

THE POWER OF PARTNERING WITH PLG FOR YOUR LSO/LRPPV REQUIREMENTS

PLG Employee Coverage*

Partner coverage



Robust global coverage

**Rapidly growing in-house coverage*

1

LPPV/LSO Location

Not all countries require the LSO/LPPV to be located in the country. If workload/language can accommodate, we'll help you to consider one person covering more than one country.

2

Expert staff available with well-established transition & change management experience

Decrease recruitment delays and costs and minimize risk with well-established transition planning

3

Regulatory requirements

Our experts are familiar with the local regulatory requirements, reducing your risk and getting the project off to the right start.

4

Role of the Deputy

Deputies with LRPPV/LSO qualifications are assigned for leave coverage. Deputy costs are based on an established retainer fee structure.

5

Full range of Local PV services offered

PLG provides the full range of local PV services from case processing and submissions to assisting with Health Authority inspections. A single contract decreases your time commitment and oversight.

6

Partnership & Customization

We strive to be excellent partners, maximizing quality and regulatory compliance while minimizing cost through efficient processes and automation. Supported by routinely scheduled client meetings, we listen and customize the offering to meet your needs.

Services offered

LRPPV/LSO

- | Main nominated contact person for National Competent Authority (NCA) and Marketing Authorization Holder (MAH) for respective country regarding any PV safety information; 24/7 availability when required
- | Oversight of the local PV system, backup system
- | Periodic and documented communication with the MAH and LSO Coordinator on the safety information and local PV system & local Quality Management System (QMS)
- | Monitors official authority websites and informs the MAH of impacting **safety information** or necessary change to the MAH's **local PV system/QMS**
- | PV audit and inspection support, including PV inspection readiness coaching (before, during and after inspection)
- | Assistance with safety-related communications and product recall
- | Authoring/review and management of:
 - Safety Data Exchange Agreement (SDEA) and local product information(SPC)
 - PV Technical Agreement
 - PV Standard Operating Procedures

