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Module I

Pharmacovigilance Systems and Their Quality Systems

Version 1.0

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List of Abbreviations

GVP:	Good Pharmacovigilance Practices
ICSR:	Individual Case Safety Report
LSR:	Local Safety Responsible
MAH:	Marketing Authorization Holder
PSMF:	Pharmacovigilance System Master File
PSUR:	Periodic Safety Update Report
QMS:	Quality Management System
QPPV:	Qualified Person responsible for Pharmacovigilance
SDEA:	Safety Data Exchange Agreement

I.A. Introduction

This Module contains guidance for the establishment and maintenance of quality-assured pharmacovigilance systems for Marketing Authorization Holders (MAHs) while undertaking specific pharmacovigilance processes described in each of the respective modules of GVP.

The pharmacovigilance system is defined as a system used by the MAH to fulfil tasks and responsibilities and designed to monitor the safety of authorized medicinal products and detect any change to their risk-benefit balance.

MAHs should establish and implement an adequate and effective quality management system for the performance of their pharmacovigilance activities. Please refer to Module II, Section 1.II.2 for the definitions of terms.

I.B. Structure and processes

I.B.1. Pharmacovigilance system

A pharmacovigilance system, like any system, is characterized by its structures, processes, and outcomes. For each specific pharmacovigilance process, a dedicated Module is included in the present GVP.

I.B.2. Scope of the quality system

The quality system should be adequate and effective for performing pharmacovigilance activities. It consists of its own structures and processes. It covers organizational structure, responsibilities, procedures, processes, and resources, and includes appropriate resource management, compliance management, and record management. It is based on quality planning, quality adherence, quality control, quality assurance, and quality improvements, which means establishing structures and consistent processes; carrying out tasks and responsibilities, monitoring and evaluating structures and processes, and correcting and improving these structures and processes where necessary.

All elements and requirements adopted for the quality system should be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality plans, quality manuals, and

quality records. The Quality Management System (QMS) should be described in the Pharmacovigilance System Master File (PSMF) (see Module II).

I.B.3. Overall quality objectives for pharmacovigilance

The overall quality objectives of a pharmacovigilance system included in the GVP modules are:

- Complying with the legal requirements for pharmacovigilance tasks and responsibilities;
- Preventing harm from adverse reactions arising from the use of authorized medicinal products;
- Promoting the safe and effective use of medicinal products, through providing timely information about the safety of medicinal products to patients, healthcare professionals, and the public;
- Contributing to the protection of patients and public health.

I.B.4. Principles for good pharmacovigilance practices

The following principles should guide the design of all structures and processes in an organization, as well as the conduct of all tasks and responsibilities:

- Upper management leadership and the involvement and support of personnel in the pharmacovigilance system are crucial for continuous quality improvement;
- Every individual within the organization should actively participate in and endorse the pharmacovigilance system based on their task ownership and responsibilities, commensurate with the nature of their assigned tasks and responsibilities;
- Resourcing and organization of tasks to support the conduct of the pharmacovigilance system and the use of available evidence on the risk-benefit balance of medicinal products to support decision making;
- Good cooperation between all parties, such as MAHs, the national competent authority, public health organizations, patients, healthcare professionals, and other relevant bodies.

I.B.5. Responsibilities for the quality system by the marketing authorization holder

For the purpose of a systematic approach towards quality in accordance with the quality cycle, responsibility lies with the managerial staff to ensure the following:

- Document control for the quality system, including creation, revision, approval, and implementation of related documents;
- Provision of adequate resources and training to support pharmacovigilance operations;
- Availability of suitable premises, facilities, and equipment necessary for pharmacovigilance activities;
- Regular risk-based reviews of the pharmacovigilance system, including the quality system, and implementation of corrective and preventive measures as needed;
- Establishment of effective communication and escalation processes for safety concerns, along with investigations into non-adherence to quality and pharmacovigilance requirements, and ensuring the performance of audits;
- Compliance with regulatory requirements and maintenance of adequate record management, ensuring that all relevant pharmacovigilance data and documentation are appropriately recorded, stored, and accessible for audits and inspections.

As for the upper management, they should provide leadership by fostering a motivating environment based on shared values, trust, and freedom for staff to speak and act responsibly, while recognizing their contributions within the organization. They should also assign roles, responsibilities, and authority to staff members based on their competencies and effectively communicate and implement these assignments throughout the organization.

I.B.6. Training of personnel for pharmacovigilance

The MAH should have a sufficient number of competent and appropriately qualified, and trained personnel working in the performance of pharmacovigilance activities.

