

# Integrated Quality and Compliance Management

A Unified Approach for Better Business Performance



# Preface

The growing mix of complex products, a global supply base and stringent customer requirements has created a need for organizations to have real-time visibility into their quality processes and to implement systems that ensure closed loop quality processes and support easy access to and efficient routing of information. Many organizations are deploying industry standard quality management methodologies such as ISO 9000, cGMPs and Six Sigma or implementing other quality practices to reduce costs, shorten cycle times and improve overall product and process quality.

Traditionally, homegrown systems, stand-alone applications or even manual paper-based systems have been used to manage product and process quality at departmental level. Such point-solutions fail to address systemic quality problems as they lack a broad enterprise reach. As a result, many companies are seeking to deploy enterprise class solutions that can unify quality and compliance management across their worldwide operations.

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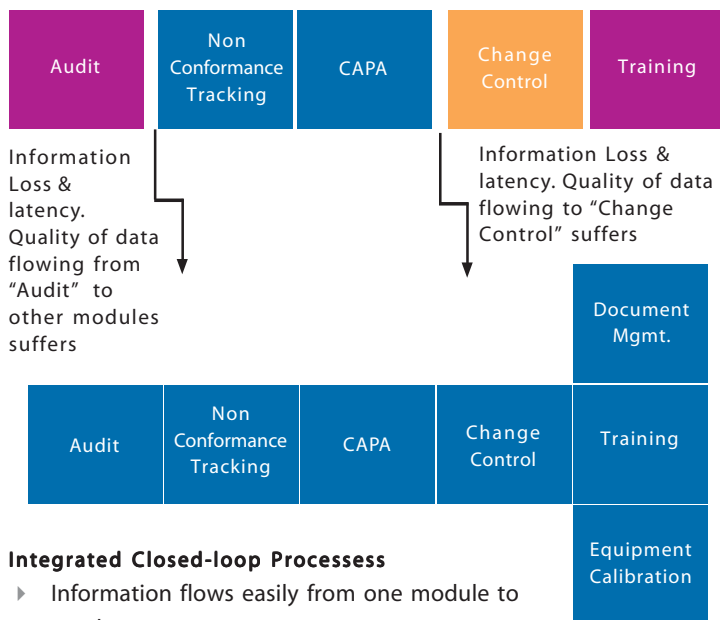
# Introduction

Combination of product proliferation, outsourced manufacturing operations, stringent regulatory environment and rigorous customer requirements has created a need for organizations to proactively manage their quality and compliance processes.

Traditionally, homegrown systems, stand-alone applications or even paper or spreadsheet based systems have been used to manage product and process quality or compliance (such as cGMP). These solutions are typically implemented at the plant or departmental level. Such point-solutions, while designed to track product and process quality data, fail to address systemic quality problems as they lack a broad enterprise reach. Additionally, these systems do not have the mechanisms to manage by exceptions – as a result things slip through the cracks. The risks from not meeting regulatory compliance requirements include fines, severe penalties from regulatory bodies and loss of brand equity in the market place. Risks from non-compliance with quality standards or industry mandates include loss of key customers, higher internal manufacturing costs and delays in customer shipments. As a result, organizations are now implementing systems with a closed loop quality process, define and execute an enterprise-wide approach to quality and compliance management and leverage automatic notifications to ensure that nothing falls through the cracks.

## Stand Alone Processes

- ▶ No closed-loop feedback
- ▶ No integrated process dashboards



## Integrated Closed-loop Processes

- ▶ Information flows easily from one module to another
- ▶ Powerful drill down across analytics

## Capabilities of MetricStream Quality Solution

- ▶ Non-conformance Management
- ▶ Complaints Management
- ▶ Incoming Inspections
- ▶ Variance & OOS Management
- ▶ Audits Management
- ▶ CAR/CAPA Management
- ▶ Documents Management
- ▶ Equipment Mgmt and Calibration
- ▶ Employee Training Management
- ▶ Supplier Quality Management
- ▶ Customer Quality Management
- ▶ Cost Recovery/Charge Back
- ▶ Product Change Notification
- ▶ Safety & Risk Management

## BENEFITS OF INTEGRATED QMS



## Integrated Quality and Compliance Management Solution

There are three major quality management processes in an organization – supplier quality processes, internal quality processes and customer quality processes.

These processes may typically require compliance with a quality framework or guidelines such as ISO 9000 or CMMI or 21CFR Part11/cGxP. Historically these quality processes have been managed in silos. Best practices call for supplier quality, internal quality and customer quality processes to be managed using a single underlying quality management system, since the resolution of customer quality-related complaints may require working closely with one or more internal manufacturing sites and even a certain supplier to address the root cause of the issue.

A single system makes it easy to track and manage the process, ensure the issue has been resolved and response communicated to the customer. A single system makes it easy to aggregate quality-related metrics from downstream sites and report it to customers. Finally, a single underlying system also provides the organization a 360 degree view of quality-related risks.



