



CASE STUDY

**'TORAY'**

Toray Composite Materials America, Inc.

Maximizing Workflow  
Configurability for  
Effective Deviation  
Management

**AssurX**

## A time-tested, scalable system designed for rapid adaptability.

Toray Composite Materials America Inc. (Toray CMA) is a subsidiary of global leader Toray Industries Inc. The company designs and manufactures an extensive portfolio of advanced materials used in the Aerospace & Defense, General Manufacturing, Automotive, and Sports & Recreation industries. For the last decade, Toray CMA has utilized AssurX's extensive configuration capabilities to replace manual processes with efficient, automated workflows for deviation and quality incident management.



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*David Knight,  
Business System Analyst  
Toray Composite Materials America Inc.*

### Moving from Paper Processes

In 2013, Toray CMA was managing all nonconformances in a paper-based system. In the deprecated system, there was no way to confidently report on prior incident results and dispositions without pulling details from paper files. In addition, there was no ability to analyze comprehensive incident data to enable quality improvements.

As with most other paper-based quality systems, common inefficiencies existed as well, including:

- Extensive in-person meetings
- A protracted approval process
- Time-consuming retrieval of archives
- Inability to effectively escalate and track issues

As a result, Quality Assurance (QA) began to evaluate automated quality systems to improve process efficiencies. The transition would effectively align with the corporate culture of creating value through innovative technologies and products.

### The AssurX Solution

In December 2013, Toray CMA went into production with AssurX as their quality management system (QMS.) The deciding factor among QA and management was the importance of having a QMS that enables extensive configurability. AssurX met the company's stringent process requirements, and provided future flexibility to accommodate changes as driven by the business needs of the organization.

"Toray CMA had very specific processes requirements that required a system that was very configurable and adaptable, and AssurX did that," explained David Knight, Business System Analyst, Toray CMA.

Toray CMA efficiently demonstrates alignment with both AS9100 quality management standards for Aviation, Space, and Defense Quality Management Systems and ISO 9001 Quality Management Standards.



"Whether your organization requires some configuration to out-of-the-box quality solutions, or if you want to build unique configurations from scratch, AssurX offers the flexibility to do both."

*David Knight,  
Business System Analyst  
Toray Composite Materials America Inc.*

### Implementation

AssurX Professional services worked with Toray CMA QA to map out the initial workflows for the deviations and corrective and preventive action (CAPA) processes. After the initial mentoring and AssurX-delivered administration [training courses](#), Toray CMA was able to quickly gain the knowledge needed to expand the quality system. "With a little bit of SQL knowledge and AssurX administrator training, the system is incredibly easy to configure to our specific needs," said Knight.

**AssurX Form Builder** provides virtually unlimited configurability and drag-and-drop capabilities that enables Toray CMA to enact changes with ease and minimal disruption to operations.

### User Onboarding

Resistance to change is often part of a new system implementation. To get ahead of the challenge, Toray CMA developed training videos and desktop manuals for new users. "Once our users are acclimated to the interface and workflow processes, there are few if any useability issues," explained Knight. "At this point it's hard for them to imagine doing their job any other way."

### AssurX Scalability

Today, Toray CMA uses **over 60 active action request forms** within AssurX. AssurX currently automates:

- Complaint intake and classification
- Deviation/non-compliance investigations
- Corrective and preventive actions (CAPA)
- Change requests and approvals
- Audit findings
- *Other custom configurations outside of QA*

Each action request addresses a particular quality issue, from intake through root cause analysis and resolution/prevention. Deviations are identified through multiple channels including testing and inspection, internal and external audits, as well as customer complaints.

Due to a complex manufacturing portfolio, there are different classifications that must follow very specific investigatory paths. Each incident follows an automated path from investigation, root cause identification, corrective action plan, plan approval, implementation and (for some processes) effectiveness audit. The AssurX quality system enables any data captured within the forms accessible for reporting and audit-readiness. Furthermore, Toray CMA utilizes data to make faster, informed decision making based on identified trends.

***AssurX workflows are so configurable that over a dozen different departments in the organization have leveraged it to automate internal processes.***

Toray CMA currently has over **60 action forms** configured across the organization — *without any source code changes*.



"With a little bit of SQL knowledge and AssurX administrator training, the system is **incredibly easy to use and configure** to our specific needs. If we require additional assistance, AssurX Professional Services is always ready to assist."

*David Knight,  
Business System Analyst  
Toray Composite Materials America Inc.*

### Audit Preparedness

Toray CMA maintains ISO 9001 (Quality Management Systems) and AS9100 (Quality Management System for Aerospace) standards, which are both evaluated annually. AssurX helps facilitate the audit process electronically. The Quality Assurance is able to provide links to specific nonconformance records as requested for efficient review.

In turn, audit details become permanent records in the system, making it easy to query and access audit findings and reports to facilitate continuous quality improvement.

### Conclusion

Configurability is often an important consideration in manufacturing industries with a greater state of design and production complexity. Toray CMA used AssurX to build a system for tracking and resolving deviations within specific QA requirements, *without any changes to the source code*.

The transition to AssurX provided clearly defined, consistent, and controlled processes that significantly reduce time to resolution of issues or potential issues. In addition, AssurX enables Toray CMA to access meaningful data to improve quality and maintain a greater state of customer satisfaction.

### AssurX Benefits At-a-Glance

- ▶ Faster time to task completion through automated routing, escalations and notifications
- ▶ Ability to create, store, control, and locate records in a central location
- ▶ Data integrity with electronic audit trail
- ▶ Elimination of paper and centralization of quality records
- ▶ Reduction in labor hours used for manual processes
- ▶ Compliance with 21 CFR Part 11 electronic signatures
- ▶ Alignment with ISO and ANSI certification standards
- ▶ Increased enterprise-wide accountability through an unbreakable chain of tasks
- ▶ Greater management visibility into the state of compliance
- ▶ Greater economy of scale through utilization in other areas of the business

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