MAHs should have a training management system in place for maintaining and developing the competences of their personnel, covering:

- All personnel involved in the performance of pharmacovigilance activities should receive initial and continuous training for their role and responsibilities.
- Adequate training should also be considered for those staff members to whom no specific pharmacovigilance tasks and responsibilities have been assigned, but whose activities may have an impact on the pharmacovigilance system or the conduct of pharmacovigilance. Such activities include, but are not limited to, those related to clinical trials, technical product complaints, medical information, sales and marketing, regulatory affairs, legal affairs, and audits.

The organization should keep training plans and records for documenting, maintaining, and developing the competencies of personnel. Training plans should be based on a training needs assessment and should be subject to monitoring.

There should be a process in place within the MAH to check that training results in the appropriate levels of understanding and conduct of pharmacovigilance activities for the assigned tasks and responsibilities.

Information on training plans and records for pharmacovigilance activities and a reference to their location should be kept in the PSMF.

I.B.7. Facilities and equipment for pharmacovigilance

The quality of pharmacovigilance processes and outcomes is dependent on having appropriate facilities and equipment, including office space, IT systems, and storage space, all aligned with the defined quality objectives for pharmacovigilance.

Critical facilities and equipment used in pharmacovigilance must undergo appropriate checks, qualification, and validation to ensure they are suitable for their intended purpose.

Processes should be established to maintain awareness of valid terminologies and update IT systems accordingly to support efficient and effective pharmacovigilance operations.

I.B.8. Compliance management by marketing authorization holders

For the purpose of compliance management, MAHs should have specific quality system procedures and processes in place in order to ensure the following:

- Continuous monitoring of pharmacovigilance data and consideration of options for risk minimization and prevention;
- Scientific evaluation of all information on the risks of medicinal products;
- Timely submission of accurate and verifiable data on adverse reactions to the national competent authority;
- Effective communication with the national competent authority; and the quality, integrity, and completeness of the submitted information;
- Up-to-date product information with current scientific knowledge;
- Communication of relevant safety information to HCPs and patients;
- Where a MAH has delegated certain tasks of its pharmacovigilance activities to a service provider, it should retain responsibility for ensuring that an effective quality system is applied in relation to those tasks.

I.B.9. Record management and data retention

The organization should record all pharmacovigilance information and ensure that it is handled and stored so as to allow accurate reporting, interpretation, and verification of that information.

A record management system should be put in place for all documents used for pharmacovigilance activities to:

- Ensure the retrievability and the traceability of how safety concerns have been investigated, the timelines for these investigations, and how and when decisions have been taken;
- Allow accurate reporting, interpretation, and verification of the pharmacovigilance information;
- Enable the traceability and follow-up of adverse reaction reports while complying with data protection legislation.

There should be appropriate structures and processes in place to ensure that pharmacovigilance data and records are protected from destruction during the applicable record retention period. Documentation arrangements are documented in the PSMF.

The retention of the PSMF and PSSF as long as the system described in these two documents exists, and for at least another 5 years after it has been formally terminated by the MAH.

The retention of pharmacovigilance data and documents relating to individual authorized medicinal products as long as the marketing authorization exists, and for at least 10 years after the marketing authorization has ceased to exist.

I.B.10. Documentation of the quality system

The quality system should be documented by:

- Documents on organizational structures and assignments of tasks to personnel;
- Training plans and records;
- Instructions for the compliance management processes;
- Performance indicators are used to continuously monitor the good performance of pharmacovigilance activities;
- Reports of quality audits and follow-up audits, including their dates and results.

In addition to the quality system documentation, MAHs should document:

- Job descriptions defining the duties of the managerial and supervisory staff, including the Qualified Person responsible for Pharmacovigilance (QPPV) or Local Safety Responsible (LSR);
- Organizational chart defining hierarchical relationships;
- Initial and continued training in relation to the role and responsibilities;
- Training plans and records for documenting, maintaining, and developing competencies and for audit or inspection;
- Appropriate instructions on processes for dealing with urgent situations, including business continuity.