## MetricStream Solutions

MetricStream offers comprehensive quality and compliance management software solutions for managing quality programs within an organization, for streamlining quality processes involving suppliers and customers, as well as for managing operational regulatory compliance such as FDA cGXP, OSHA, HACCP, JCAHO etc. By improving operational efficiencies in their quality processes, MetricStream enables companies to create a transparent environment for proactively identifying, tracking and resolving quality issues. Moreover, the embedded best practices for supporting key processes and requirements for standards and regulations such as ISO 9000, FDA 21 CFR Part 11, Part 820 Quality System Regulation and ISO 13485:2003 lower the cost of regulatory compliance and risk of noncompliance.

For companies in life sciences space, MetricStream offers a 21CFR Part 11 compliance system that supports key GXP compliance issues for clinical, laboratory, manufacturing procedures including out-of-spec/nonconformance tracking; change control; integrated document management; electronic signatures; complaint and adverse event management; reporting on form 3500A or baseline form 3417 etc. Leading companies in life sciences space are already using MetricStream to manage their FDA compliance.

In addition, MetricStream's ComplianceOnline.com, a leading portal and online community for worldwide professionals, provides the latest information, best practices, training, products and tools on GRC. The combination of a powerful software platform, rich content and access to a large community of compliance professionals provides a powerful solution in an environment where the regulations and requirements are continuously changing and keeping pace with them and managing them effectively is essential to reducing the overall risk. After evaluating solutions from multiple vendors, NASDAQ decided to offer MetricStream solutions to all its listed companies to enable them to better manage their quality and compliance initiatives

# Internal Quality Management

Manufacturers strive to differentiate on the basis of product quality. The growing mix of complex products and global expansion of operations requires a new approach to quality management. Many organizations are deploying either industry standard quality management methodologies such as Six Sigma and ISO 9000, or implementing other quality practices to reduce costs, shorten cycle times and improve overall product and process quality. This has created a need for organizations to have visibility into their quality processes and to implement systems that ensure closed loop quality processes and support easy access to and efficient routing of information.

Traditionally, homegrown systems, stand-alone applications or even manual paper-based systems have been used to manage product and process quality at departmental level. Such point-solutions fail to address systemic quality problems as they lack a broad enterprise reach. As a result, many companies are seeking to deploy enterprise class solutions that can unify quality management across their worldwide operations.

MetricStream offers industry's most advanced and comprehensive suite of quality management solutions. Leading companies are replacing their point solutions and paper-based systems with MetricStream solutions to automate their quality management processes, gain real-time visibility into their quality metrics, and reduce the costs arising out of poor quality.

Some of the best practices being employed by leading global manufacturers by leveraging MetricStream solutions include:

## Closed Loop Processes

MetricStream ensures that all quality processes are well integrated to create a unified and seamless environment for quality related issues and data. The solution tracks events as they move from one stage to the next, even across departments and groups, to ensure a closed loop quality management process. For instance, a document change can initiate a training request and CAPAs triggered as a result of audit findings are tied to the audit.

## Streamlined Corrective Actions

MetricStream allows users to engage cross-functional teams to collaborate on development and implementation of corrective action plans. It enables triggering CAPAs, performing root cause analysis, assigning follow up actions while effectively tracking and routing cases from initiation to closure.

## Efficient Audit Management

MetricStream allows conducting frequent internal audits to ensure that the established product and processes quality requirements are being followed. It provides capabilities to efficiently plan, schedule and conduct audits, allows audit findings to be reviewed and analyzed by a team, enables initiation of follow-up activities such as corrective/preventive actions when needed, and provides the ability to monitor the entire process.

### **Implementing Document Control**

MetricStream streamlines document management and control processes for documents such as SOPs, batch records, regulatory filing, and quality reports. It enables companies to adopt an electronic and automated approach to managing and control documents across the enterprise with a centralized repository and tools for collaboration.

### **Tracking Nonconformance**

MetricStream accelerates non-conformance review and approval cycles with automated workflow. It supports recording and automatic rule-based routing of nonconformance issues for review and disposition by the Material Review Board (MRB).

### **Real-time Reporting**

MetricStream enables tracking quality issue and processes in real-time on executive dashboards and reports for data driven decision-making. It provides complete visibility into quality system database with comprehensive aggregate reporting as well as individual case status tracking. Graphical executive dashboards and flexible reports with drill-down capability provide statistics, analytics and trending.

## **Customer Quality Management**

Visionary organizations are realizing that handling and resolving product quality issues reported by customers in a consistent and predictable manner is key to customer loyalty and repeat business. A systematic approach towards customer complaint management also generates ideas for product enhancements and new products ensuring ongoing success. Moreover, companies regulated by the FDA or those adopting standards such as ISO 9000 comply with well-defined guidelines for recording complaints, responding to them, and resolving them

Some of the best practices employed by leading global manufacturers using MetricStream Customer Complaints Management solutions include:

### **Detailed Issue Recording**

MetricStream enables recording and defining quality problems reported by customers in measurable and specific terms to ensure accurate verification and effective investigation. MetricStream also supports capturing details such as product identification markings and event environment for comprehensive investigation and reporting.

