Responsible Person: requirements

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	Date:	Signature:
Author:	19.06.2020	Rosmarie Neeser
Technical verification:	03.07.2020	Federico Cimini
Formal verification (Release VS-QMI):	15.07.2020	Michelle Scheidegger

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1. Purpose and scope

The requirements for a Responsible Person (RP) are described in article 5, article 6, article 17, article 18, article 22, article 23, article 25, article 26 and article 39 of the Medicinal Products Licensing Ordinance. This Technical Interpretation describes the interpretation of these articles by the Swiss inspectorates. It can also be used by companies as a basis for assessing whether an individual fulfils the requirements for applying to Swissmedic to act as a Responsible Person.

2. Basics

- Therapeutic Products Act (SR 812.21)
- Medicinal Products Licensing Ordinance (SR 812.212.1), article 5, article 6, article 17, article 18, article 22, article 23, article 25, article 26 and article 39

3. Definitions and abbreviations

RP	English: Responsible Person (*German*: fachtechnisch verantwortliche Person; *French*: Responsable technique; *Italian*: Responsabile tecnico)
	The RP is a natural person and cannot be a juridical person
MPLO	Medicinal Products Licensing Ordinance (SR 812.212.1)

4. Responsibilities of a RP

The holder or applicant of an establishment licence is responsible to have a suitable RP available. The responsibilities of a RP are described in article 4, article 5, article 7, article 13, article 15, article 16, article 17, article 22, article 23, article 25, article 26 of the MPLO. The RP must be able to execute his/her responsibility, understand the Swiss GMP/GDP requirements and meet regulatory compliance. The direct supervision of the company by the RP in order to ensure compliance with the legal requirements must be guaranteed at any time.

5. Qualification to be a RP

According to the MPLO, the criteria for assessing whether a person can be designated as a RP are his education, knowledge, experience, trustworthiness and independence (art. 5, art. 6, art. 17, art. 18, art. 22, art. 23, art. 25, art. 26 and art. 39 MPLO). Further criteria concern the language and the direct supervision (including domicile and part-time RPs).

5.1 Education and knowledge

Knowledge can be acquired by education and training. The education has to be completed successfully, a diploma or degree must be available.
For the education, especially higher studies (university or equivalent / higher technical institute) in the area of natural sciences (or if applicable medicine or engineering) are valued. With regard to manufacturing and/or market release of dosage forms emphasis is placed on pharmaceutical or biological-natural sciences knowledge. With regard to the manufacturing of active substances emphasis is placed on analytical/chemical knowledge.

5.2 Experience

Depending on the type of activities performed by the company and education/knowledge of the RP, the required experience ranges from a minimum of 1 year up to 4 years.

The experience expected includes primarily the following points:

- technical know-how of the processes a RP will be responsible for;
- for manufacturing, import, wholesale, Mäkler- and / or agent activities including market release of pharmaceutical products: knowledge and experience of GMP as well as GDP;
- for the import, wholesale, export and trade in foreign countries: knowledge and experience of GDP;
- for manufacturing, import and wholesale of blood and blood products including market release of labile blood products: knowledge and experience of blood collection for transfusion, haematology or blood transfusion.

This experience can be acquired:

- by activities where the individual is in charge of, or partially responsible for, the manufacturing of medicinal products or transplant products (GMP), or the wholesale of medicinal products (GDP);
- by involvement in quality assurance work within a company that manufactures medicinal products or transplant products;
- or possibly by means of experience with regulatory issues, such as the drafting of the quality modules of the CTDs / eCTDs within the framework of authorisation procedures.

5.3 Trustworthiness

Swissmedic considers RPs to be untrustworthy if they have infringed the Therapeutic Products Act, the Federal Act on Narcotics and Psychotropic Substances or any subsidiary ordinance, or if they have committed other relevant infringements to other related legislation (e.g. drug counterfeiting, illegal trading, drug-trafficking). The infringements must have been the subject of a legal judgement or confirmed in form of a legal valid decision or directive.

5.4 Independence

In order to guarantee that decisions regarding quality are taken independently, the RP should not be a member of production or be subordinate to the head of production. Whether an exception can be granted for a given company (i.e. for a very small company) is examined on a case-by-case basis.

Furthermore, article 5 paragraph 6, article 17 paragraph 6, article 23 paragraph 6 and article 26 paragraph 6 of the MPLO state that the RP must be competent to decide whether or not to release a batch, independently of the company's executive board. Therefore, a CEO of a company or someone having a similar function (i.e. a member of the very restricted executive board) cannot normally be appointed RP. A dual role as RP and chairman of the board of directors or principal shareholder is normally not acceptable. However, a dual role as a member of the upper management and a RP is basically acceptable. Under certain circumstances it is easier to enforce quality-relevant decisions towards the management when the RP is also part of the upper management. Whether an exception can be granted for a given company (i.e. for a very small company) is examined on a case-by-case basis.

The company must be able to provide written rules stating the responsibilities of the RP within the company (including those of deputies) and the RP's authority to issue directives and to take decisions.

5.5 Language

The RP should at least understand the Swiss national language spoken in the company. If this is not the case, the RP must be able to show that she/he is nevertheless capable of fulfilling her/his responsibilities and that she/he has sufficient knowledge of the relevant Swiss laws and ordinances.

5.6 Direct supervision

The RP is responsible for the direct supervision of the company and is expected to be regularly present at the facilities where the activities take place in order to overview the organisation and all activities to ensure compliance with the legal requirements at any time.

