Manufacturing Execution and Factory Automation Drive Product Quality

Silvio Saouaf – Product Manager, Camstar Systems, Inc.
Camstar Has Been a Leader for Over 25+ Years

• **Company At A Glance**
  – Privately Held
  – Founded 1984

• **Offices**
  – **USA** – Charlotte, NC; San Jose, CA
  – **APAC** – Singapore; Shanghai; Malaysia
  – **EMEA** – Germany; Netherlands; Ireland

• **Industries**
  – Solar
  – Semiconductor
  – Medical Devices
  – BioTech/BioPharma
  – Rolled Goods
  – Electronics

Headquartered in Charlotte, North Carolina
Camstar Customers Across Life Sciences

- Medical Equipment
- Medical Device
- Medical Supplies
- Hybrid
- Pharmaceutical Finishing
- Pharmaceutical Active Ingredient
- Biotech & Personalized Medicine

Discrete Assembly | Discrete Repetitive | Batch

- Top 5 Med Dev
  - 2 Subsidiaries
- Top 5 Med Dev
  - 2 Subsidiaries
- Top 5 Med Dev
  - 3 Subsidiaries
- Top 5 Med Dev
  - 3 Subsidiaries
- Top 5 Med Dev
  - 3 Subsidiaries

- ZEISS
- BIOTRONIK
- CaridianBCT
- Abbott
- 3M
- Noven
- life technologies
- ZOLL
- CIBA Vision
- COVIDEN
- Boston Scientific
- Abbott Nutrition
- Roche
- FAVRILLE
- STIRLING Medical Innovations
- Hutchinson Technology
- TERUMO
- ISA Tarheel Capital Area Section
- North Carolina Biotechnology Center
- Carolina-South Atlantic Chapter

Setting the Standard for Automation

Engineering Pharmaceutical Innovation
Product Quality Realized across Innovation Lifecycle & Value Chain
Advancing Product Quality: A Holistic Closed-loop Approach

**Advancing Product Quality**

- Define the product/process
- Enforce manufacturing per product/process
- Manage service & repair, and bring together internal and customer feedback
- Improve current and future product designs through learning from all prior stages
- And continuously enhance process and product quality.

*Then regulatory compliance becomes a natural outcome, rather than a singular objective.*
Product Quality Realized across Innovation Lifecycle & Value Chain

Investing in Prevention will Drive Down Overall Cost

Value Chain
- Supplier Assessment
- Design Engineering
- Manufacturing
- Distribution
- Customer Field

Cost of Resolution

High

Low

Cost of Good Quality

Cost of Poor Quality

Supplier Quality

Mfg Enforcement

Non-Conformance

Complaint

Recall
Recalls, Recalls Everywhere

Battery Recall Could Cost Dell About $246 Million

Dell said the Sony laptop battery debacle would not lead to any "material" financial PC giant, despite the fact that the recall is expected to cost at least $246 million.

By Edward F. Moltzen
CRN
August 18, 2006 03:23 PM

Toyota recall costs: $2 billion

Senior writer February 4, 2010: 10:00 AM ET

CNNMoney.com) -- Toyota Motor says the massive recalls of gas pedal problems could end up costing it $2 billion.

Toyota's market share plummets

Toyota's January recall and the subsequent halt in sales of top models could be its worst sales month in more than a decade. Its U.S. market share dropped by 11.3%.


Setting the Standard for Automation®
Product Quality Realized across Innovation Lifecycle & Value Chain

ERP
- Demand Variability
- Orders

ERP/PLM
- Design Variability
- Product

Suppliers
- Receiving Inspection

Process/Product Variability
- Material Certification
- Operator Certification
- Equipment Calibration
- Process Control/Test Data
- Rework
- Route Assurance
- Identification and Traceability
- “As Built” History

CRM

Providers

Patients

Customer

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INTEERING PHARMACEUTICAL INNOVATION
Real-Time Enforcement - Material

Enforcing materials per BOM or recipe
- Correct component and revision
- Correct quantity or volume
- Not expired

