PTC® Live Global

PTC 105 - Consolidating Multiple CAPA Systems: The Case for Quality Management in PLM

Michael Prudhomme
Product Owner Global Quality

June 8 2015

Importance of Consolidated Quality Management

"Best-in-Class manufacturers are creating **closed-loop quality management** by implementing QMS at an enterprise-wide level and establishing real-time interoperability with PLM"

31% fewer defects per million

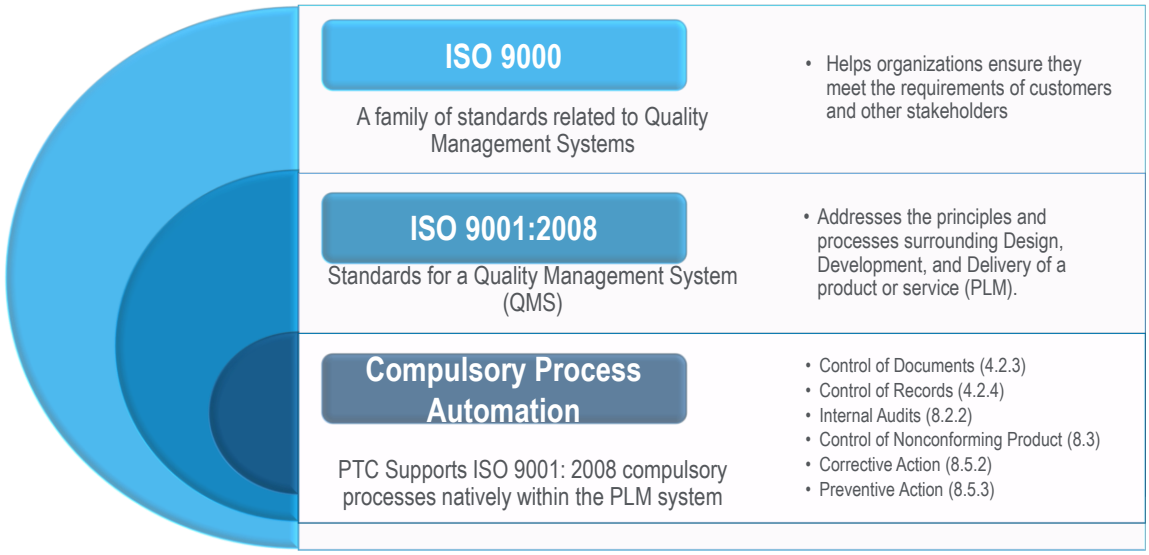
29% less spent on internal failures

Aberdeen Group, Closed Loop Quality Management
June 2011

What is a **Quality Management System**?

