

From Disconnected Records to Audit-Ready Quality

How sterilizable packaging provider, Technipaq, Inc., strengthened control with QT9 QMS.



THE CHALLENGE

Eliminating disconnected records for greater control and audit readiness

Technipaq provides flexible, sterilized packaging that healthcare, medical device, diagnostic and pharmaceutical companies rely on to protect their products. Maintaining ISO 13485 certification, Technipaq's work requires extensive documentation and quality control throughout their operations. Yet, when Quality Director Tara Arient came on board, its quality operation ran on paper and shared drives. Individual records could take 20 to 30 minutes to locate, approvals were harder to track, and quality staff often had to involve subject-matter experts simply to retrieve information. Shared files also created revision-control risk. In fact, an internal audit found a department using an altered form rather than the current approved version, reinforcing the need for tighter control.

THE SOLUTION

One connected system, ready to go

The ability to use QT9 QMS largely as delivered was a major reason Technipaq chose QT9 over other solutions. The company wanted a configurable system that could meet its requirements without extensive custom development or the validation and maintenance demands that often come with it. Taking advantage of QT9's user-defined fields gave the team enough room to configure workflows while staying within the system's standard operating conditions.

Today CAPA, engineering changes, nonconformances, deviations, supplier and customer records, documents and training all live in one linked system, where every related quality event sits a click away from the customer or product it touches. By avoiding custom software configuration, validation and maintenance tasks stay light. After QT9's team helped implement the first modules, Technipaq was able to self-implement the rest.

THE RESULTS

Faster, cleaner and audit-ready

Implementing QT9 QMs has given Technipaq greater visibility, speed and control. The team has real-time insight into every process, pulls data faster and enjoys automated approval workflows and electronic sign offs. Technipaq's 25 to 30 customer audits a year, plus its notified body audit, are handled almost entirely by one person and often finish early. Centralized document control minimizes risk, with records easily tracked and instantly retrievable for improved traceability.

"Now I can handle each and every single audit 99.9% of the time completely by myself. ... My audits end early because everything is clean, everything is crisp, everything's in order."

— Tara Arient, Quality Director, Technipaq, Inc.

80%

Decrease in audit prep. time

70%

Decrease in administrative time



Increased visibility across all quality processes