### **Streamlined Corrective Actions**

MetricStream allows engaging teams to collaborate on development and implementation of corrective action plans. MetricStream enables triggering CAPAs, performing root cause analysis, assigning follow up actions while effectively tracking and routing cases from initiation to closure.

### **Real-time Issue Tracking**

MetricStream allows tracking customer issue and complaints management process in real-time. It provides complete visibility into the customer issues and complaints lifecycle with comprehensive aggregate reporting as well as individual case status tracking. Graphical executive dashboards and flexible reports with drill-down capability provide statistics and data by a variety of parameters such as by status, category, priority and action type.

### **Product Changes**

MetricStream enables Automating of review and approval workflows for product changes with standardized processes for initiating and communicating product changes. It allows systematic decision-making and timely communication to all affected customers as well as internal groups.

### **Industry Standard Reporting**

MetricStream supports automated creation of reports for investigation and resolution in industry standard formats to eliminate the manual effort and long cycle-times in consolidating data and information for external reporting. It supports generating investigation and corrective action reports in flexible industry standard or customer mandated formats and file types to streamline reporting to customers or regulatory agencies. Examples of such reports include 8-D report for issue resolution process and adverse event reports for compliance with FDA's reporting regulations.

## **Supplier Quality Management**

The nature of an organization's relationship with its suppliers has dramatically changed. Global outsourcing and co-development is on the rise as companies increase focus on their core competencies. These changes have created a need for organizations to put in place a supplier quality management system to increase visibility into supplier quality and improve supplier accountability.

Some of the best practices being employed by leading global manufacturers by leveraging MetricStream Supplier Quality Management solutions include:

### **Supplier Access**

Deploying quality management systems with web-based access for suppliers enabling them to easily access and rapidly adopt a web-based superior quality management system. Even suppliers with basic IT infrastructure can access the application without any additional investment in hardware or software.

### **Real-time Quality Analysis**

Automating review and approval workflows for quality data in real-time by following a systematic process for collecting, plotting and analyzing inspection data to identify material nonconformance before lots are shipped.

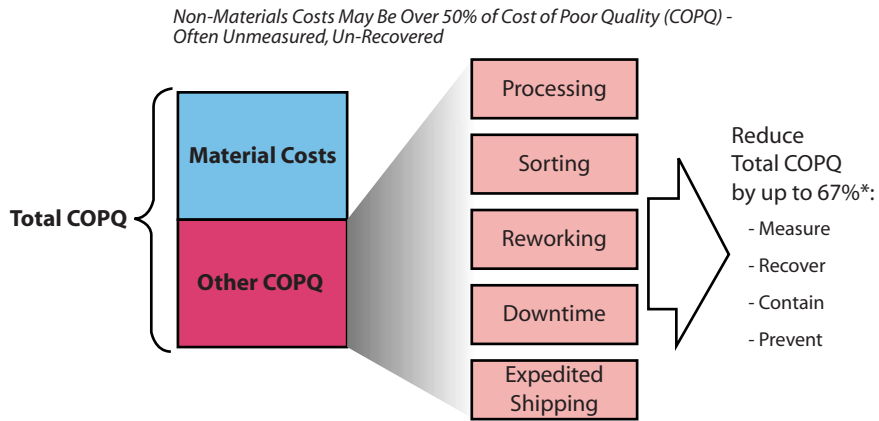
### **Issue Tracking**

Tracking supplier nonconformance issues in real-time by establishing consistent procedures for components and lots that do not conform to specifications. MetricStream supports identification, evaluation, segregation, and disposition of nonconforming material as well as issue investigation and tracking.

### Streamlined Corrective Actions

Implementing a proactive approach to supplier corrective action requests (SCARs) or corrective/preventive action requests (CAPAs) across the supply-base. MetricStream enables triggering SCARs/CAPAs, performing root cause analysis, assigning follow up actions while effectively tracking and routing cases from initiation to closure.

**Supplier Charge-backs** Charging cost of poor quality back to the supplier for the costs incurred by a manufacturer due to nonconforming components, materials, and late deliveries in order to introduce business discipline and accountability into the supply chain. MetricStream supports recovery of both - material costs and processing costs associated with the nonconformance. It allows users to manage the end-to-end chargeback process - aggregate all costs from an incident, route for approvals internally and to the supplier, collaboratively resolve the disputed recovery amounts, and notify back office systems for financial closure.



*\*AMR Report Adding Quality Management to supplier Collaboration*

### Supplier Scorecards

Monitoring supplier performance on scorecards to proactively identify and implement timely corrective actions improves supplier performance. MetricStream scorecards measure key performance indicators (KPI) in real-time and track improvements over time supporting sound decision-making based on data.

### Supplier Audits

Conducting supplier audits to ensure that suppliers meet the established product and process quality requirements and the audit process drives continuous improvement. MetricStream provides capabilities to plan, schedule and conduct audits, allows audits finding to be analyzed and enables the initiation of follow-up activities such as corrective action requests and re-audits.