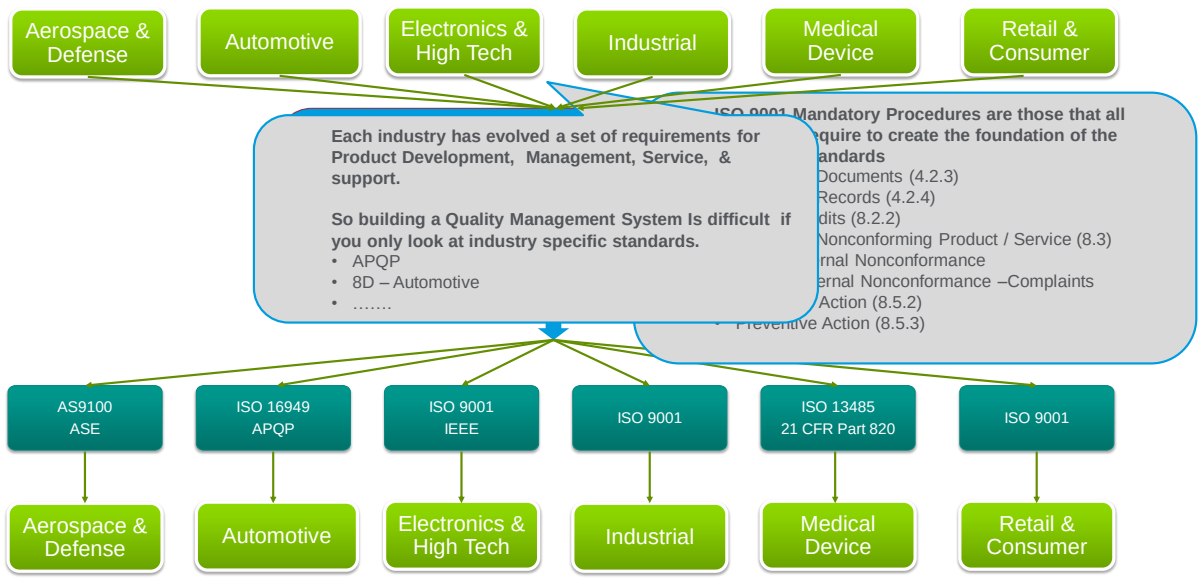
PTC® Live Global

A system of processes that provides a structured way of delivering better service or product



Common standard for QMS - Core Elements

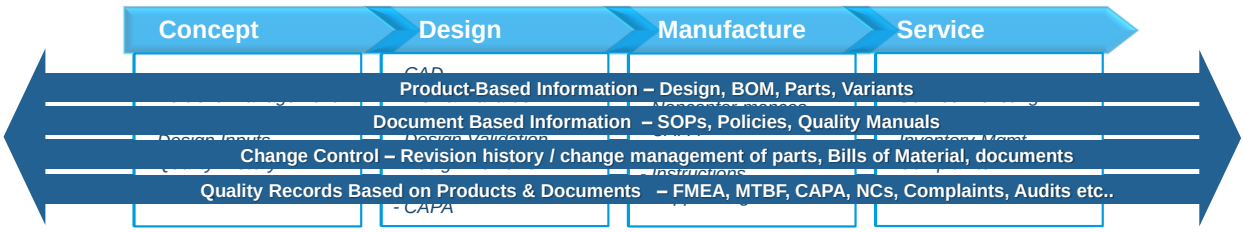
PTC® Live Global



ISO & PLM

PTC Live Global

PLM is the backbone to evolve the complete definition of a product over its entire life:



- Products - Provide Control of Product information / CAD Mgmnt, BOM, BOO, history, documentation
- Documents - Manage & Control all key documents, with associativity to related parts
- Change – Manage change process to capture inputs, workflow, approvals and execution of change
- Quality – Quality Activities & Processes interact with the Anchor Points for Products and Processes

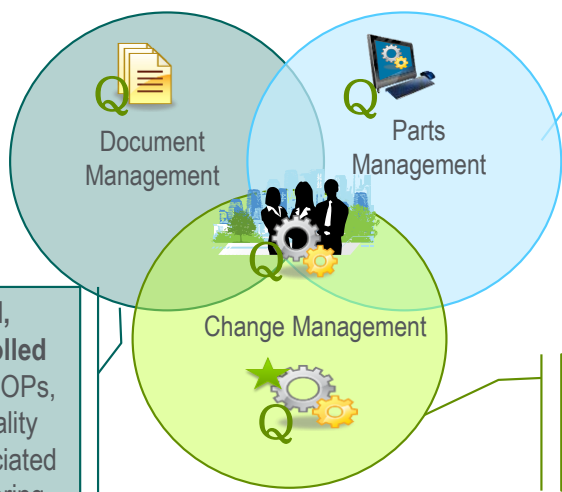
Enables:
- Control of Documents (4.2.3)
- Control of Records (4.2.4)
- Internal Audits (8.2.2)
- Control of Nonconforming Product (8.3)
- Corrective Action (8.5.2)
- Preventive Action (8.5.3)

Benefits:
- Supports all ISO 9001 Derivative Standards: ISO 13485 & 16949, AS9100
- Provides a uniform approach
- Speeds implementation – reduces costs
- Provides immediate value

The **Quality** Perspective on Integration with PLM

PTC Live Global

Integrating **PLM with Quality** leverages change-managed PLM data and functionality



Directly reference Enterprise parts from Quality processes such as Complaints, NCs, CAPAs, Audits

