



pSMILE Quality Policy

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QA 2410 pSMILE Quality Policy

Copy of version 2.2 (approved and current)

Last Approval or Periodic Review Completed 05-Jan-2026
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Printed By Anne Leach BS, MT(ASCP)
Organization Johns Hopkins University - pSMILE

Author
Anne Leach

Comments for version 2.2

changed "co-operate" to "cooperate" and "whilst" to "while"

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	SOP Committee Review	14-Jan-2026	2.2	 Anne Leach BS, MT(ASCP)	
Periodic review	Mark's Biennial Review	05-Jan-2026	2.1	 Mark Swartz MBA, MT(ASCP)	
Periodic review	Mark's Biennial Review	04-Jan-2024	2.1	 Mark Swartz MBA, MT(ASCP)	
Approval Captured outside MediaLab	Lab Director	17-Jun-2022	2.0	Mark Swartz	Recorded on 06-Mar-2023 by Anne Leach BS, MT(ASCP) when document added to Document Control (previous system of record: Zavanta)

Periodic review Captured outside MediaLab	Designated Reviewer	07- Jan-2022	2.0	Peggy Coulter	Recorded on 06- Mar-2023 by Anne Leach BS, MT(ASCP) when document added to Document Control (previous system of record: Zavanta)
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Approvals and periodic reviews that occurred before this document was added to Document Control may not be listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.2	Approved and Current	Minor revision	05-Jan-2026	14-Jan-2026	Indefinite
2.1	Retired	Minor revision	15-Mar-2023	15-Mar-2023	14-Jan-2026
2.0	Retired	First version in Document Control	06-Mar-2023	17-Jun-2022	15-Mar-2023

Linked Documents

- QA 2410a pSMILE Quality Management System

QA 2410 v. 2.2

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General Description

Description:

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. The pSMILE QMS is included as an attachment to this policy.

Purpose:

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.

Scope:

This policy will be communicated to all employees and organizations working for or on our behalf. Employees and other organizations are expected to cooperate and assist in the implementation of this policy, while 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.

Responsibility:

Principal Investigator
Project Manager
Quality Officer/ Deputy Quality Officer

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.

Attachments – See linked documents

QA 2400a_pSMILE Quality Management System

Categories

Regulations:

ISO 9001: 2015 Clause 5.2
 ISO 9001: 2015 Clause 4.3
 ISO 9001: 2015 Clause 4.4
 ISO 9001: 2015 Clause 6.1
 ISO 9001: 2015 Clause 6.3

Revision Management

Revision History Log:

Revision #:	Date:	Nature of Change:	Recorded By:
v2.0	6/15/2022 7:29 AM	Major changes made to pSMILE Quality Management System_v.2.0 attached.	Anne Leach
v1.4	5/4/2022 10:02 AM	Changed review cycle from annually to biennially.	Anne Leach
v1.3	10/23/2020 12:42 PM	Minor changes were made to the attached document, pSMILE Quality Management System v1.3.	Amy Rada
v1.2	6/2/2020 12:05 PM	Updated QMS attached.	Anne Leach
v1.1	5/7/2019 10:41 AM	Content Overlay	Rod Julius

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Revision #:	Date:	Nature of Change:	Recorded By:
		changes applied to document.	
v1.0	10/18/2018 10:22 AM	New document	Mandana Godard

Biennial Review

Review History :

Name:	Date:	Comment:
Peggy Coulter	7 January 2022	No changes

Authorizations and Sign-offs

Sign-off Authorizations:

Name:	Title:	Approved Date :	Revision #:	Comments:
Anne Leach	Project Manager	4/30/2019	1.0	
Mark Swartz	Project Manager	6/17/2022	2.0	

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