CASE STUDY:

Documentation for a New Cell Therapies Manufacturing Facility

PROJECT OVERVIEW

A global biopharmaceutical company with a wide-ranging portfolio was building a new cell therapies manufacturing facility (CTMF) for cancer treatments. The information technology (IT) infrastructure was an essential component of this facility and needed to be compliant with 21 CFR 11 US FDA regulations. While the company's IT department was tasked with creating the digital infrastructure to support the CTMF, they did not have the in-house expertise required to write the necessary regulatory documentation to support full compliance with regulations. Due to our team's extensive experience with producing technical documentation for pharmaceutical companies, the customer contracted with Kalleid to create a process for writing and reviewing the technical documentation for the facility so that it could meet its aggressive timeline for opening.

BUSINESS CASE

The customer had several different IT systems that required documentation, including networking, security, and computer storage, and there were multiple teams working on the IT infrastructure in the US and India. A coordinated process of collaborative editing and review sessions was critical to develop the technical content, but the IT team did not have a staff technical writer assigned to this project, and the project manager who was charged with overseeing the entire project could not closely supervise content development. Unless an effective process for producing the required documentation was implemented quickly, this bottleneck issue would likely delay the opening of the facility.

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

- **Implement a framework for writing and reviewing documents for the systems required for building the facility.**
- **Coordinate the demands of each department while ensuring content is complete and meets regulatory requirements.**
- **Ensure consistency and accuracy among different sets of documentation.**

SERVICES PROVIDED

The Kalleid Team provided the following services to meet the customer's needs:

A documentation plan – Kalleid assessed the project and then proposed a process for developing and releasing the IT infrastructure deliverables that included rolling out document templates, training of the IT staff on using the templates to write the documentation, and hosting interactive review meetings on the documents.

A writing and review process – There were a number of challenges to creating and implementing a writing and review process:

- **Multiple groups located around the world were involved**
- **Writing skills varied widely amongst the engineers doing the writing**
- **The regulatory documents required significant technical detail**

Before any writing was done, Kalleid led the coordination of other consultancies to gather necessary information from the engineers. Next, Kalleid trained the engineers on the templates and worked with them, often one-on-one, to ensure that they wrote technical content that was complete, clear, and accurate.

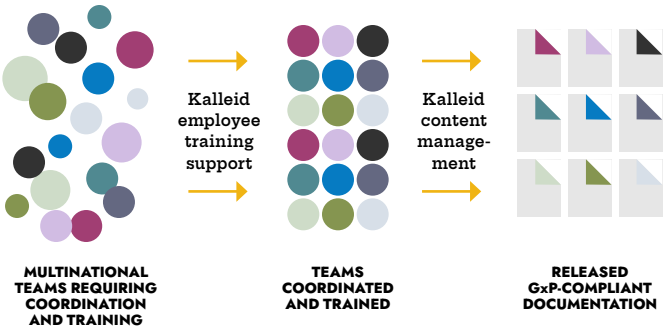
Upon release of one document set for an infrastructure system, Kalleid leveraged this success by having another engineering group use the released documents to complete another set. Over the course of a quarter, sixteen documents supporting infrastructure in the new facility were thoroughly edited through the review sessions. Kalleid kept ongoing action items to systematically solve issues with the documentation.

Content management and document release – After the infrastructure documentation was complete, Kalleid drove content management for document release. Charged with releasing the documents through customer's quality management system (QMS), Kalleid carefully proofread the documentation and then routed the documents through the QMS. Kalleid facilitated the engineers and QA, often on a daily basis, in the process of document approval. Kalleid worked across departments through effective negotiation for the release of compliant regulatory documentation. After the infrastructure documentation was complete, construction of the cell therapies facility to treat cancer patients proceeded on schedule.

RESULTS DELIVERED

Kalleid successfully developed a process for technical content development that utilized the client's authoring and content management tools and leveraged the expertise of QA and business analysts to meet regulatory requirements. Through this process, Kalleid effectively eliminated the customer's documentation bottleneck.

Several sets of documents enabling regulated use of computer infrastructure at the customer's new cell therapy manufacturing facility were successfully finalized and released, allowing the new facility to meet its aggressive go-live timeline. In addition, Kalleid created documentation on the process utilized to help streamline any necessary revision of regulatory documentation moving forward.



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