

CASE STUDY:

Content Migration for a Toxicology and Infectious Disease Testing Laboratory



PROJECT OVERVIEW

In order to perform COVID-19 testing, a national toxicology and infectious disease laboratory needed to align its regulatory compliance with its parent company. To meet the objective, the subsidiary had to update its standard operating procedures (SOPs) with content from the parent SOPs that already met CLIA/GMP, GLP, GCP requirements. Neither the parent company nor the subsidiary had the resources in-house to perform the content migration. Due to our extensive experience producing technical documentation in regulated environments, Kalleid was hired to align the SOPs. Kalleid promptly engaged two seasoned technical communicators to complete the project.

BUSINESS CASE

Between the subsidiary laboratory and parent company, there were over 75 SOP documents that needed to be analyzed for consistency and brought into alignment on a tight deadline of just a few weeks. These SOPs contained procedures for clinical testing, quality control, patient safety, and critical information on sample preservation. The subsidiary laboratory had organized these documents into high-risk, medium-risk, and low-risk categories.

The project demanded great attention to detail. In some instances, the subsidiary laboratory was completely missing SOPs. This content gap required Kalleid to migrate content from the parent company SOPs into subsidiary SOPs. In other subsidiary SOPs, there were substantial gaps in laboratory and safety procedures. In this case, Kalleid merged content from the parent company SOP to fill the gaps in the subsidiary laboratory SOPs. Migrating and merging content from parent to subsidiary SOPs demanded close reading by the Kalleid technical communicators to move only content that was relevant.

The customer contracted with Kalleid to meet the following business needs:

- **Perform a gap analysis to determine the differences in content between parent and subsidiary SOPs**
- **Create rules of engagement to ensure successful content merge/migration**
- **Migrate and merge content so that the resulting SOPs complied with the parent company QMS (CLIA/GMP, GLP, GCP)**

SERVICES PROVIDED

Kalleid engaged with the stakeholders of the subsidiary company early in the project to obtain detailed information about the laboratory procedures. Once a sufficient understanding of these procedures was achieved, the Kalleid Team provided the following services to meet the customer's business needs:

- **Gap Analysis** – The Kalleid Team performed an assessment between parent and subsidiary high-risk SOPs to determine the key discrepancies between subsidiary laboratory and parent company SOPs that needed to be addressed. Kalleid initially analyzed the high-risk documents in order to deeply understand the style and content of the SOPs. Deep understanding of the high-risk SOP content facilitated progress and ensured high consistency in the medium and low risk SOPs.
- **Proofreading** – When performing the gap analysis on the SOP documents, Kalleid also reviewed the content for accuracy and consistency. During this process, Kalleid found and corrected a mistake in a chemical formula.
- **Documentation Plan** – The Kalleid Team developed a documentation plan that contained the following:
 - ◆ Summarized the results of the gap analysis and defined the deliverables for the project
 - ◆ Defined the procedures and editorial rules that would be used to guide the document migration/merge process
 - ◆ Specified the team that would be involved in the migration and merge process, along with those responsible for reviewing and finalizing the SOPs
 - ◆ Defined the project timelines
 - ◆ Elucidated the dependencies necessary to complete the project
- **Style Guide** – The Kalleid Team wrote a style guide to ensure consistency of the migrated content in the subsidiary SOPs.
- **Content Migration and Merge** – The Kalleid Team migrated and merged the appropriate content. Content migration created new subsidiary SOPs, whereas content merging added parent content to existing subsidiary SOPs. Throughout the project, Kalleid worked closely with the client to ensure only relevant procedures were migrated and merged for successful implementation by the subsidiary laboratory.
- **Peer Review** – After content migration, Kalleid performed peer review of the SOPs to assure high quality.

RESULTS DELIVERED

Kalleid seamlessly integrated clinical laboratory procedures from two toxicology laboratory companies by successfully developing and executing a process for migrating and merging content to achieve regulatory compliance. This process allowed the subsidiary laboratory to achieve the higher level of CLIA/GMP, GLP, GCP compliance necessary for COVID-19 testing. Through this effort, Kalleid saved the client over 100 hours of in-house resources, and Kalleid completed the project one month ahead of the subsidiary schedule. Kalleid and the clinical testing laboratory are looking forward to working together on new projects.



245 Main Street, Cambridge, MA 02142
+1 617-366-2656 or info@kalleid.com
Twitter: @kalleidinc