



**NATIONAL RESILIENCE, INC.**  
**LA JOLLA, CALIFORNIA**

**CASE STUDY**

# Digital System Implementation

## Kneat Gx and Boomi



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### Why CAI?

CAI was selected for this process based on our reputation of strong guidance for our clients in manufacturing operational readiness. Our subject matter experts in digital transformation and computer system implementation, validation, and quality assurance brought years of experience with the systems being launched as well as the project management and communication skills necessary for timely project execution.

### Project Overview

Resilience embarked on a digital-first approach to develop and implement global systems for use across their GxP sites. CAI was engaged to develop the digital roadmap and drive the implementation of numerous systems, including their chosen digital validation platform (Kneat Gx) and an integration platform (Boomi). This required key personnel with a deep understanding of digital system implementation, project management, GxP compliance, and CSV / CSA processes to successfully deliver compliant digital solutions within the project timeline and budget.

### Client Challenges

- Numerous concurrent system development and implementation programs with competing resource needs and timelines
- Digitalization of both newly designed and in-development global validation programs
- Anticipating and navigating rapidly shifting internal requirements as the organization matured
- Minimizing project disruption due to frequent changes in client stakeholders and team members
- Developing new communication and project management tools to ensure effective and efficient communication of technical and logistic requirements to all stakeholders
- Identifying and meeting divergent needs for greenfield vs acquired / legacy sites, and GxP vs non-GxP systems and data
- Enabling and facilitating global harmonization while simultaneously transitioning legacy / acquired sites to the digital validation tool



#### CLIENT:

National Resilience, Inc.

#### LOCATION:

Remote support for a global team, headquartered in La Jolla, California

#### PROJECT DURATION:

2.5 years (Aug 2021 – Dec 2023)

#### CAI KEY CONTACTS:

Amy Kuntzman

Josh Hoops

Pat Hayes

#### CLIENT REFERENCE:

Tamara Redondo (Kneat)

Miles Minvielle (Boomi)

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### CAI Solutions

- Developed and piloted effective project management tools in coordination with the client PMO
- Championed compliance to regulatory and client requirements throughout, including mentoring team members with limited GxP experience
- Developed visual management tools to clearly show sequencing and status of technical and QMS activities
- Advocated for and obtained external technical resources to supplement the client team where needed to ensure project success
- Development of standard project plans and adoption tools to be used for ongoing and future site adoption activities

### Project Success

Kneat Gx was successfully qualified, two validation programs digitalized, and the global platform was officially launched within 6 months of the formal project kickoff. Based on the success of this project, the CAI team successfully digitalized additional validation programs, led the global harmonization efforts for two validation programs, and the adoption of the Kneat Gx validation platform at multiple sites.

The Boomi project was added to the scope of work late in the overall project. CAI led the project team through the chartering, initiation, and planning phases of the project as well as requirements development, system architecture and development, and initial validation activities. At the time CAI's involvement in the project ended, the client was staged for successful completion of the validation effort and project closure.



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