



Kalleid Newsletter - September 2021

Welcome to Kalleid's newsletter for the month of September, where you'll find some of our most recent content and information about our upcoming events.

Featured Blog Posts



Computer Software Assurance: The FDA's New Approach to CSV

The FDA intends to release a new guidance document later this year (2021) entitled **Computer Software Assurance for Manufacturing and Quality System Software**. This guidance will shift the focus of computer system validation (CSV) processes towards critical thinking, risk management, patient and product safety, data integrity, and quality assurance.

[Read more](#)



How to Apply Organizational Change Management in Agile Implementations

Agile software development methodology has become the framework of choice for many businesses where continuous change is the norm. Traditional change management, built for a Waterfall environment with heavy process and lengthy timelines, doesn't work well in an Agile project where collaboration and adaptation happen daily.

[Read more](#)

[Sign up for our blog](#)

Strategies for Creating Effective Technical Documentation

Writing and releasing effective technical documentation requires a best practice methodology to ensure the maximum benefits for your organization. Like any other project deliverable or product, technical documentation needs to be planned, created, delivered, and managed in a way that intersects the needs of users with the needs of the business.

[Read more](#)

Past Events

Informatics Alliance Webinar - Strategies for Creating AI-Ready Chemical Data



Many data scientists spend the majority of their time on preparing data instead of creating knowledge and building new AI/ML tools and models from the data. Watch our recent webinar where experts from the Informatics Alliance moderate a panel discussion on strategies that can be applied to make chemical data, such as chemical compound and chemical reaction data, more ready for use by AI.

[Watch here](#)

Upcoming Events

Kalleid Sponsors 2021 Association of Laboratory Managers (ALMA) Digital Leadership Program

Kalleid is proud to be a sponsor of the 2021 ALMA Digital Leadership Program starting in September of this year. The Association of Laboratory Managers is a non-profit organization led by a volunteer

board of active laboratory managers who are committed to helping managers of laboratory-based organizations grow their skills and become better leaders.

[Learn more](#)



ALMA

Enabling Lab
Managers to Become
Better Leaders

Featured White Paper

WHITE PAPER



Five Steps to Successfully Convert your Classroom Training to eLearning

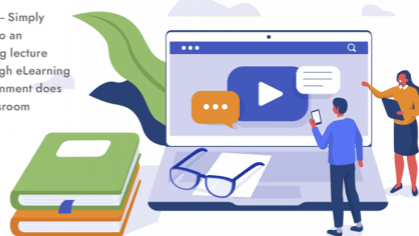
Nearly 70 million strong, Millennials are now the largest generation in the American workforce. This generation is tech savvy and, having grown up with 24/7 internet access, sees the world as being connected through technology. Millennials often prefer to interact with others via e-mails and text messaging as opposed to face-to-face communication. As such, corporate training for the Millennial generation may best be accomplished through internet-based delivery systems.

Over the last several decades, corporate training has made significant shifts toward online learning (eLearning). This trend is showing no signs of abating. A recent Global Market Insights forecast predicts that the eLearning market size will grow at a CAGR of 8% between 2020 and 2026.¹ According to a recent UF Canvas study, the eLearning market is expected to reach \$325 billion by 2025.²

This shift is being driven by the fact that the majority of today's workforce prefers eLearning and the significant benefits it can provide over traditional classroom instruction. With a rapidly changing business environment and an increasingly global and virtual workforce, companies need training options that are cost-effective, scalable, and can be rapidly deployed to address employee knowledge gaps.

As a first step towards implementing eLearning, many companies convert their in-person training content (i.e., PowerPoint presentations, videos, audios, documents, etc.) into an eLearning format. Simply moving this content directly into a Learning Management System (LMS) using an eLearning content authoring tool is a mistake. There are several reasons for this:

- **Incomplete information** – Most traditional classroom training material only contains a small fraction of the information that is conveyed to the students. This is because a substantial part of classroom teaching comes from the instructor's anecdotes, examples, and personal experiences, none of which will be captured in the course materials. Just a few bullet points in an instructor guide can lead to a 15-minute conversation in the classroom. An eLearning class needs to document all the important information communicated to students.
- **Outdated information** – Traditional classroom training materials may contain incorrect or outdated information which requires correction before being transferred to an eLearning format.
- **Information needs to be transformed** – Simply transferring classroom training materials to an eLearning format can result in an engaging lecture being converted into a boring, click-through eLearning course. What works in a classroom environment does not always work in an online setting. Classroom training content needs to be transformed into a structure and format that will produce a successful eLearning course. This requires a careful analysis of course objectives and requirements, along with application of instructional design principles.