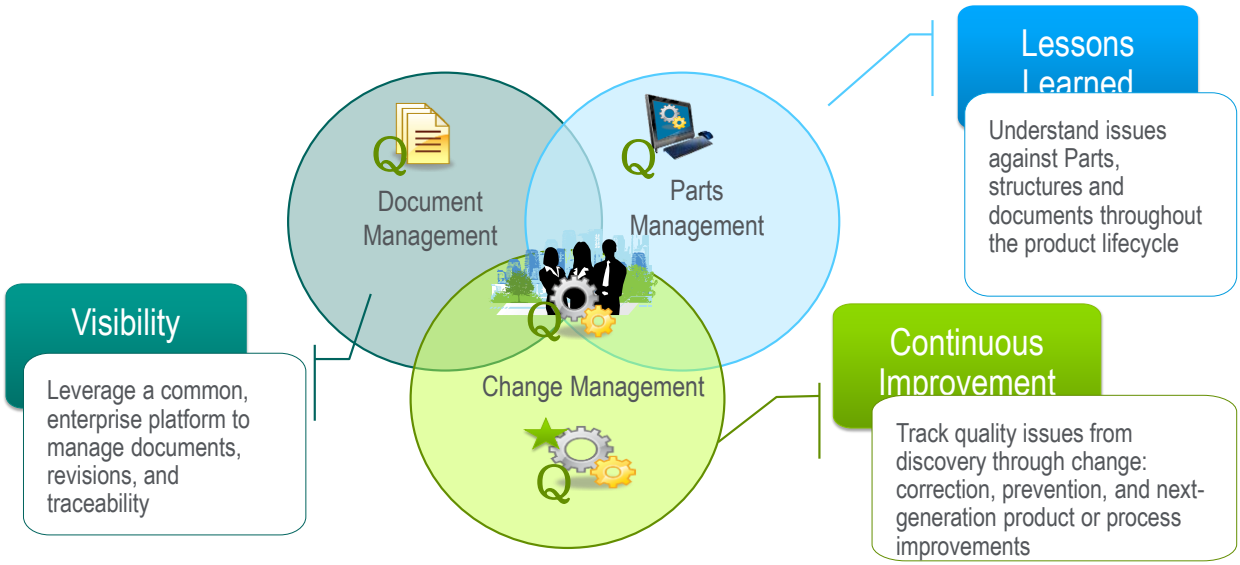
Change-managed, configuration-controlled quality documents (SOPs, work instructions, quality manuals, audits) associated to quality *and* engineering

Drive change directly from quality investigations in the same system from their related quality artifacts

The **Engineering** Perspective on Integration with Quality

PTC Live Global

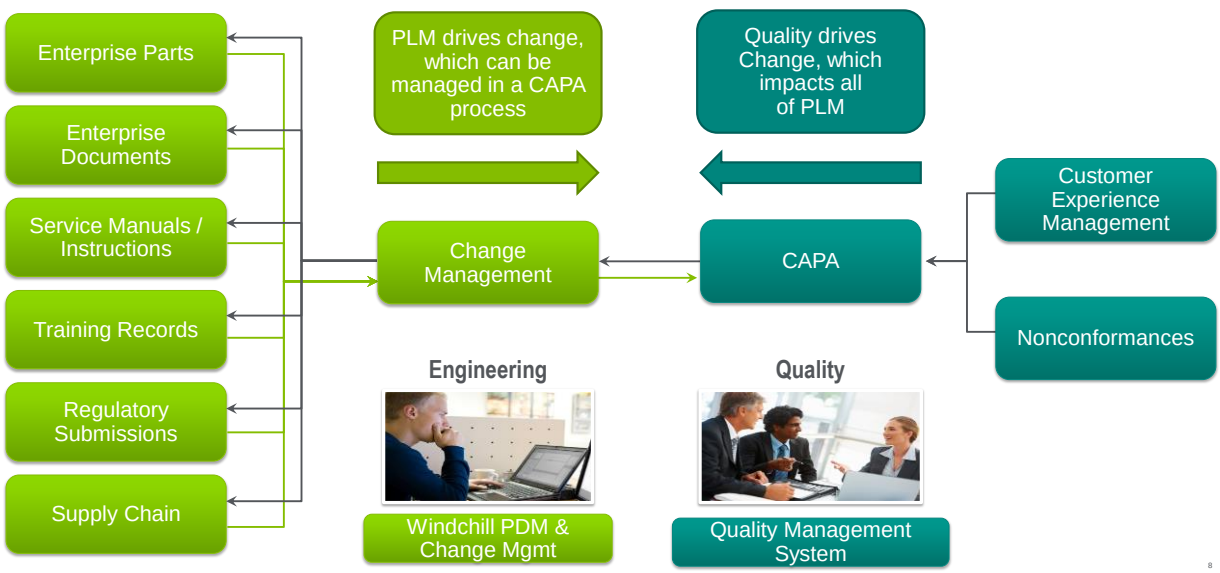
Integrating **Quality into PLM** enables Lessons Learned, Visibility, Continuous Improvement



