PURPOSE

At Clarivate, we achieve practice excellence by providing our clients with trustworthy, data-driven guidance and improving practice efficiencies with powerful workflow solutions and access to experts they can trust to meet their goals and thrive in competitive markets.

Clarivate's Life Sciences & Healthcare (LSH) business segment – including Biopharma Intelligence, Medtech Intelligence, Pharmacovigilance, and Consulting Services offerings – enables our customers to act quickly and confidently, utilizing connected data and systems, to drive desired outcomes in the complex global healthcare system, all while keeping the patient journey at the heart of everything we do.

Our Quality Policy is driven by our Clarivate company values:

Aim for Greatness

We challenge the status quo, pursing continuous performance improvements, and aiming for greatness and customer delight in all we do.

Value Every Voice

We work together in respectful partnership with our colleagues and customers which is our evergreen source of sustainability and success. The best results come from a diverse, collaborative, and inclusive environment.

Own Your Actions

We act with integrity and are accountable to ourselves, our colleagues, our customers, and our communities.

Our Operational Teams are continually striving to achieve ever greater levels of quality. Our Quality Management System (QMS), based on our Company values, is the framework we use to embed quality into our day-to-day business at every level in the LSH business.

This Policy will define the high-level approach to ensuring LSH products and services (collectively, the "offerings") that have been assessed as having GxP intersection and/or other regulatory compliance obligations are managed in a robust and compliant manner, resulting in offerings of the highest quality that further the LSH business segment mission to "provide **data, deep expertise and intelligence platforms** to enable our customers to deliver **safe, effective and commercially successful** treatments/solutions **to patients** faster."

SCOPE

The Scope of this Policy covers all offerings, employees and external services held or utilized by Clarivate's Life Sciences & Healthcare (LSH) business segment that have been assessed as having GxP or other regulatory compliance/industry standard obligations.

Systems, information, colleagues and external services that are provided as a managed service to Clarivate are not directly within the scope of this Policy, however, the right to audit said services

relevant to an individual client project or projects remains within the purview of the LSH Quality team.

POLICY

Life Sciences & Healthcare (LSH) Quality Policy

Overview

Clarivate's LSH business segment has developed and maintains a Quality Management System (QMS) with quality efforts overseen by a governance committee comprised of senior leaders from across the organization, and supported by policies, procedures and processes designed to ensure strategic goals are met for regulatory compliance and quality. The LSH business segment has adopted the following seven quality management principles: Leadership; Colleague Engagement; Customer Focus; Process Approach; Relationship Management; Evidence-Based Decision-Making, and Continuous Improvement. Please see the Quality Manual (eQMS ID: 576889) for additional details on how Quality is managed within the LSH business segment.

Quality Manual

- The Quality Manual dictates the overall Quality standards for Clarivate's LSH business segment based upon the applicable regulations.
- The Quality Manual applies to all regulated operational activities owned and/or managed by the LSH Quality team.
- It is the responsibility of all in-scope colleagues to follow the Quality Manual.

Computer System Validation

- The Agile Computer System Validation for GxP Regulated Applications SOP (eQMS ID: 826312) and/or Waterfall Computer System Validation for GxP Regulated Applications SOP (eQMS ID: 848568) dictate the approach to be taken for the formalized validation, qualification, periodic review and/or revalidation of regulated offerings based upon classification and applicable regulation(s).
- It is the accountability of the LSH Quality team to ensure computer system validation activities are carried out where required. Where validation by Clarivate is determined to not be required, the onus of satisfying any additional validation or qualification activities resides with Clarivate's clients, in accordance with their internal practices and processes.
- It is the responsibility of all in-scope colleagues support validation undertakings, as assigned.

Data Integrity

- Ensuring that the integrity of all data ingested, modified, and/or maintained by Clarivate that is processed on behalf of or otherwise offered to clients is maintained at all points of its lifecycle is of critical importance to Clarivate. As such, elements of data integrity maintenance/protection are built into multiple Quality and corporate practices, which includes such elements as a robust, ISO 27001-certified Information Security program, and dedicated data integrity assessments that are carried out as part of Computer System Validation (CSV) efforts.
- It is the responsibility of all LSH colleagues to understand the importance of data integrity and to identify and report any data integrity issues or concerns, in the event they should be encountered.

Information Security and Risk Management

- Corporate Information Security provides internal policies, standards, and processes for the protection of information holding assets belonging to Clarivate.
- The corporate Risk Management office provides internal policies, standards, and processes for the identification and mitigation/resolution of risks across the organization.
- It is the responsibility of all those within LSH to identify and support information security and risk management activities and direct these, as appropriate, to the corporate information security and/or risk management teams.

COMPLIANCE

- The Quality Unit is responsible for the compliance and monitoring of this Policy and to provide awareness to all in-scope Life Science and Healthcare employees through eQMS training on a routine cadence.

REFERENCES

- Where applicable, in addition to those procedures referenced herein, Clarivate's LSH business segment will work to the following regulatory and industry guidance and standards:
  - EMA/541760/2011 Module I; Guidelines on good pharmacovigilance practices (GVP) – Pharmacovigilance systems and their quality system.
  - 21 CFR Part 11 Electronic Records; Electronic Signatures
  - EU GMP Directive 2003/94/EC
  - EU Volume 4 Good Manufacturing Practice (GMP) Guidelines, Annex 11, Computerized Systems (Jan 2011)
  - ISPE - GAMP5: A Risk-Based Approach to Compliant GxP Computerized Systems
  - ISO9001:2015 Quality Management Systems
  - ISO27001 Information Security Management Systems
  - ICH Q10 Pharmaceutical Quality Systems
  - ICH E6 Guideline for Good Clinical Practice

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