LIFE SCIENCES

DIGITAL INNOVATION FOR LIFE SCIENCES:

ACCELERATING OPERATIONAL READINESS AND EXCELLENCE

Facing increasing regulatory oversight and the need to meet timelines and budgets without sacrificing quality, life sciences companies turn to CAI and its unique approach of mixing deep industry expertise and technological solutions to deliver results.

UNDERSTANDING THE CHALLENGES, ALIGNMENT WITH CUSTOMER

The demands of operational readiness and excellence

Life sciences companies operate in an incredibly high stakes environment - perfection is required. Strict and increasing regulatory oversight requires work to be done to precise standards, along with the demands of meeting firm timelines and budgets, making operational readiness and operational excellence paramount.

A lot hangs in the balance. Hurdles like validating complex manufacturing lines and supporting systems, and constructing or expanding production facilities, must be cleared to pave the way for potentially life-saving work like clinical trials or large-scale drug production.

Increasing regulatory challenges

Looming over everything are stringent regulatory requirements and compliance. Audit and compliance risk adds a degree of difficulty to all stages of operational readiness and excellence. Any errors or deviations from established procedures can be costly and potentially delay facility openings or drug approvals. This starts in the commissioning, qualification and validation process for new facilities and requires constant vigilance to maintain operational standards.

Complex validation processes and documentation to meet regulatory requirements, as well as the need to reduce errors or deviations and quickly resolve those that do occur, add to the challenge.

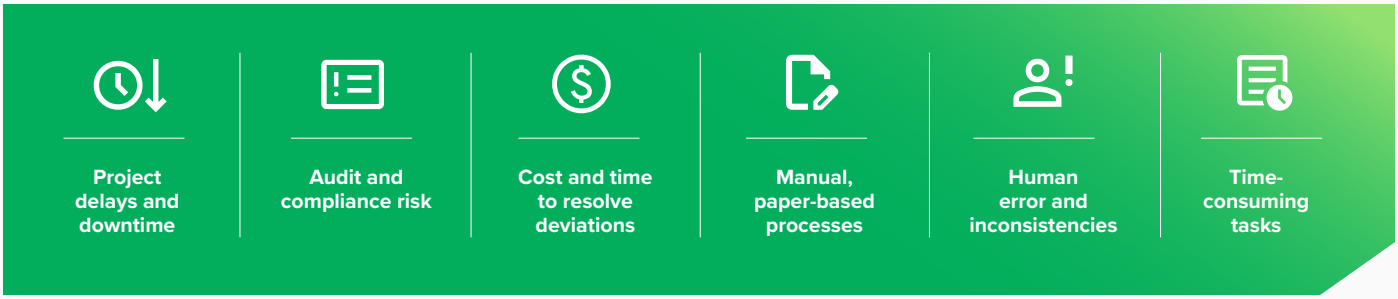
Meeting timelines and budgets, too

Achieving regulatory compliance is a challenge on its own, but it is multiplied by the need to accelerate time-to-market. Particularly as technology leads to more medical breakthroughs, the pace of building the manufacturing infrastructure needs to keep up. Timeline delays can impact clinical trial start dates and project funding. Facilities must be fully operational and compliant before drug production can begin.

The final factor is financial; any errors, delays or problems with compliance are likely to increase project costs, decrease revenue or require write-offs.

The challenge then becomes: How do you optimize operational readiness and excellence in life sciences to meet all compliance requirements without sacrificing quality, time or cost?

CHALLENGES



THE CAI APPROACH: THE OVERALL SOLUTION AND KEY COMPONENTS

At CAI, we believe that quality, cost and schedule can be mutually reinforcing, and trade-offs are not necessary. Technology becomes the great equalizer.

We bring deep industry expertise and top-tier talent along with technology-driven solutions that accelerate operational readiness and operational excellence. Our tech-enabled solutions are what allow us to help clients maintain compliance, quality standards and efficiency while also managing cost, schedule and scope.