Process: PLM Enables Quality

PTC Live Global

Handoff Between Engineering and Quality

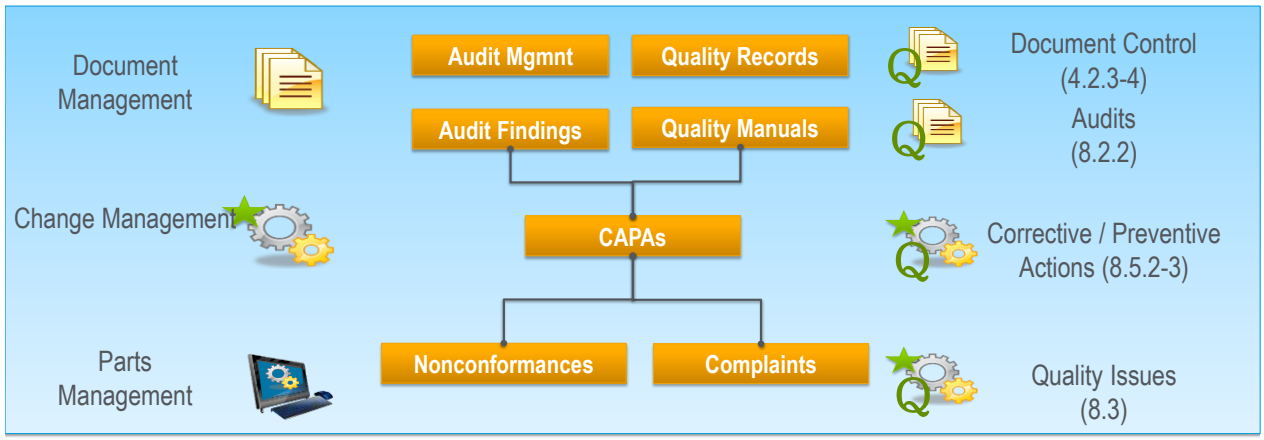


Technology: PLM Enables Quality

PTC® Live Global

PLM Enablers:

ISO Processes :



Engineering

Quality

Value of Consolidation: to Engineering and to Quality

PTC® Live Global

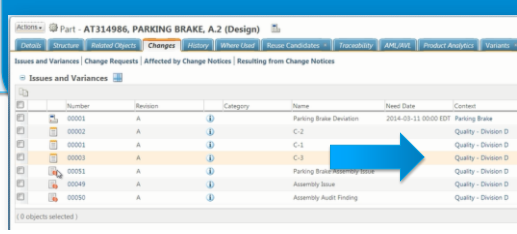
"Quality data enriches your PLM environment; and the richer your PLM environment, the better your Quality Management – because everything you need to manage Quality is housed centrally." – PTC Customer

Value to Engineering:

Centralized visibility into Quality issues / part performance

Direct connection to / communication with Quality processes

Systematic reuse of Lessons Learned from Part Selection to End of Life

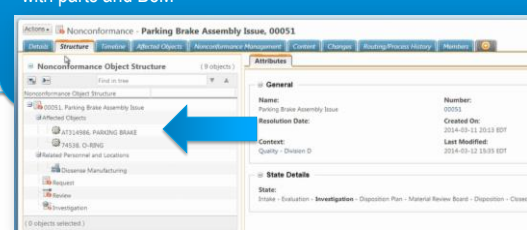


Value to Quality:

