Pharmacovigilance Quality Manual Policy Summary

The Pharmacovigilance Quality Manual (“PVQM”) and the quality systems described within it are applicable to all stakeholders of the Pharmacovigilance System (“PV System”) worldwide. The purpose of the PVQM is to provide an overview of the policies and procedures that are required to maintain the quality management system for any PV System under our responsibility. The PVQM defines the framework of the policies, procedures and systems that are necessary to ensure that the activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem relating to medicinal products are handled in compliance with applicable laws, regulations and our expectations.

The requirements defined within the policies and procedures as incorporated within the PVQM are intended to achieve the commitment to quality and product safety compliance as established in the mission statement. We will ensure that all products and programs consistently meet or exceed regulatory and consumer expectations. We will meet our commitment to quality and product safety through leadership, sponsorship and teamwork; through effective training for employees; through adherence to applicable rules, regulations, policies and procedures; by providing a constant and consistent approach to quality improvement; and by promoting technological leadership and innovation."

It is the responsibility of all levels of management to:

- Participate in the design, implementation, monitoring and maintenance of the quality systems;
- Demonstrate strong and visible support for the quality system and to ensure its implementation;
- Ensure that a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management;
- Define and communicate individual and collective roles, responsibilities and authorities of all organizational units, and to ensure that interactions are defined and understood; and
- Advocate continual improvement.

It is the responsibility of PV System stakeholder functions to:

- Establish and follow written policies and/or procedures describing activities that are an element of the PV System.

It is the responsibility of Global Quality / Global Operations Auditing (GOA) to:

- Consult PV System stakeholder functions on policies and SOPs that relate to activities required for the PV System and to approve such quality documents; and
- Establish Quality Assurance for the PV System.