Kalleid Newsletter - June 2021

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

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.

Recent Blog Posts

Communication Strategies to Combat Change Fatigue

With the COVID-19 pandemic, the digital revolution, and shifting macroeconomic conditions, conducting business in a highly volatile environment is near-unavoidable. Change fatigue in employees is inevitable, and addressing it properly is crucial. Can your company tackle employee burnout?

Read more

User Acceptance Testing: Tools of the Trade

Any software project will fail to provide the desired business value if the delivered software does not meet user expectations. This article explores the importance of good and effective user acceptance testing (UAT) to ensure a successful system rollout.

Read more

Digitization Does Not Equal Digital Transformation

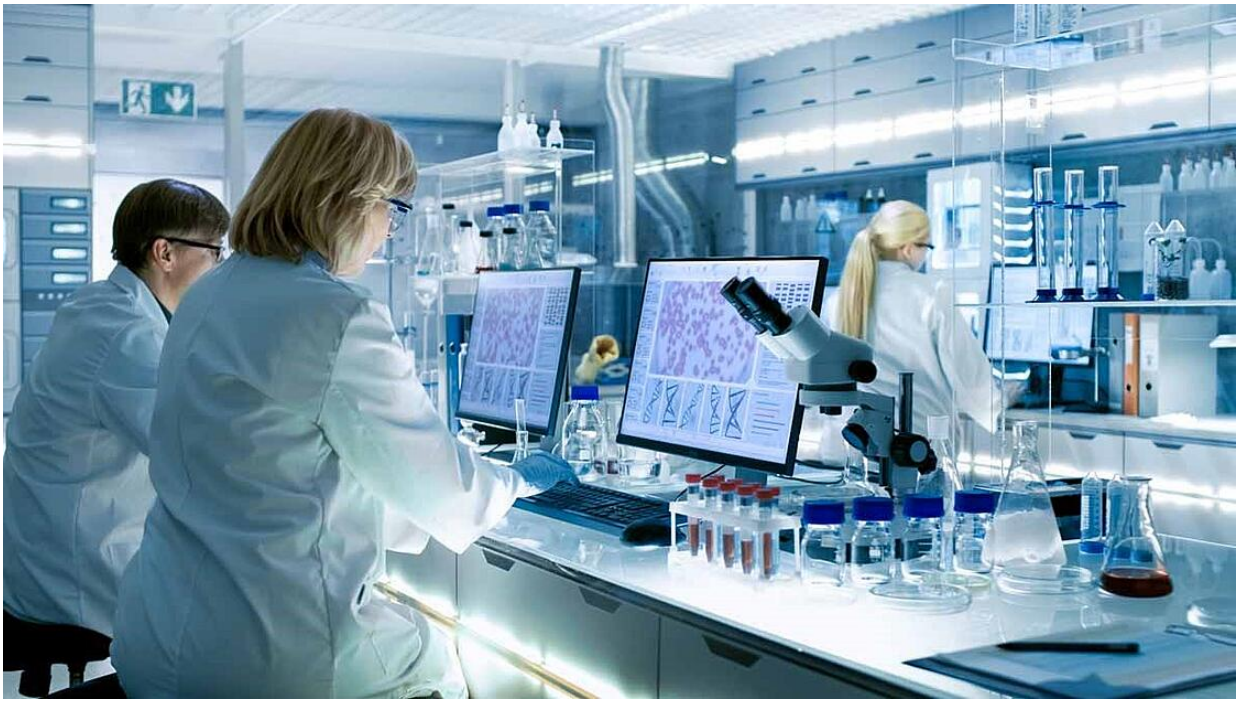
Given the rapid change driving today's digital economy, your current business model is likely under threat. Learn more about leveraging digitization, digitalization, and digital transformation in this 3-step digital maturity model to remain competitive in your market environment.

Read more

Sign up for our blog

Upcoming Events

Webinar: Strategies for Creating AI-Ready Chemical Data



Date: Tuesday, June 29th, 2021
Time: 10 AM EDT, 4:00 PM CEST

In recent years, artificial intelligence (AI) and machine learning (ML) have become important tools to help solve challenges in almost every domain, including science. Unfortunately, many data scientists nowadays spend the majority of their time on preparing data instead of creating knowledge and building new AI/ML tools and models from the data.

In this webinar, Informatics Alliance chemical data experts Gerd Blanke (StructurePendium GmbH) and Thomas Doerner (Independent Consultant) discuss the following topics with Esben Jannik Bjerrum (AstraZeneca), Andreas Bender (ICB/Nuvisan and Cambridge University) and Ted Slater (Elsevier):

- Why do we want chem data to be AI ready
- What are the criteria for AI ready chemical data

- How to capture chem data in an AI ready way
- How to improve AI-friendliness of existing chem data
- Recommendations for improving the quality of chemical data

Learn more

Featured White Paper

WHITE PAPER

Cybersecurity for the Life Sciences R&D Ecosystem

The rate of data generation is increasing exponentially in today's technology driven world. This is especially true for R&D activities in the life sciences, where technologies like next generation sequencing (NGS) are creating terabytes of genomics data in a single run. Researchers in pharmaceutical and biotech companies typically work with massive repositories of research, clinical trial, and patient data to help identify and optimize potential new drug candidates, generating proprietary intellectual property (IP) in the process.

Large amounts of sensitive data and valuable IP make biotech and pharmaceutical companies prime targets for cybercriminals. While you can change your credit card number, you cannot change your DNA. Personal health and/or genomics data is thus very valuable and sought after by hackers, with electronic health records sometimes going for over $1000 on the dark web.[1] But it is not just external threats from hackers or malware that life science companies face, there can also be serious internal threats from disgruntled, noncompliant and/or malicious employees.

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The first high-profile cyberattack against a pharmaceutical company came in 2017, with the NotPetya ransomware attack, which was perpetrated by state-sponsored hackers. While the NotPetya malware affected companies around the world, it hit the global drug maker Merck particularly hard, crippling more than 30,000 laptop and desktop computers, along with 7,500 servers. NotPetya malware locked up critical Merck files via encryption, with the hackers promising to release the files for $300 in bitcoin per affected computer. Unfortunately, the malicious malware damaged files beyond repair in the process of encrypting them. All told, the NotPetya ransomware attack cost Merck an estimated $870 million in revenue in 2017 alone.[2]

Since 2017, cyberattacks on pharmaceutical and biotech companies have been on the rise. A report by the cybersecurity firm BlueVoyant reveals that publicly declared cyberattacks on the biotech and pharmaceutical industry jumped by 200% in 2018, and another 50% in 2019.[3] This past year (2020) has seen aggressive and focused hacking attempts by nation-state actors on pharmaceutical companies pursuing COVID-19 vaccines and treatments. The COVID-inspired remote work trend has provided a promising attack vector for hackers seeking to exploit vulnerabilities in remote connections. As noted in the BlueVoyant report, of the 25 cyberattacks on the pharmaceutical and biotech companies reported to the media since 2017, 40% took place in 2020.

Cybersecurity for the Life Sciences R&D Ecosystem

Despite cybersecurity investment by major biopharmaceutical companies being on the rise, CIOs and CISOs are experiencing

multiple pain points in operationalizing their cyber risk management across a vast research network that often includes collaborators in emerging markets. The life science industry has a need for an effective cybersecurity approach that serves to facilitate secure, productive and cost-effective collaboration in drug discovery research.

Read more

Featured Case Study

CASE STUDY:

Kalleid

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)**

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Content Migration for a Toxicology and Infectious Disease Testing Laboratory

Project Overview:

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