Consistently reference the latest BoM and Part data

Direct capability to create and follow the process of an Engineering Change

Quality documents & artifacts controlled by PLM in context with parts and BoM

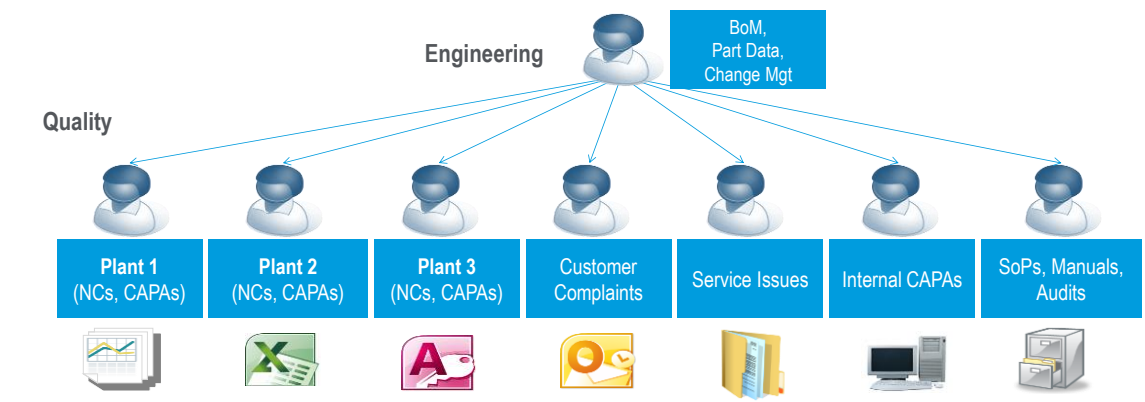


Consolidated Quality Management Systems

Business Process Improvements

"Before" State

Inefficiency of tracking down data from multiple quality management systems



Inefficient & Time-consuming
Manual process, lack of reuse, lack of insight into change impact

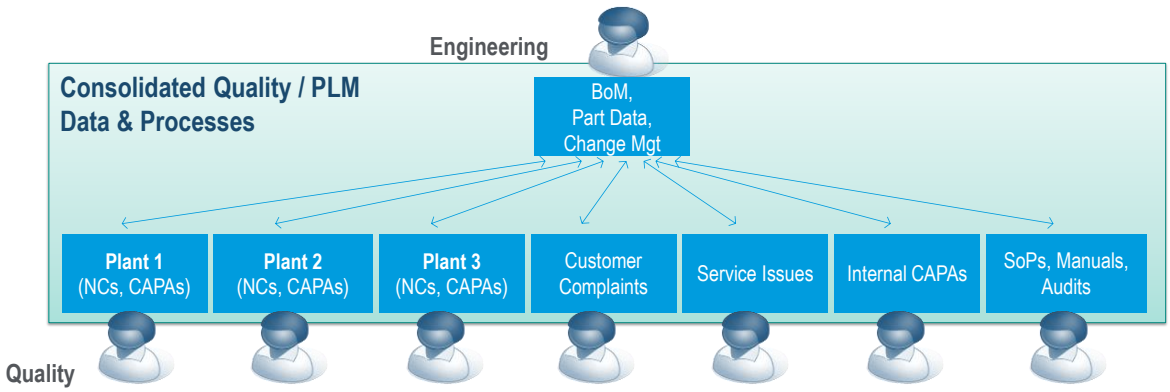
Lack of communication:
Of quality fixes & lessons learned; of product updates

Quality Issues & CoPQ
Repeat issues, costly fixes, scrap, rework, warranty, recall.

