

Quality Policy Statement

Patient Safety Monitoring in International Laboratories (pSMILE) is a contractual resource at Johns Hopkins University designed to evaluate and develop the capability of laboratories to participate in the National Institute of Health (NIH) - Division of AIDS (DAIDS) - supported prevention, vaccine and therapeutic clinical studies conducted in developing countries; and ensure the integrity and reliability of tests for monitoring safety and efficacy of experimental products investigated in DAIDS - supported studies in developing countries.

A key way to achieve this is by operating a Quality Management System (QMS) in accordance with the requirements of ISO 9001: 2015.

pSMILE management is committed to:

- Satisfying applicable requirements by ensuring that customer and applicable statutory and regulatory requirements are determined, understood and consistently met.
- Continual improvement of the QMS by ensuring the risks and opportunities that can effect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed and the focus on enhancing customer satisfaction is maintained.

pSMILE management shall:

- Take accountability for the effectiveness of the QMS.
- Ensure the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the Company. Quality objectives have been set and are maintained as part of the QMS internal auditing, monitoring and management review processes, in order to enhance customer satisfaction.
- Promote the use of a process approach and risk-based thinking.
- Ensure that the resources needed for the QMS are available; including training, support and encouragement.
- Communicate the importance of effective quality management and of conforming to the QMS requirements.
- Ensure that the QMS achieves its intended results.
- Engage, direct and support persons to contribute to the effectiveness of the QMS.
- Promote improvement.
- Support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
- Establish partnerships with suppliers and interested parties to provide an improved service.

This policy will be communicated to all employees and organizations working for or on our behalf. Employees and other organizations are expected to co-operate and assist in the implementation of this policy, whilst ensuring that their own work, so far as is reasonably practicable, is carried out without risk to themselves, others, or the environment.

This policy will be reviewed biennially by pSMILE management and where deemed necessary will be amended and re-issued. Previous versions of this policy are archived.

This policy is available to relevant interested parties, upon reasonable request.