# Case Study - A Fortune 500 Manufacturer of Diesel Engines



System Alignment and Integration for Excellence in Quality and Compliance

## Overview

The Company is a leading manufacturer of diesel and natural gas engines, electric power generation systems, and engine-related component products serving customers in over 160 countries and territories. With \$11.4 billion in revenue, the Company is ranked high in the Fortune 500 list of corporations. The Engine Business Unit is the company's flagship business unit. It manufactures and markets a complete line of diesel and natural gas-powered engines that are used in trucks, buses, recreational vehicles (RVs) and light-duty automobiles and in a number of industrial products including agricultural, construction, mining, marine, oil and gas and military equipment.

The Company's commitment to quality management principles is illustrated by its success with Six Sigma program. The Company has been using Six Sigma methods for nearly 10 years in a wide variety of situations, such as improving the way the company matches its manufacturing components, improving the shipping area's ability to meet customers' requested dates for accessories and establishing an automated planning control method. The program has reached a point where Six Sigma concepts now permeate every aspect of the company culture.

To ensure the organizational focus on customer satisfaction and continuous improvement the Company takes a process-centric approach towards quality management and assurance. The company has established well defined processes to comply with key industry standards and regulations such as QS 9000, TS 16949, ISO 18000, OSHA, Six Sigma, ISO 14000 and Environmental Health and Safety.

## Challenge

Driven by the strong senior management leadership for continuous improvement, the Company had a well-deployed process focus and good knowledge of statistical and analytical tools for quality management well embedded across its global

## Benefits

Reduced direct labor costs with higher efficiency of Quality Engineers, Auditors and Compliance Managers

Improved line utilization by preventing line downtime caused by poor material quality and material nonconformance

Continuous improvement focus with an enterprise-wide platform for tracking all quality and compliance metrics and data

Assured compliance with internal quality initiatives, industry standards and regulatory mandates

*"Our goal was to simplify the deployment of common approaches enabling us to focus on continuous improvement of our products and critical processes across the entire supply chain", MetricStream's Enterprise Compliance Platform and its comprehensive suite of applications will offer us the enterprise-wide standardization capability that localized point-applications do not provide."*

**George Strodbeck**

Executive Director of Corporate Quality

operations. These were supported by a number of systems developed and managed in house.

The key challenge facing the Company was that each of its 80 plants had independent and stand-alone IT applications for storing and managing the data, records and information for all its quality and compliance processes. While some processes were managed using custom applications built on outdated client-server technologies, some were managed manually using spreadsheets and even paper-based records.

These standalone, heterogeneous applications were being used to key track quality and compliance data and processes such as non-conformances, corrective actions, calibrations, claims management, document control, employee training, etc. at each the Company plant location. Inability to share knowledge and information across the processes created a multitude of data islands and hindered sharing of best practices, standardizing on processes and capturing of trends. Further, dispersed information caused deadlocks in generating reports and analysis of the overall results.

## Solutions

To keep up with the increasingly complex set of products and an expanding global customer and supplier base, the Company launched an initiative to unify its operational quality and compliance management across our worldwide operations. The business objective was to consolidate 115 local applications across 80 sites that were supporting various programs for quality initiatives, industry standards and regulatory mandates by implementing a web-based system. This system was to enable global access and collaboration for employees, supplier and customers as well as provide visibility and data analytics at the enterprise level.

The MetricStream solution was selected due to its comprehensive suite of applications that were built on an extensible platform-based architecture. This provided the Company with pre-built application modules for managing product and process related non-conformances, issue investigations and reporting, managing control documents, developing and executing corrective and preventive action (CAPA) plans and ongoing compliance auditing. In addition, the MetricStream Enterprise Compliance Platform, the underlying infrastructure for all MetricStream applications, provided core services and tools that enabled the Company to rapidly develop and deploy

## Why MetricStream

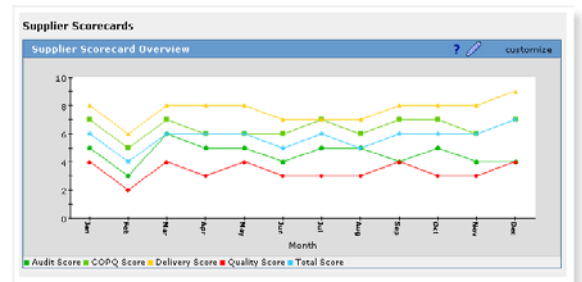
Comprehensive solution set with support for all quality and compliance processes

Flexibility to meet specific requirements and adapt to changing business processes

Powerful reporting with executive dashboards for analytics and trending

Web-based architecture with an easy-to-learn and easy-to-use interface

Embedded best practices ready to be used out-of-the- box



specialized applications for its specific business needs.

By leveraging a common infrastructure for all its quality and compliance applications, the Company has achieved enterprise-wide visibility and control which localized point-applications did not provide. Issues affecting the efficiency, quality and productivity of compliance teams have been resolved. The system provides direct access suppliers enabling them to actively participate in the business process. Earlier, there was no easy way to track open cases, know the number of issues per plant or per supplier or generate a list of over due corrective actions requests. This information is now easily available along with sophisticated data analytics on visual dashboards and charts.

