of knowledge / experience in relevant topics and documented qualification of review and release / rejection of batches, where the decision is the responsibility of the company QP Or otherwise As presently written, we propose deleting the option of a delegate QP

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#	Comment	Alternative Suggestion
5	We didn't find reference to a structured process for rejecting a candidate	We propose there be a structured process including providing justification for the rejection and possibility of appeal before a committee, the composition of which is defined in the SOP
6	The SOP does not distinguish between the QP of a manufacturer and the QP of an importer. In the absence of a formal training pathway (see comment #1) an importer has no way to train a QP to meet the requirements of the SOP. The SOP is therefore likely to worsen the acute shortage of QPs.	We suggest one of two options, with preference to the first: 1. Separate between the requirements for training an importer's QP and a manufacturer's QP. In fact, the Ministry has already separated between the two types of QPs in that they do not permit a QP of an importer to transfer to a manufacturer without additional training. We agree with this approach, but with this in mind, it seems logical to differentiate the requirements. 2. Alternatively, if there must be identical requirements, it should be possible for the QP of an importer to transfer to a manufacturer on the basis of identical minimal requirements defined by the law.