I.B.11. Critical pharmacovigilance processes

The following pharmacovigilance processes should be considered critical:

- Continuous safety monitoring and benefit-risk evaluation of authorized medicinal products;
- Establishment and implementation of risk management systems with ongoing effectiveness evaluation;

- Collection, processing, management, quality control, follow-up for missing information, coding, classification, duplicate detection, evaluation, and timely transmission of individual case safety reports (ICSRs) from various sources;
- Signal management to identify and evaluate potential safety signals related to medicinal products;
- Scheduling, timely preparation, and submission of Periodic Safety Update Reports (PSURs);
- Meeting commitments and responding to requests from the national competent authority, including providing complete and accurate information;
- Interaction between the pharmacovigilance and product quality defect systems;
- Communication about safety concerns between MAH and the national competent authority, in particular notifying changes to the risk-benefit balance of medicinal products;
- Communicating information to patients and healthcare professionals about changes to the risk-benefit balance of products;
- Ensuring up-to-date product information aligned with scientific knowledge and regulatory recommendations;
- Implementation of variations to marketing authorizations for safety reasons;
- Business continuity plans considering potential impacts on staff, infrastructure, and pharmacovigilance processes, back-up systems for urgent information exchange (internal and external).

I.B.12. Monitoring performance and effectiveness

Processes to monitor the performance and effectiveness of a pharmacovigilance system and its quality system should include:

- Reviews of the systems by those responsible for management;
- Audits;
- Compliance monitoring;
- Inspections;
- Evaluating the effectiveness of actions taken with medicinal products for the purpose of minimizing risks and supporting their safe and effective use in patients.

Performance indicators may be used to continuously monitor the good performance of pharmacovigilance activities and their documentation in an annex to the PSMF.

Regular risk-based audits should be conducted by individuals not directly involved in or responsible for the audited matters. Corrective and preventive actions should be taken based on audit findings, and follow-up on deficient matters should be conducted as necessary. Additionally, follow-up audits may also be performed when required. The audit report and any follow-up audit results should be communicated to the relevant applicable management, including those responsible for the audited matters.

I.C. Operations of pharmacovigilance systems in Lebanon

Each MAH should have an appropriate and suitable pharmacovigilance system in place in order to assume responsibility and liability for its products on the market and to ensure that appropriate action may be taken when necessary. Figure 1 at the end of this section summarizes the different entities involved in pharmacovigilance operations with a clear distinction between national MAHs, multinational MAHs, and other companies (referred to as International Companies in the Arab GVP). Please refer to Module II, Section 1.II.2 for the definitions of terms.

I.C.1. National MAHs in Lebanon

I.C.1.1. Responsibilities of national MAHs in relation to the national QPPV in Lebanon

- The MAH must appoint a permanently and continuously present QPPV;
- The QPPV's duties and responsibilities should be clearly defined in a job description, and their hierarchical relationship within the organization, alongside other managerial and supervisory staff, should be outlined in an organizational chart;
- The QPPV's information should be included in the PSMF;
- The MAH must ensure that the QPPV has sufficient authority to influence the performance of the quality system and pharmacovigilance activities, allowing them to implement changes to the system and provide input into risk management plans and regulatory actions;
- Mechanisms should be in place to ensure the QPPV receives all relevant information, including emerging safety concerns, clinical trial updates, information from contractual arrangements, and procedures relevant to pharmacovigilance across the organization;

- The MAH should provide compliance information and outcomes of quality system reviews to the QPPV on a periodic basis, assuring adherence to risk management plans and post-authorization safety systems;
- The QPPV should be informed of scheduled pharmacovigilance audits and be able to trigger an audit if appropriate, receiving copies of corrective and preventive action plans to ensure appropriate actions are taken.
- Each pharmacovigilance system can have only one QPPV. A QPPV may be employed by more than one MAH (i.e., only in case of subcontracting to a service provider), for a shared or for separate pharmacovigilance systems, or may fulfil the role of QPPV for more than one pharmacovigilance system of the same MAH, provided that the QPPV is able to fulfil all obligations. The ability of a QPPV to adequately oversee more than one pharmacovigilance system depends on several factors, including but not restricted to the number of medicinal products covered by that system, the safety profile of these products, and the complexity of the MAH organizational structure. Depending on these factors, it is NOT expected that a QPPV can adequately fulfil all the obligations for more than 1-5 MAHs in maximum.
- The MAH must ensure that there is an appropriate back-up procedure, including QPPV Deputy nomination, in the absence of the national QPPV.