Key quality business processes have been completely automated and streamlined with the implementation of the MetricStream solution. For instance, the MetricStream Nonconformance CAPA Management applications provide a central database and process flow system where information on nonconforming products or parts is entered, referenced and dispositioned. The engine plants issue nonconforming material records (NCMRs) upon detection of non-conforming product. NCMRs are routed to various quality personnel in the plant according to local procedure. If it is determined that the defect was caused by a supplier, the NCMR is sent to the supplier and the supplier responds with a Return Material Authorization (RMA) number. In the case of a major or repeated defect, the plant generates a supplier corrective action requests (SCAR) based on the information in the NCMR and send it to the supplier. The supplier responds to the SCAR with a 7-step corrective action; the short-term portion is evaluated by plant personnel and the long-term portion is evaluated by Supplier Quality Improvement Engineers (SQIEs) in purchasing. On acceptance of the long-term response, the purchasing SQIE recommends the SCAR to be closed by the respective plant contact.

The solution has enabled suppliers to respond quickly to NCMRs and SCARs and plays a critical role in preventing continued disruptions at the plants. It has significantly improved the speed and efficiency of communication among various internal groups as well as external suppliers, provided a common access point for quality information of all plants and facilitated automated reporting of defect data.

**MetricStream**  
MNC | Dashboards | Reports | Documents | Setup | Users | Infolets | Alerts | Data | Assignments | Help

**Initiate Non-conformance**  
Fields marked in red \* are required.

**Issue ID:** \_\_\_\_\_

**Initiated On:** 06/21/2005 04:48 PM      **Initiated By:** MNC Initiator plant ABC

**Issue Type\***: Logistic Issue      **Plant Name\***: Select one...

**Severity Level\***: Select one...      **Issue Found In\***: Select one...

**Sorting**  
**Sorting/Rework\***: Select one...      **Sorting Criteria**: \_\_\_\_\_

**Issue Details**  
**Date Occurred\***: mo. day year  
06 / 21 / 2005

**Issue Details\***: \_\_\_\_\_

**Requirement/Specification**      **Actual Observation/Measurement**      **How it was Verified**

**Comments**: \_\_\_\_\_      **Comments History**: [Initiate Non-conformance Comments Histor](#)

Report Data as of: 2005-07-15 04:16:20 +0000

Show Filters

Showing 1 - 6 of 6 records.

Supplier Name	Quality Score	Delivery Score	COPQ Score	Audit Score	Total Score
Benchmark Score	7	8	7	6	7
Supp 101 New York US	3	3	2	3	3
Supp 201 Boston US	4	5	4	5	5
Supp 203 Chicago US	5	4	3	5	4
Supp 302 Milwaukee US	5	4	6	6	5
Supp 403 New Jersey US	3	5	4	4	4

Email    Export    Print    Done

# Case Study - Fairchild Semiconductor



Aligning Global Quality Processes with Customer Focus

## Overview

Fairchild (NYSE:FCS) is one of the largest and most well-known semiconductor companies focused solely on high performance multi-market products. Its products are the building blocks for virtually all electronic devices, from sophisticated computers and Internet hardware to telecommunication equipment to household appliances. Approximately 10,000 Fairchild products are sold to over 50,000 OEM and channel customers worldwide. In turn, Fairchild products reach millions of end-consumers.

OEM and channel relationships in the high-tech industry are built on strategic commitments around product design and quality. Given the complex nature of semiconductor manufacturing and the varied scenarios in which they are used, Fairchild works closely with its customers to ensure responsiveness to and alignment with customer needs. Handling and resolving product quality issues reported by customers in a consistent and predictable manner is key to customer retention. In addition, proactive communication of product changes, obsolescence, alerts and recalls to affected customers is critical to ensuring customer loyalty while reducing product liability and risk.

## Challenge

Being a pioneer in semiconductor manufacturing, Fairchild has established quality management processes that are seen as the best practices in the industry. But as these have developed over decades during which Fairchild operations have spread worldwide and into a variety of product categories, the challenge faced by the company was ensuring adoption of these quality management processes across sites and product lines consistently and efficiently.

For instance, Fairchild has in place an elaborate procedure to log customer quality cases and take them through a complete cycle of investigative and resolution steps and, finally, close the loop by sending a comprehensive report to the customer in a

## Benefits

### Efficiency

The average issue resolution time for customer quality issue has gone down substantially as the automated workflows take cases through the investigation and closure process without delays. Email notifications, task list, and case status reports on the users' homepage keeps pending tasks on top of the mind improving responsiveness and proactive participation.

### Visibility

With MetricStream, Fairchild and its customers have complete visibility into quality issues as well as upcoming products changes in real-time and across the global enterprise. This transparency has made customer quality management a predictable process while improving customer satisfaction and lowering product liability.

### Data-driven

Access to global data and the ability to analyze this data in real-time is allowing Fairchild to monitor process performance metrics that provide a sound basis for ongoing continuous improvement. Quality issues are now proactively identified, tracked and resolved and decisions are based on hard facts and metrics. The powerful analytics and reporting capability with graphical dashboards allows managers to adopt a data-driven approach to quality management.

prescribed format. An internal system that was combination of homegrown or desktop applications and manual processes could handle this to a certain level. But as the number and

complexity of products grew, operations became globally distributed, and customers started demanding quicker turn-around on issues, the internal system just did not offer the flexibility and power Fairchild needed to stay ahead in the competitive environment.