"After" State

PTC® Live Global

Single source of truth for engineering and quality data, processes



Improved Efficiency
Automated closed-loop process, speeds TTM, differentiation

Common processes: QM & PLM
Communicate lessons learned, product updates, recurring issues

Reduced Cost of Quality
Reduces repeat issues & CoPQ, improves customer satisfaction

PTC® Live Global

Consolidating CAPA Systems

Ford & Firestone Example

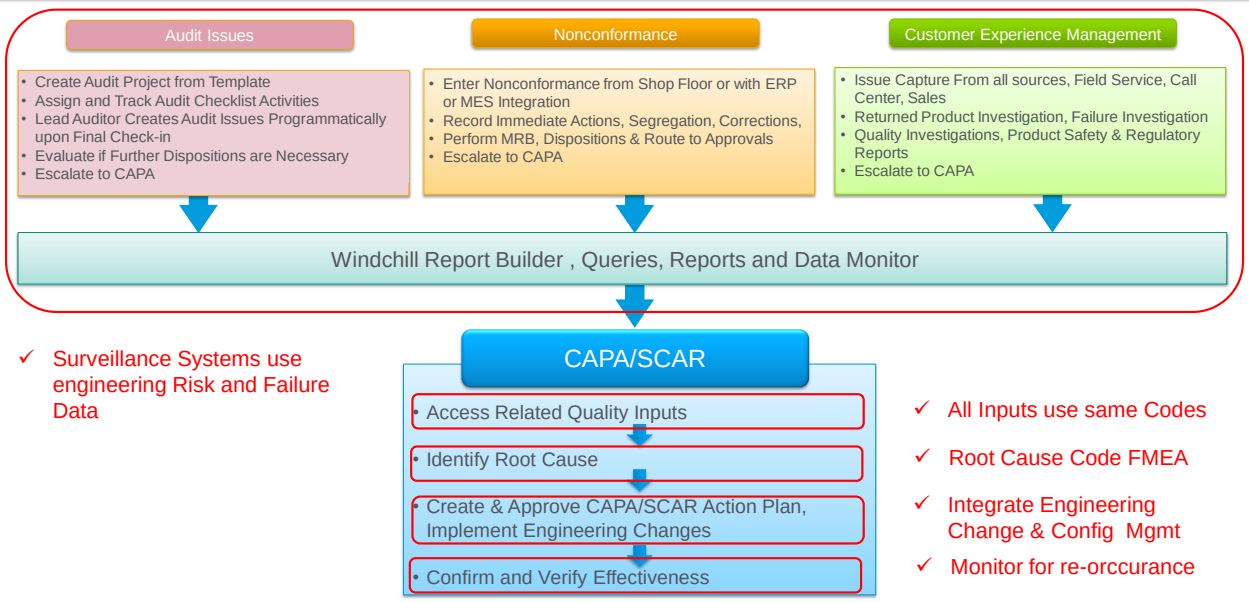
CAPA Systems

PTC Live Global

- A True CAPA is not an Issue Log
  - Surveillance + Corrective Actions & Preventive Actions = Continuous Improvement
  - CAPA systems create self righting products & processes
- CAPA Corrective Action Preventive Action
  - Corrective Action: Action taken to prevent re-occurrence of a problem
  - Preventive Action: Action taken to prevent the initial occurrence of a problem
- How best to Consolidate CAPA systems
  - Focus on key elements
  - Consolidate using Key elements
- Key Elements – "The Loop"
  - Leverage System Engineering especially Risk and Failure Analysis work
  - Integrated Engineering all the way though
- Ford & Firestone – " A Thought Experiment"
  - Use Historic example to illustrate what is important

Centralized Quality Management With PLM – "The Loop"

PTC Live Global



- ✓ Surveillance Systems use engineering Risk and Failure Data
- ✓ All Inputs use same Codes
- ✓ Root Cause Code FMEA
- ✓ Integrate Engineering Change & Config Mgmt
- ✓ Monitor for re-orccurance

Firestone / Ford Tire Controversy

PTC® Live Global

Background

The Ford Motor Company had a historically strong relationship with Firestone since its inception, with Henry Ford and Harvey Samuel Firestone being personal friends and even the two families being linked in marriage with their respective grandchildren, William Clay Ford, Sr. and Martha Parke Firestone being married in 1947. United States-based Firestone became a subsidiary of Japanese tire manufacturer Bridgestone in 1988.