I.C.1.2. Qualifications and conditions for the national QPPV in Lebanon

The National MAH should ensure that the national QPPV has:

- Minimum of a bachelor's degree in pharmacy or medicine.
- Adequate theoretical and practical knowledge for performing pharmacovigilance activities.
- Skills in managing pharmacovigilance systems;
- Expertise or access to expertise in relevant areas such as medicine, epidemiology, and biostatistics;
- Basic medical training unless assisted by a medically trained person and duly documented;
- Knowledge of Lebanese pharmacovigilance requirements;
- Experience in pharmacovigilance;
- Training in the specific pharmacovigilance system, appropriately documented, prior to taking up the QPPV position;
- Additional training, as needed, in the medicinal products covered by the pharmacovigilance system;

- Should be a full-time employee dedicated to pharmacovigilance duties.

I.C.1.3. Nationality and residence requirements for national QPPV in Lebanon

The national QPPV for local pharmaceutical companies must be of Lebanese nationality and residing in Lebanon.

I.C.1.4. Nomination of the national QPPV

The national MAH should nominate and submit an official nomination letter to the national competent authority in Lebanon for the national QPPV, including:

- The name of the QPPV;
- Qualification (and evidence of PV training completion or any other certification documentation);
- CV;
- Contact details (postal address, email address, telephone numbers);
- Description of the QPPV responsibilities;
- Details of back-up arrangements to apply in the absence of the QPPV, including name and details of the deputy QPPV.

Any changes regarding the QPPV/ Deputy QPPV, their contact details should be submitted to the national competent authority in Lebanon promptly, and under any circumstances, no later than 14 days after such a change takes place. For the new QPPV/ Deputy QPPV, the same set of the above information should be included in the nomination.

I.C.1.5. Role and responsibilities of the national QPPV in Lebanon

The main roles of the QPPV are:

- With the pharmacovigilance system, the QPPV's responsibilities include:
  - Establishing and maintaining the MAH's pharmacovigilance system, ensuring compliance with legal requirements, and having authority over pharmacovigilance activities and influencing the performance of the quality system;
  - In a position of authority to ensure and to verify that the information contained in the PSMF is an accurate and up-to-date reflection of the pharmacovigilance system;
  - Acting as the single pharmacovigilance contact point for the national competent authority, being available on a 24-hour basis, and overseeing all aspects of the pharmacovigilance system's functioning, including database operations and compliance;

- In relation to the medicinal products covered by the pharmacovigilance system, specific additional responsibilities of the QPPV should include:

  - Having an overview of medicinal product safety profiles and any emerging safety concerns; providing input into the preparation of regulatory action in response to emerging safety concerns (e.g., variations, urgent safety restrictions, and communication to patients and healthcare professionals);
  - Having awareness of any conditions or obligations adopted as part of the marketing authorizations and other commitments relating to safety or the safe use of the products;
  - Having awareness of risk minimization measures;
  - Being aware of and having sufficient authority over the content of risk management plans;
  - Being involved in the review and sign-off of protocols of post-authorization safety studies; having awareness of post-authorization safety studies requested by the national competent authority, including the results of such studies;
  - Ensuring the conduct of pharmacovigilance and submission of all pharmacovigilance-related documents in accordance with the legal requirements and GVP;
  - Ensuring the necessary quality, including the correctness and completeness, of pharmacovigilance data submitted to the national competent authority in Lebanon;
  - Ensuring a full and prompt response to any request from the competent authority in Lebanon for the provision of additional information necessary for the benefit-risk evaluation of a medicinal product;
  - Providing any other information relevant to the benefit-risk evaluation to the national competent authority in Lebanon.

I.C.2. Multinational MAHs/International and Other Companies in Lebanon

I.C.2.1. Representation of multinational MAHs/international and other companies in Lebanon

For multinational MAHs/ international and other companies, there are two possible scenarios:

a) Multinational MAHs/international and other companies with operating scientific offices in Lebanon are represented at the national competent authority in Lebanon through this office with regard to pharmacovigilance duties.

b) Multinational MAHs/ international and other companies **without** an operating scientific office in Lebanon are represented at the national competent authority in Lebanon through their **local agent** with regard to pharmacovigilance duties. Furthermore, it is expected that the pharmacovigilance system run on the local level appropriately integrates with the pharmacovigilance system of the MAH, and a **Safety Data Exchange Agreement (SDEA)** should be in place between both parties.

In both of the above scenarios, the MAH should have the following:

- LSR in Lebanon at the MAH scientific office or the local agent (as applicable); and
- Global QPPV who provides oversight to the MAH's global PV system and resides at the headquarters or where the main pharmacovigilance processes take place (Figure 1).