Limited reporting and data analytics, lack of collaboration between teams at different sites, manual and inefficient follow-up on action items, time-consuming data gathering for customer reports, poor integration between applications, and constraints around system configuration were issue that Fairchild wanted to resolve by deploying an integrated customer quality management solution to streamline and modernize its global quality and reliability operation.

## Solutions

After extensive evaluation of various quality management solutions on the market, Fairchild selected MetricStream. The key driver for choosing MetricStream was the unique combination of its broad-based Enterprise Compliance Platform and specific functional modules that support individual quality processes that tie together to unify the enterprise-wide quality operation. *"We wanted a company-wide system that could provide a 'foundation' for our closed-loop quality initiatives. MetricStream's platform provides this strategic foundation while providing specific solutions that enable Fairchild to achieve our near-term quality improvement objectives", says Mark Rioux, Vice President of Global Quality & Reliability at Fairchild.* After a thorough analysis, we selected MetricStream. We felt that it will provide us a functionally rich solution at a cost-of-ownership that was clearly superior to other alternatives".

MetricStream's Customer Issue Management module allows Fairchild customer support engineers to carry out investigation and tracking of customer-reported quality issues including containment, failure analysis and corrective actions. The system can track the manufacturing history of failed components and enable engineers to get to the root-cause of the problems. Company wide standardization of failure codes ensures consistency across all sites and drives trend analysis. One of the most time-consuming and labor intensive task was consolidating all the analysis and investigative information and reporting to the

## Why Fairchild Selected MetricStream

Robust Enterprise Compliance Platform with a broad set of functional modules that serves as the foundation for the company's quality and compliance needs

Ability to configure off-the-shelf modules to adapt to best practices followed in the company

Powerful reporting for internal data analysis as well as customer reporting

Multi-site web-based access with collaboration tools to support team-work

Low total-cost-of-ownership

*"MetricStream worked very closely with our quality and reliability organization to develop these applications. We believe that these modules capture the best practices in customer quality management in the industry today."*

### Mark Rioux

Vice President of Global Quality & Reliability  
Fairchild Semiconductor

customers for their final approval and case closure. With the MetricStream solution's powerful reporting engine, these reports can now be generated at the click of the button. All relevant data is pulled from various stages of the process and a document is created in Microsoft Word using a desired template and format applicable to a particular customer.

MetricStream's **Change Notification** module has enabled Fairchild to standardize and automate the processes for initiating and communicating product changes to enable systematic decision-making and timely communication to all affected customers as well as internal groups. The module covers product changes as well as product obsolescence.

MetricStream's **Document Management** module is at the core of Fairchild's quality management system, enabling an electronic and automated approach to managing control documents across the enterprise. It integrates with the central repository of documents and provides tools for collaboration and workflow management. It has accelerated review and approval cycles as documents automatically move from one stage to the next as per the prescribed lifecycle. The solution facilitates communication and teamwork across departments and functional areas reducing the cycle-times significantly.

The underlying infrastructure for all the applications is the robust MetricStream Enterprise Compliance Platform. Deployed in a clustered environment to provide 24x7 availability, the system supports 15 sites across 8 countries and over 2000 users. The platform provides core services and capabilities such as automatic email notifications and alerts, roles-based information routing, real-time analysis of data on reports and dashboards, and ability to slice-and-dice statistics by a variety of parameters such as product lines, sites, and customers. document is created in Microsoft Word using a desired template and format applicable to a particular customer.

Supplier Name: Supplier 101 New York US Class: B Commodity: Side Impact Beam

Supplier Information

Report Date as of: 2005-07-24 10:20:34 -0700

Show Filters

Showing 1 - 26 of 26 records.

Supplier Name	Current Score	Weight	Score for Previous Month
Supplier Total Score	3	100	6
Supplier Quality Score	5	40	5
PPM Score	2	25	4
PPM Value	0		170
SCAR Score	3	10	6
# of SCARs	9		3
Comp Score	4	5	5
# of Complaints	9		3
Supplier Delivery Score	3	20	6
Leadtime score	4	10	6
OnTime Score	3	5	5
DocktoStock score	3	5	6
Supplier COPQ Score	2	30	5
Supplier COPQ Value	748		395
Freight score	2	5	5
Freight Cost	205		90
Inspection Score	2	5	4
Inspection Cost	245		102
Other score	3	10	5
Other Cost	298		203
RFQ performance score	3	10	7
Supplier Audit Score	3	10	6
Organization Score	4	2	6
Product Score	3	4	7
Service Score	4	2	6
Process Score	3	2	7

Email Export Print Done

# Case Study - Fortune Global 200 Consumer Electronics Brand and Medical Devices Company

Supplier Quality in a Flat World: Sense and Simplicity

## Overview

While the European Company is seen as a premium brand in consumer electronics and appliances, its products for diagnostic imaging, patient monitoring and cardiac care are equally recognized in the medical and health service industry. With over \$38 Billion in revenues, the Company is among the Fortune Global 200 corporations.