Five Steps to Successfully Convert Your Classroom Training to eLearning

Over the last several decades, corporate training has made significant shifts toward online learning (eLearning). In this white paper, we discuss some of the factors that are driving the rapid growth of the eLearning industry, along with a best practice methodology for converting your classroom training to eLearning.

[Read more](#)

Featured Case Study

CASE STUDY:



Clinical Supply Chain Application Implementation for a Global Biopharmaceutical Company

PROJECT OVERVIEW

A global biopharmaceutical company was using two legacy applications and unreliable Excel-based tracking tools to manage an extremely complex clinical supply chain supporting hundreds of global clinical trials conducted annually. In order to more effectively control costs, the company decided to implement a new clinical supply chain application to support better planning and management of production, supply and demand for all clinical products.

Given the differences in the maturity of the two legacy clinical supply chain management systems, together with significant business process variations across different sites and the widespread use of paper-based tracking, the harmonization effort for this project was broad and demanded ongoing collaboration across Quality, Clinical Supply Chain, Pharmaceutical Sciences, and IT teams. Because of our expertise in facilitating organizational change management (OCM) and a track record of success with similar projects in other biopharmaceutical companies, the customer chose Kalleid to run Communications, Training, and business standard operating procedure (SOP) workstreams for this project for sites located in both the United States and Japan.

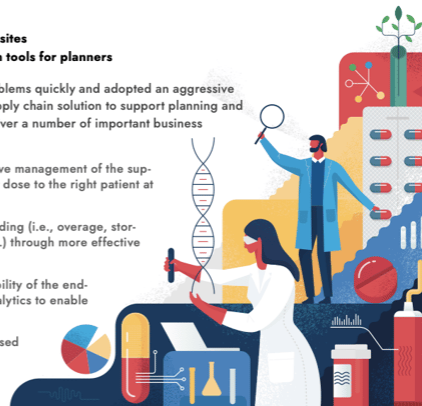
BUSINESS CASE

The customer was experiencing several issues with their clinical product supply chain that served to increase timelines and costs:

- Supply stock outs
- Excessive inventory costs
- Inconsistent business process across sites
- Lack of effective data-driven decision tools for planners

The customer hoped to eliminate these problems quickly and adopted an aggressive timeline for implementation of a clinical supply chain solution to support planning and oversight. This project was expected to deliver a number of important business improvements for the organization:

- **Improved Patient Experience:** Proactive management of the supply chain to effectively deliver the right dose to the right patient at the right time
- **Cost Savings:** Reduced inventory spending (i.e., overage, storage, number of batches purchased, etc.) through more effective trial lifecycle planning
- **Improved Governance:** Improved visibility of the end-to-end supply chain and supporting analytics to enable increased data-based decision making
- **Alignment with R&D Priorities:** Increased operational effectiveness and agility to enable effective management of a diverse pipeline of 200-250 clinical trials within an outsourced model



Clinical Supply Chain Application Implementation for a Global Biopharmaceutical Company

A global biopharmaceutical company was using two legacy applications and unreliable Excel-based tracking tools to manage an extremely complex clinical supply chain supporting hundreds of global clinical trials conducted annually. In order to more effectively control costs, the company decided to implement a new clinical supply chain application to support better planning and management of production, supply and demand for all clinical products.

[Read more](#)

Who We Are

Kalleid, Inc. is a boutique laboratory IT consulting firm that has served the scientific community since 2014. We work across the value chain in R&D, clinical and quality areas to deliver support services for software implementations in highly complex, multi-site organizations. If you would like to learn more about Kalleid and the services we offer, please visit Kalleid.com or [contact us](#) today.



Find out more about our professional services and how our integrated approach to business transformation can maximize your company's success.



[Learn more](#)