To note that the term LSR is sometimes confused with "local QPPV" at the MAH level.
For this LSR/Deputy LSR, all the qualifications, conditions, and nominations stated above for the National QPPV/Deputy QPPV (see sections I.C.1.2 & I.C.1.4) apply to the LSR/Deputy LSR on the local level. Guidance on the role and responsibilities of the LSR is provided in the sections below.

I.C.2.2. Qualifications and conditions for the Local Safety Representative (LSR)

The LSR is required to possess qualifications consistent with those outlined in Section I.C.1.2.

I.C.2.3. Nationality and residence requirements for the Local Safety Representative (LSR)

The LSR should be Lebanese and should reside in Lebanon.

I.C.2.4. Nomination of the Local Safety Representative (LSR)

The LSR is required to submit an official nomination letter to the national competent authority in Lebanon as described in section I.C.1.4.

I.C.2.5. Role and responsibilities of the Local Safety Representative (LSR)

The role and responsibilities of the LSR are to ensure appropriate operations of local pharmacovigilance processes, including the following, **but are not limited to**:

- Establishing and maintaining the local pharmacovigilance process;

- Facilitating the receipt of processed Individual Case Safety Reports (ICSRs) to the national competent authority;
- Local regulatory submissions relevant to pharmacovigilance;
- Monitoring the literature for reports on suspected ADRs;
- Implementing additional risk minimization measures and safety communications locally;
- Supporting the identification of local emerging safety issues;
- Monitoring local pharmacovigilance compliance;
- Fulfilling all local pharmacovigilance requirements as laid down by the national competent authority in Lebanon;
- Acting as the liaison for the MAH and the national competent authority in Lebanon, facilitating communication at a local level;
- Acting as the single pharmacovigilance contact point for the national competent authority, being available on a 24-hour basis, and overseeing all aspects of the pharmacovigilance system's functioning, including database operations and compliance;

I.C.3. Quality system requirements for pharmacovigilance tasks subcontracted by the MAH

There may be situations where the MAH may subcontract certain activities of the PV system to service providers, i.e., to another organization. The MAH should nevertheless retain full responsibility in ensuring the quality, efficacy, and integrity of the PV system and in ensuring that an effective quality system is applied in relation to those subcontracted tasks.

This guidance document also applies to the other organization to which the tasks have been subcontracted. The subcontracted organization may be subject to inspection at the discretion of the national competent authority in Lebanon.

I.C.3.1. Contractual agreements

When tasks are subcontracted to another organization, the MAH should draw up detailed and up-to-date subcontracts, e.g., Safety Data Exchange Agreements (SDEAs), which:

- Should clearly document the contractual arrangements between the MAH and the other organization, describing arrangements for delegation and the responsibilities of each party with the aim of enabling compliance with the legal requirements;
- The MAH should include sufficiently detailed descriptions of the delegated tasks, the related interactions and data exchange, together with, for example, agreed definitions, tools, assignments, and timelines, and regulatory reporting responsibilities;
- Should specify the processes for exchange of safety information, including timelines and regulatory reporting responsibilities. Processes should be in place to avoid duplicate reporting to the national competent authority;
- Should specify a confirmation and/or reconciliation process to ensure that all notifications are received concerning the exchange of safety information;
- Should also contain clear information on the practical management of pharmacovigilance as well as related processes, including those for the maintenance of the pharmacovigilance database;
- Should indicate which processes are in place for checking whether the agreed arrangements are being adhered to on an ongoing basis. In this respect, regular **risk-based audits** of the other organization by the MAH or the introduction of other methods of control and assessment are recommended.

I.C.3.2. Subcontracting pharmacovigilance for MAH represented by an agent in Lebanon

Based on the requirements that in case of subcontracting, the MAH should retain full responsibility in ensuring the quality, efficacy, and integrity of the PV system as well as the compliance of the subcontracted organization; thus for multinational MAHs or international and other companies represented by a local agent in Lebanon if subcontracting local pharmacovigilance tasks is decided; the whole subcontracting process should be done through and be under the control of the MAH and not the local agent individually. Furthermore, a **three-party contract** between the MAH, local agent, and the subcontracted organization may be considered (Figure 1).