Supports discrete and batch processes
- Kitting, campaign dispensing
- Serialized components or lot-based materials

Process/Product Variability

Receiving Inspection

Material Certification

Suppliers

Providers

Patients

Customer

“As Built” History

Route Assurance

Identification and Traceability

Suppliers

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Engineering Pharmaceutical Innovation
Real-Time Enforcement - Man

Enforcing Operator Training and Certification
• Presents correct process revision (existing or new)
• Allows operator to proceed only if trained and certified on product, process, spec, equipment, etc.
• Ensures regulatory compliance

Suppliers
Receiving Inspection
Process/Product Variability
Operator Certification
Material Certification
Equipment Calibration
Process Control/Test Data
Route Assurance
Identification and Traceability

“As Built” History

Providers
Customer

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Setting the Standard for Automation®
Real-Time Enforcement - Machine

Enforces Resource Usage and Readiness
• Ensures equipment or instrument is appropriate per specification
• Allows use only if maintained per schedule
• Ensures regulatory compliance

Process/Product Variability

Receiving Inspection

Equipment Calibration

“As Built” History

Suppliers

Providers

Patients

Customer

Material Certification

Operator Certification

Process Control/Test Data

Route Assurance

Identification and Traceability

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Setting the Standard for Automation
Real-Time Enforcement - Measure

Ensure all data is complete
- Can stop product or process if result is out-of-spec
- Automated data collection and machine automation for speed and accuracy

Prevents scrap with SPC and early warnings
- Real-time notification and action for OOS/OOT conditions

Prevents “quality escapes”

Suppliers

Receiving Inspection

Process/Product Variability

Providers

“As Built” History

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Setting the Standard for Automation

Material Certification
Operator Certification
Equipment Calibration

Process Control/Test Data

Route Assurance
Identification and Traceability
Real-Time Enforcement - Method

Enforce Routes, Processes, Tasks, Exceptions
Support complex processes
- Alternate accepted routes and rework procedures
- MRB hold, review, disposition
- Planned deviations
- Split, merge, bin

Process/Product Variability

Suppliers
Receiving Inspection
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Route Assurance

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“As Built” History

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Setting the Standard for Automation
Real-Time Enforcement - Supplier

Ensure Supplier Quality
- Enforcing that Supplier delivers high-quality raw materials
- Real-time visibility into Supplier process to ensure they are building to your defined specs

Eliminates Source of Poor Supplier Quality
Provides Supply Chain Material Traceability & Genealogy

Process/Product Variability

Suppliers

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"As Built" History

Route Assurance

Identification and Traceability

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Setting the Standard for Automation
How Can Automation Advance Product Quality?

- **Automates Data Collection**
  - Direct equipment integration, such as a weigh scale or machine
  - Eliminates human error of capturing and recording data collected from the equipment

- **Ensure Machine Parameters**
  - Automate downloading of machine settings, without the need for human decision

- **Error Proof Execution**

- **Transform “islands of automation”**
  - As-manufactured history is complete for correlation and root cause analysis

- **Reduces Variability**
How Can Automation Advance Product Quality?

- High Speed Data Collection for Data Analysis
  - Automatically collect hundreds of WIP and Process data points per second
  - Data can be analyzed and correlated with logistics information to improve and refine the product or process definition

- Enable Continuous Improvement
How Do You Measure the Impact of a Quality Solution Over Time?

- Process Automation
- Process Leaning
- Production & Quality Controls
- Performance Management
- Dynamic Adaptation

Performance

Maturity

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Setting the Standard for Automation
How Do You Measure the Impact of a Quality Solution Over Time?

- A reduction in the **number** of quality issues
- A reduction in the **severity** of issues
- More **preventive** actions over time
- Better **designed** products/processes
- **Fewer** issues from the field
- Improved customer **satisfaction**
- Positive impact on **top, middle and bottom line**

**Shift from “Compliance” Focus to Quality Performance Focus**

**Learning Organizations**

**Improved Product Performance (ADAPT)**
Questions?

Silvio Saouaf, Product Manager, Camstar Systems, Inc.
Thank You