Through its brand promise of excellence, the Company embodies the obsession with quality - something that European corporations have come to symbolize. It has institutionalized a culture to reach superior quality levels. It has established quality programs driven by a well-defined set of methods and tools for continuous improvement for reducing the cycle-times, adopting industry best practices by using tools and methodologies such as Breakthrough Management, Balanced Scorecard, One Page Strategy and Process Surveys.

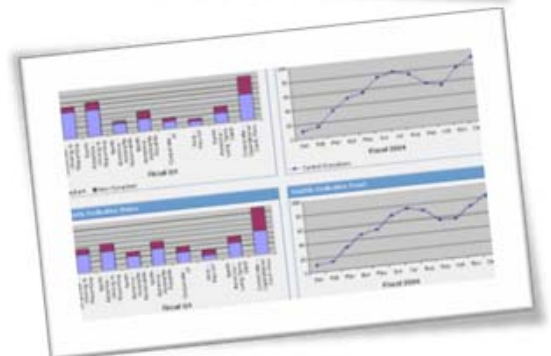
Just like any other large-scale manufacturer of industrial-grade machinery with complex mechanical, electrical and electronics design, the Company has a global supply base comprising of over 700 suppliers for thousands of parts and components on its bills of materials. Monitoring and managing supplier quality is as critical for it as is its internal quality processes because each stage in the entire supply and manufacturing chain has to conform to a common set of standards to ensure reliability of the end-products. Moreover, as medical devices is a regulated industry, the Company has to meet compliance obligations and reporting requirements such as Current Good Manufacturing Practices (cGMPs), device safety standards, marketing laws, industry mandates (like ISO 13485) and country specific guidelines such as the US FDA 21 CFR Part 11 and Part 820 (Quality System Regulation). As a result, the Company has the onus of managing liabilities and mitigating risks arising from its own operations as well as from its large supplier ecosystem.

## Benefits

By implementing the MetricStream solution, Philips has achieved tremendous efficiencies and complete traceability in its supplier quality management process across its businesses and supplier base.

Philips has improved average CAPA throughput time from 60 days to 48 days by reducing process waiting time, ensuring immediate communication and setting clear priorities.

Philips estimates significant savings from elimination of redundant paper archiving and through productivity gains in activities such as information routing, trending and data analysis and data entry.



## Challenge

The Company introduced an initiative to create an online communication platform and single interface for its supplier management. A critical part of making this project successful was providing integrated functionality for supplier quality management, particularly the Supplier Corrective Action Request (SCAR) process – the cornerstone of a closed-loop quality management program.

The SCAR program, accepted at a high level, had standardized information collection and flows based upon the industry standard 8D methodology to analyze, resolve and prevent quality issues. However, the implementations were different across locations and businesses and hence the process was inefficient and not fully traceable. The data was collected, stored and handled in many different ways by different groups. Some parts of the process were paper-based, requiring hardcopies of records to be signed and stored in document vaults. Others used local systems developed on legacy and proprietary technologies or standalone client-server applications. In all cases SCAR data was emailed (as attachments), faxed or mailed between the Company and suppliers and entered into various systems manually, by the employees.

The Company wanted to harmonize and consolidate all supplier facing processes and systems to decrease cost and to increase efficiency and speed. To fully realize this vision, the Company was looking for a solution that could extend this platform for supplier quality management centered on the SCAR process.

While laying out the criteria for selecting the right solution, the Company identified key challenges that had to be overcome for the success of the project – and many were unique to its business setup and environment. Moving from various heterogeneous backend systems to a common enterprise-wide data model for all its internal business and suppliers, supporting the complex organizational hierarchy and providing secure web-based access for internal and external users, integrating with existing SAP ERP, QN and BW systems and providing quality metrics for measuring supplier performance were some of the critical success factors.

## Why MetricStream

Complete visibility into suppliers' quality processes for driving continuous improvement

Powerful supplier scorecards and reporting for monitoring quality metrics and supplier performance

Transparent environment for suppliers and manufactures to collaborate and coordinate in real-time

Web-based architecture with an intuitive and easy-to-use user interface

Flexibility to meet specific requirements and adapt to changing business processes

Standard-based integration with external systems and enterprise applications



## Solutions

By implementing the MetricStream solution, the Company has achieved tremendous efficiencies and complete traceability in its supplier quality management process, across its businesses and supplier base.

MetricStream was selected after an extensive evaluation of various offerings in the market. Primary factors that led to MetricStream's selection were its feature-rich solution with embedded best practices being employed by the Customer, MetricStream's expertise and experience in implementing applications for regulatory compliance (particularly in the life sciences industry) and its robust Enterprise Compliance Platform (ECP) that provides the configurability and extensibility essential for the long-term success in complex IT environments typical of larger corporations.