In May 2000, the U.S. National Highway Traffic Safety Administration (NHTSA) contacted Ford and Firestone about the high incidence of tire failure on Ford Explorers, Mercury Mountaineers, and Mazda Navajos fitted with Firestone tires. Ford investigated and found that several models of 15-inch Firestone tires (*ATX*, *ATX II*, and *Wilderness AT*) had very high failure rates, especially those made at Firestone's Decatur, Illinois plant. This was one of the leading factors to the closing of the Decatur plant.[1]

Firestone / Ford Tire Controversy

PTC® Live Global

Problem Description – CAPA

- The Ford Explorer was first offered for sale in March 1990. Ford internal documents show the company engineers recommended changes to the vehicle design after it rolled over in company tests prior to introduction, but other than a few minor changes, the suspension and track width were not changed. Instead, Ford, which sets the specifications for the manufacture of its tires, decided to remove air from the tires, lowering the recommended pressure to 26 psi. Low air pressure leads to increased heat; heat can damage the tire.

- The failures all involved *tread separation* [1] - the tread peeling off followed often by tire disintegration. Tread separation, due to the interaction of steel and rubber tire elements, has been a challenge in radial tire design since their development by Michelin in 1946. In 1968, Michelin proposed a nylon cap over the steel elements to counteract this, and Firestone adopted this nylon cap design in 2000, following investigation by the United States Congress.

Firestone / Ford Tire Controversy – Outcomes

PTC® Live Global

- Over 240 Deaths [2]

- Over 3,000 serious injuries [3]

Rollover-to-tire failure rates

VEHICLE	TIRE FAILURES	ROLLOVERS	RATE
Explorer	2,450	306	13%
Other Ford SUVs and light trucks	507	24	5%
Other SUVs and light trucks	416	12	3%
Other vehicles	160	4	2%
TOTALS	3,533	346	

Source: NHTSA Firestone Wilderness AT Investigation Database, Safety Forum

Times art

Firestone / Ford Tire Controversy – Outcomes

PTC® Live Global

- Ford Blames Firestone [5]
  - Nasser blamed Firestone
- Firestone Blames Ford –
  - John T. Lampe CEO of Bridgestone / Firestone – blames Ford
- Massive Tire Recall
- 100 Year supply Relationship Ended

© Newsmakers

Top Of The News: Bridgestone Says Don't Tread On Me

In 1999 alone, almost 2,000 Americans died when their sport utility vehicles rolled over.
But last year, nearly all the attention was on the 174 deaths "linked to"Bridgestone/Firestone tires. Now Bridgestone has finally had enough and with Ford Motor recalling more of its Explorer vehicles with Firestone tires, it has severed its century-old relationship with the auto giant.

Yesterday, there were widespread reports that Ford would replace 10 million to 13 million Firestone tires, in addition to the 6.5 million recalled last summer. But before Ford could act, Bridgestone/Firestone said it no longer would sell tires to Ford, ending a relationship that began with the Model T.
……
Ford said it has prepared its own statistical analysis of the tire problem done in conjunction with the **National Highway Transportation Administration**, but apparently without Bridgestone. This study, Ford says, indicates the remaining Firestone tires on Explorers fail more often than tires made by other manufacturers, although not as much as the tires already recalled.
…..
Feeling backstabbed, Bridgestone is calling an end to its dealings with Ford. "Business relationships, like personal ones, are built upon trust and mutual respect. We have come to the conclusion that we can no longer supply tires to Ford since the basic foundation of our relationship has been seriously eroded," said John Lampe, CEO of Bridgestone/Firestone.

What if … Effects

PTC® Live Global

Everyone was looking for who is most to blame but what if ….

An Engineer who designed the vehicle was riding in it the first time the tread separated

He/She would probably immediately recognize the effect of tire separation

Firestone / Ford Tire Controversy – Quality Component

PTC® Live Global

We use a consolidated PLM QMS to define and look for the high risk issues

- Maybe we can mitigate the issue without changing the inputs
  - We agree to go to market as they did
  - But use the consolidated Quality and Engineering system to predict, identify & mitigate the negative outcomes.
- If we look at this from a quality management perspective
  - We understand it is a multi-mode failure
    - Tires separation compounded by
    - Vehicle Instability – reduced the safety window
  - Use predictability and risk based FMEA to create surveillance codes
  - Actively monitor for failures that are predicted to have bad outcomes
    - Ie Tire Separation or failure by using the FMEA Effects
  - Anticipate a Preventive Action which will be triggered by fist notice of tire separation
- What we effectively do is put the Engineer in the Vehicle
  - Probably we head off the first serious injury or death
  - We don't re-design until we know it doesn't work in the real world