In this context, a purposeful operative organization means that the RP carries out his/her direct supervision on the site(s) where the authorised activities according to the establishment licence are being performed by the company's personnel (including the RP) and that the RP has sufficient decision power to take any action which is necessary to ensure compliance with legal requirements. The direct supervision of a company is considered to be to some extent independent of the number of batches or products which are manufactured and/or distributed. It is therefore assumed that a regular, minimal presence is necessary even if very few medicinal product related activities take place. It is also expected that the RP will be present during an inspection and demonstrates, at this point, that he has sufficient knowledge with regard to the company's processes to assume overall responsibility. Recurrent compliance issues may be regarded as the result of insufficient RP supervision.

5.6.1 Domicile

A direct supervision implies that the RP must live within reasonable distance of the site. As a guidance value the RP should live within two hours travelling time from the site. In case of emergencies the RP must be able to reach the site at any time. The RP may reside in a neighbouring country (in a region close to the Swiss border).

5.6.2 Part-time RP

In accordance with the MPLO, article 5 paragraph 7, article 17 paragraph 7, article 23 paragraph 7 and article 26 paragraph 7, it is in principle possible, that the function of the RP can be carried out on a part-time basis or as a specific mandate, as long as the size and type of the facilities permit so.

5.6.2.1 Presence on site

The direct supervision by a part-time RP is understood as the supervision of at least all the critical steps/operations with regard to the company's processes. It is expected that the part-time RP will establish and maintain a current list of critical steps/operations for which his/her presence on site is mandatory (art. 5 para. 1 and 7, art. 6 para. 3, art. 17 para. 1 and 7, art. 18 para. 3, art. 23 para. 1, 7 and 8 and art. 26 para. 1, 7 and 8 MPLO). Based on this list, the part-time RP will set his/her minimum hours of presence (see also below). This list will also help the establishment licence holder/applicant to fulfil the requirement of having a purposeful operative organization (art. 3 let. d, art. 11 let. e, art. 21 let. c, art. 24 let. c MPLO).

5.6.2.2 Hours of presence

In any case, the minimum number of working hours of the RP which are dedicated to his or her function as RP must be specified in an employment contract and/or job description. The minimum hours of presence on site of a part-time RP should normally not be below 10% of a full time position and should allow direct supervision of the company as defined above. If in spite of this, fewer hours are considered to be sufficient by the company, this must be justified in writing.

It is expected that proof of the specified minimum hours of presence can be provided (e.g. by means of a presence list).

5.6.2.3 Number of mandates

When employing a person as RP on a part-time or mandate basis, it should be considered whether he or she is working for multiple companies. If a part-time RP has other liabilities of any kind (as RP or not) it is expected that the total number of working hours do not exceed 100% of a full time position and that the RP does not hold more than 5 mandates. This information should be available and included in a regular review of the mandate of the RP.

6. Deputies

The MPLO, article 5 paragraph 4, article 17 paragraph 4, article 23 paragraph 3 and article 26 paragraph 3, states that a deputy RP must have sufficient qualifications to execute this role. The criteria for assessing the said qualifications are basically the same as those applying to a RP. An individual whose application to become a RP has been rejected because of trustworthiness is considered not suitable to act as a deputy RP. In order to take into account the reality within smaller firms, the level of formal education of a deputy can be somewhat reduced compared with the requirements established for the RP her- or himself. In the case of less comprehensive qualifications, however, the rights and duties of the deputy must be restricted accordingly. The scope of the deputy's activities should in all cases be stated in writing in a job or function description. The RP is responsible that his/her deputy possesses the necessary qualifications for his/her role. The ultimate and overall responsibility for the safety, efficacy and quality of the medicine and for ensuring adherence to the legal obligations and standards lies always with the RP. In case of job sharing (the tasks are shared in terms of content but not of time), one person must be stated as RP in the establishment licence and the other (internally) as his/her deputy. In this case, the responsibility lies with the RP.

7. Possibilities regarding delegation

A RP has a clearly defined area of work within which he or she is granted unrestricted responsibility and authority to issue directives and take decisions. The direct supervision of the facilities and the responsibility for the relevant tasks cannot be delegated to others by the RP. The delegation of certain, partial tasks from the RP to one or several other persons is nevertheless possible as long as GMP and GDP regulations are respected (e.g. contract manufacturing, contract testing, certain tasks of a RP within a large company, bringing in external experts). It is therefore possible that a company designates more than one person, internally, for the certification of a batch. The ultimate and overall responsibility for the safety, efficacy and quality of the medicine and for ensuring adherence to the legal obligations and standards lies, however, always with the RP. The compliant execution of delegated tasks must be ensured via an established QM system (SOP, job description, training, etc.), and regular controls must be carried out by the RP (e.g. audit system).

Critical processes cannot be delegated. For example, approving the PQR or initiating, carrying out and evaluating recalls must be supervised by the RP personally.

8. Absence of the responsible person

The absence of a responsible person should not be longer than 4 months, provided the deputy responsible person is on duty. The absence of the responsible person can be accepted in justified situations such as job vacancies or absence due to illness.

9. Changes to the previous version

- Chapter 5.2: Supplemented with Mäkler- and / or agent activities
- Chapter 5.6.2: The sentence “Justified exceptions are possible in individual cases” has been deleted

10. Annexes

- None