SCARs can be initiated directly in the system based on supplier quality issues identified during receiving and incoming inspection of parts or based on issues logged at the production line via the SAP QN (Quality Notification) application. Through its integration with SAP, MetricStream allows users to search for issues in the QN application (QNs) and initiate a SCAR for one or more QNs. The real-time integration transmits all the relevant data from SAP to MetricStream for QNs for which SCARs are triggered, eliminating duplicate data entry and ensuring information integrity.

The flexibility of the system is leveraged in many ways, for example, the solution supports workflows for Information Only type SCARs to make supplier aware of failures for trending purposes and internal investigation as well as Analysis Required type SCARs that require the supplier to respond to the Company with a detailed root cause analysis and corrective and preventive action plan.

The SCAR record includes detailed and standardized information fields such as SCAR type, part number and details, serial and traceability numbers, quantities received failed and returned and RMA number. The solution also supports calculation of Cost of Poor Quality based on direct and indirect costs such as defective PPM metrics and time and capacity loss – data used by the Company for supplier performance monitoring and negotiations.

The SCAR solution supports information flow and data gathering based on the industry standard 8D Problem Solving Methodology. The initial stages allow the SCAR owner to record problem symptoms, emergency responses, team members, problem descriptions and containment strategies to be adopted. After an internal review, the SCAR is assigned to the supplier for documenting the subsequent steps for the root cause analysis, permanent corrective action plan and implementation, preventive action plan and implementation. The supplier response is routed back to the SCAR owner review and closure after specifying if an audit or a follow-up activity is needed to ensure the effectiveness of the SCAR. At each stage of the workflow, users can add comments and upload supporting information such as images and reference documents as attachments that become a part of the SCAR record.

While the Company has over 1,500 suppliers, the distribution follows the Pareto principle with a minority of suppliers accounting for a majority of business interactions. To this set of core suppliers, the Company wanted to provide direct web-based access to the MetricStream system for managing SCARs. But for many suppliers, the limited SCAR-related interactions did not justify providing them with access to the system. MetricStream provided an innovative approach to support both these categories of suppliers. Suppliers who have access to the application get SCAR assignments that they can respond to by directly logging into the web-based system. For the remaining suppliers, SCAR assignments are sent as emails with an MS Excel spreadsheet template that contains the SCAR information. Following the instructions provided, suppliers can enter their responses in the spreadsheet itself and email it back to the SCAR owner. This spreadsheet is uploaded directly

into the MetricStream solution and the data entered by the supplier is parsed and stored as a standard SCAR record. This has enabled the Company to follow a common data model, ensuring consistent business practices for SCARs across its supplier base while avoiding any error prone and inefficient manual data entry.

The MetricStream solution maps the Company's 6-level organization hierarchy covering corporate as well as all the divisions, business groups, business lines and locations. For these organizational entities, roles are defined for carrying out various activities and responsibilities. Employees are mapped to appropriate roles in the system enabling flexible user administration with easy management of access rights and privileges. The system front-end is linked with the supplier portal (built on SAP Enterprise Portal technology) from where users can directly access the MetricStream solution through single sign-on based on shared authentication of credentials.

Beyond the efficiencies gained by streamlining the SCAR process, the Company has greatly benefited by the access to data and metrics provided by MetricStream powerful reporting and search capability. Users can easily find and track SCARs using flexible search criteria such as date range, owner and status. The system provides comprehensive metrics for measuring supplier performance based on PPM data, Cost of Poor Quality and SCAR results. Users have easy access to scorecards and dashboards that present data analytics such as SCARs per supplier per business unit per year/month/week and SCAR cycle times.

Designed to support over 2,000 users globally, the MetricStream supplier quality management solution handles 12,000 SCARs across 1,500 suppliers of the Customer.

The screenshot shows the 'CAPA Request Form' in the MetricStream application. The form includes fields for 'Event number' (80368), 'Requester' (QA\_Manager QA), 'CAPA Category' (Production), 'Submitted' date (06/16/2005 12:27 AM), 'Sub Category' (Process Not Followed), 'Facility Location' (Plant C - Chicago), and 'Action Type'. There are also sections for 'Target Due Date' and 'Problem' description. The interface is clean with a light blue header and various input fields and dropdown menus.

The screenshot shows the 'Audit Response Summary' in the MetricStream application. It displays a table of audit details including 'Audit name', 'Package', 'Scheduled On', 'Scheduled Start', 'Scheduled End', 'Description', 'Auditing Firm', 'Auditor Full Name', 'Partners', and 'Location'. Below the table, there are sections for 'Form Status', 'Corrective Action Response Due Date', 'Schedule Re-Audit', and 'Re-Audit Schedule Date'. The interface is organized into sections with clear labels and data fields.

## About MetricStream

MetricStream is the leading provider of solutions for Governance, Risk, Compliance (GRC) and Quality Management. Organizations today need a systematic approach to defining and managing GRC initiatives and quality management programs through a sustainable and integrated process that is aligned with the corporate strategy instead of a series of unrelated tactical projects. MetricStream has enabled leading corporations in diverse industries to make the shift from isolated compliance initiatives and departmental silos of risk-related information to integrated enterprise-wide strategy for GRC and quality management.

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