Digital innovation services at CAI utilize advanced tools like large language models, knowledge graphs and digital twins to add automation and efficiency, reducing errors, streamlining validation, shortening timelines and ensuring compliance. We have a full suite of tools at our disposal that improve quality, timing and cost, including:

- **Digital twin technology** creates a virtual replica of a physical space, overlaid with real-time data, for uses such as time-saving virtual inspections and improved asset management. An example is SiteSync, a mobile solution that replaces clipboards and manual reports from site walks with a more precise, real-time digital solution.
- **Artificial Intelligence** common use cases include automation of validation and summarization documents, trending and root cause analysis and comparison of systems to regulatory requirements. With its deep expertise, industry leadership in digital innovation and partnerships with technical experts, CAI can help identify where AI can add business value and support organizational priorities–and then deliver the solution.
- **Knowledge graphs** empower organizations to harness their data's full potential, creating a data structure that improves searchability, analytics and decision-making.
- **Digital validation tool** services, or DVT, sometimes referred to as Electronic Validation Lifecycle Management Systems (eVLM), do not just digitize the validation process, they redesign it around standardization, traceability and data-driven decision-making. This results in a reduction in cycle times, fewer errors and enhanced audit readiness.

With certified experts across Kneat, ValGenesis and Valkit, and digital validation software like Project Ready, CAI can deliver the right solution for the organization's validation needs.

Importantly, these tools address the specific challenges that life sciences companies are facing.

AI and other tools help automate tasks and speed up analysis and problem-solving, which in turn accelerate project timelines. Reduction of write-offs, fewer errors and more efficient processes improve the bottom line. Improved accuracy and data integrity, as well as better and faster documentation, address the compliance challenges.

USE CASES

- Automation of time-consuming tasks
- AI-enabled documentation
- Virtual facility inspections
- Digital simulations
- High-quality insights
- Digital validation processes
- Automated protocol generation

EXPECTED OUTCOMES AND NEXT STEPS

For CAI, digital innovation is a differentiator in the way we support or improve Operational Readiness and Operational Excellence for life sciences companies.

The use of digital tools and AI speeds up the process of getting plants ready for operation. Automation can shorten the time required for everything from documentation and validation to data analysis and investigations.

- 90 percent reduction in summary report writing time with Technical Summarization AI Application
- 30 percent shorter overall validation project timeline with DVT
- 40 percent automation of CQV process
- 30 percent improvement in data retrieval efficiency with knowledge graphs

Customers also see a significant reduction in human-error-related deviations, along with faster, more effective root-cause analysis using knowledge graphs to prevent future errors and improve overall compliance. The tools improve documentation and audit traceability.

- 50 percent fewer documentation errors with DVT
- 40 percent improvement in compliance readiness

Lastly, companies realize direct and indirect cost savings from implementing these solutions. There are savings through reduced downtime, fewer safety incidents, fewer write-offs and avoidance of regulatory fines. More efficient processes significantly reduce hours required on projects, saving on FTE equivalents. Even the ability to do virtual inspections with digital twins reduces travel expenses.

- 25 percent decrease in validation-related costs with DVT
- $35 million savings in product write-offs in one knowledge graph case study
- 3,000 hours a year in savings in maintenance planning in one digital twin use case

In life sciences, there is no margin for error when it comes to operational readiness and operational excellence. With our combination of industry expertise and tech-enabled solutions, CAI provides solutions that directly address the challenges life sciences companies face, improving speed, cost and quality, and delivering accelerated excellence and readiness at the highest standard.

> $35 million savings in product write-offs in one knowledge graph case study

OUTCOMES

- Faster root cause analysis
- Reduction of human error
- Improved data accuracy
- Better traceability and compliance monitoring
- Fewer product write-offs
- Significant time savings with automation
- Improved compliance readiness

Accelerating innovation and compliance

The CAI suite of cutting edge technologies provides solutions that directly address the operational readiness and excellence challenges life sciences companies face, leading to improvements in speed, cost and quality.

CHALLENGES

- Project delays and downtime
- Audit and compliance risk
- Cost and time to resolve deviations
- Manual, paper-based processes
- Human error and inconsistencies
- Time-consuming tasks

USE CASES

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CAI is here to be your trusted partner, accelerating operational readiness and excellence through technology-driven solutions tailored to your business needs.

Let's get started. Contact us today for a comprehensive assessment of your technological maturity and a customized roadmap for digital innovation.

Call us at **(317) 271-6082** or contact us **online**.

Are you ready?