



Fall 2024 Newsletter

The latest news from the Kalleid team.

What's New?

Register for Kalleid's Upcoming Webinar 'GxP Compliance in Project Management: Navigating the Regulatory Landscape', Dec 3

In industries like pharmaceuticals, biotechnology, and medical devices, adhering to GxP regulations is critical for ensuring product quality, safety, and efficacy. This roundtable webinar will delve into the intricacies of GxP compliance within the context of project management. Expert panelists will share insights and best practices for successfully managing projects while meeting stringent regulatory requirements.

Register now for our December 3rd webinar. We look forward to sharing our insights and engaging in thought-provoking discussion.

Register Now!

ICYMI: Kalleid's Webinar- From Resistance to Resilience: The Human Centered Approach to Change

On September 24, Kalleid was pleased to present a webinar titled, '**From Resistance to Resilience: The Human-Centered Approach to Change**'. The webinar, hosted by 20/15 Visioneers, challenged the status quo by advocating for a shift away from rigid, automation-driven change management methods. Instead, Kalleid proposed a more dynamic approach that emphasizes robust assessments, aligns with organizational culture, and remains adaptable to real-time feedback.

Founder and President of Kalleid, Mary Beth Walsh, along with Dana Karen Ciccone, Kalleid's Strategy and Operations Advisor, led the compelling presentation. The webinar laid-out case studies from Kalleid's portfolio of work, highlighting common initiative implementation pitfalls. Kalleid provided key lessons learned and best practices to ensure humans remain the focus of change initiatives.

If you missed the webinar and would like to give it a listen, check out the webinar recording.

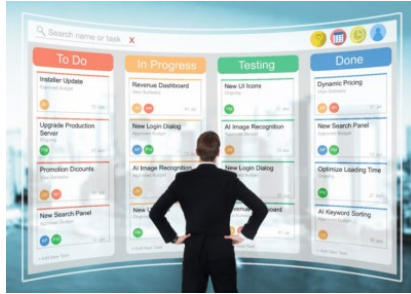
Webinar Recording

Kalleid Partners with Sapio Sciences

Exciting news! Kalleid is proud to announce we have joined the [Sapio Sciences Partner Program \(SSPP\)](#)! Our team will be helping Sapio Sciences' customers get the most out of their lab informatics platform solutions with custom implementation, testing, training, and change management support. Stay tuned for more info on our service packages coming this fall!

Read more

Featured Blogs



Utilizing Hybrid Project Management Approaches in Drug Development

In the face of the unique challenges inherent to drug development, it may benefit the project managers in the pharmaceutical and biotech sectors, to adopt a hybrid project management approach—one that blends the structured, linear nature of Waterfall with the adaptability and iterative processes of Agile.

[Read more](#)



AI in Biotech: A Game Changer for Project Management

AI tools are helping project managers move their project faster and more efficiently. These new tools allow for the automation of repetitive tasks, analysis of vast amounts of data, and making more informed decisions in less time and with greater efficiency. AI's ability to optimize project management operations is especially appealing in pharmaceutical and biotech space.

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Featured Case Study



CASE STUDY:

Setting Up for Success

How Kalleid Helped an AI-Driven Drug Discovery Startup Meet IT Policy and Internal Control Compliance



PROJECT OVERVIEW

In an era when artificial intelligence (AI) could revolutionize the healthcare industry, a dynamic startup, harnessing AI to identify clinical candidates with therapeutic needs, found itself on the fast track to growth. With rapid expansion the startup needed to align its IT policy with widely adopted NIST SP500-53 requirements and internal control standards, as defined by the Committee of Sponsoring Organizations (COSO) framework. Recognizing these challenges, the startup turned to Kalleid, known for its expertise in supporting life sciences and pharmaceutical companies through similar compliance landscapes.

BUSINESS CASE

The startup's existing documentation and internal processes required either new or revised policies and procedures to meet IT policy requirements and COSO internal control standards. Without the necessary documentation development, the startup risked coming up short on its annual audits. Meanwhile, the startup's leadership understood that their small team lacked the resources to

Kalleid was engaged to fill this critical gap, because it could leverage its experience in meeting compliance requirements for the startup.

develop the required documentation. Kalleid was engaged to fill this critical gap, because it could leverage its experience in meeting compliance requirements for the startup.

SERVICES PROVIDED

Kalleid first thoroughly reviewed the startup's existing documentation. Assessing the startup's documentation against the compliance requirements, the initial assessment revealed gaps in the startup's IT policy framework and inconsistencies within the internal control documentation. Kalleid implemented a plan toward creating a tailored IT policy and strengthening internal control at the startup. The first step of the plan was to create templates to hold content in a predictable way. The templates also guided users to provide content consistently, while strengthening the startup brand. The second step of the plan was to work with the startup to write two suites of documents that would be the IT policy. One set was new policies Kalleid wrote that contained the requirements to meet NIST IT policy. The policy set described what to do to meet Level 1 IT compliance. During the third step of the plan, Kalleid and the startup met over several writing sessions to hammer out a

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[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](https://kalleid.com) or [contact us](#) today.



Kalleid

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

[Learn more](#)