Qualities of effective CAPA systems – The Loop

PTC® Live Global

Consolidate your CAPA system around these points

- Engineering input to Surveillance Systems –
  - Engineering should push Failure Modes and effects down stream to monitoring systems that function as quality inputs for CAPA system
- Surveillance Drives CAPA – “Put the engineer in the vehicle”
  - CAPAs should take quality inputs codified in the way the engineer thought it could fail
  - Predict Poor Outcomes w Risk Based Codification – we know the worst failures to look for
- Effective CAPAs have strong Root Cause Analysis -
  - Core to CAPA effectiveness is Root Cause Analysis (RCA)
  - RCA Coded by using FMEA’s allow for measurement
- Root Cause Root Cause allows for Effective Change / Improvement
  - Systems are tied to Change and Configuration Management
  - New or Updated FMEA’s are pushed down stream again “Lessons Learned”
- Monitor for Effectiveness using new or Changed FMEA Codes
  - Integrated system loops back

Key Capabilities

PTC® Live Global

Quality Management Best Practices

- Corrective Action / Preventive Action
- Nonconformance Management
- Customer Complaints Management

Key Quality Management Capabilities

Integrated PLM Objects	Navigate easily between Quality artifacts and their associated PLM objects.	Visibility between engineering, Quality; connect to Quality documents, audits
Pre-defined Process Workflows	Establish workflows including engineering and quality teams	Track status, ensure structured comm-unication, leave no issue unresolved
Generate Engineering Change	Drive changes in product design from identified quality issues	Ensure a closed-loop process for Engineering to fix Quality issues.
End User Reporting Tools	Easy, intuitive controls to view Quality metrics and reports OOTB	Enterprise visibility into Quality

Enterprise QMS Combines Quality with Engineering

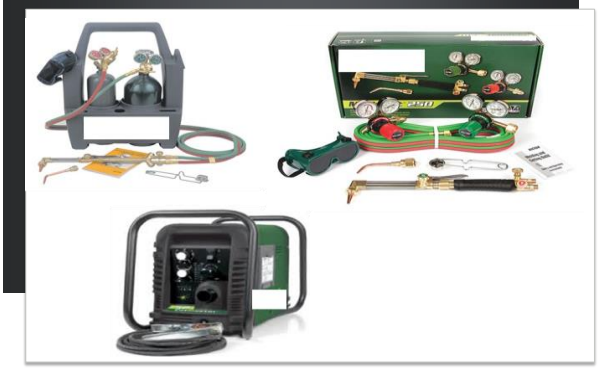
PTC® Live Global

Leading global provider of metal cutting, welding, and gas control technologies

With markets in the Americas, Europe, Asia Pacific, and Russia, this company is an ISO-certified global manufacturer seeking to solve end-user problems with branded solutions in cutting, welding and gas control. The application of their products serves a wide range of industries including automotive, construction, education, energy, fabrication, farm and ranch, maintenance and repair, manufacturing, mining, and transportation.

"You can't do QMS without PLM. It helps us join our engineering and our quality data for improved organizational efficiencies. … We want our customers happy, to reduce our losses, and to hopefully grow our business through that."

– Director of Quality
PTC Live, 2014



Source: PTCLive 2014.

References

PTC® Live Global

[1] http://www.tirefailures.com/coopertire/tirefailures.html

[2] http://www.autosafety.org/ford-explorer-firestone-tire

[3] http://www.firestone-tire-recall.com/pages/overview.html

[4] http://www.forbes.com/2001/05/22/0522topnews.html

- Your feedback is valuable
- Don’t miss out on the chance to provide your feedback
- Gain a chance to win an instant prize!
- Complete your session evaluation now

PTC® Live Global

PTC® PRODUCT & SERVICE ADVANTAGE®