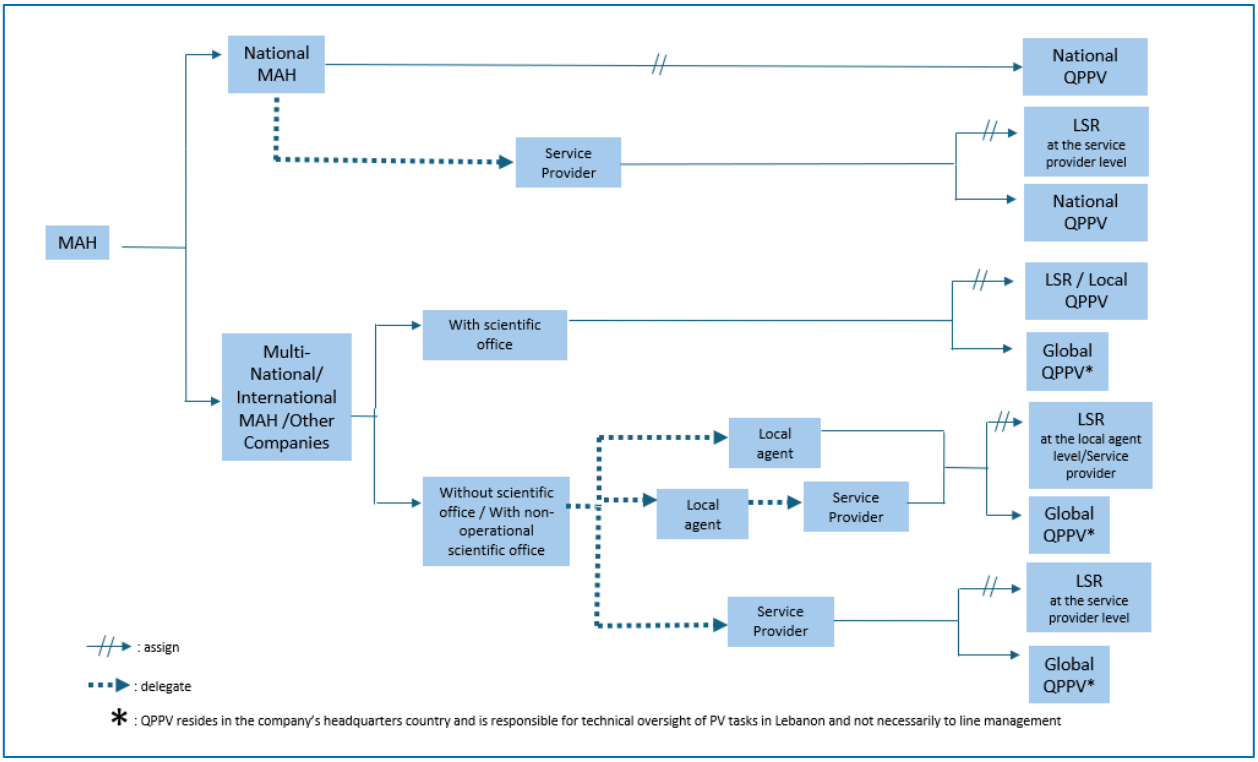

Figure 1. MAH Representation for PV Activities in Lebanon

***Legend**:*

- *A national MAH must assign a QPPV to oversee its PV activities in Lebanon.*
- *The national MAH can subcontract its PV activities or part of them to a service provider. It must assign an LSR at the service provider level to represent it with regard to PV activities. However, the national QPPV has to oversee its activities in Lebanon.*
- *A multinational MAH//international and other companies with a scientific office in Lebanon must assign an LSR residing in Lebanon (also known as "local QPPV") to represent it with regard to PV activities, along with a global QPPV residing in the country of headquarters to oversee the MAH's global PV system.*
- *A multinational MAHs/international and other companies without a scientific office in Lebanon, or with a non-operational scientific office, may be represented by a local agent with regard to all or part of their PV activities. The local agent may also subcontract a service provider with regard to all or part of its PV activities, where a three-party contract between the MAH, the local agent, and the service provider is then considered. In both cases, an LSR (residing in Lebanon) must be assigned at the agent level, or the service provider level, to represent it with regard to PV activities, along with a global QPPV residing in the country of headquarters to oversee the MAH's global PV system.*
- *The multinational MAHs/international and other companies without a scientific office in Lebanon, or with a non-operational scientific office, may also subcontract PV activities directly to a service provider. It must assign an LSR at the subcontracted organization level to represent it with regard*

to PV activities, along with a global QPPV residing in the country of headquarters to oversee the MAH's global PV system.

- *Global QPPV residing in the company's headquarters is responsible for having technical oversight for all PV tasks and responsibilities, and is not necessary to line management.*
- *Avoid confusing an LSR title within an MAH company with roles delegated by the MAH in other countries, such as a PV manager, as the LSR function involves national PV tasks and responsibilities*