



Manufacturing Execution and Factory Automation Drive Product Quality

Silvio Saouaf – Product Manager, Camstar Systems, Inc.



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Section**

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**North Carolina
Biotechnology Center**



ENGINEERING
PHARMACEUTICAL
INNOVATION

**Carolina-South
Atlantic Chapter**

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**



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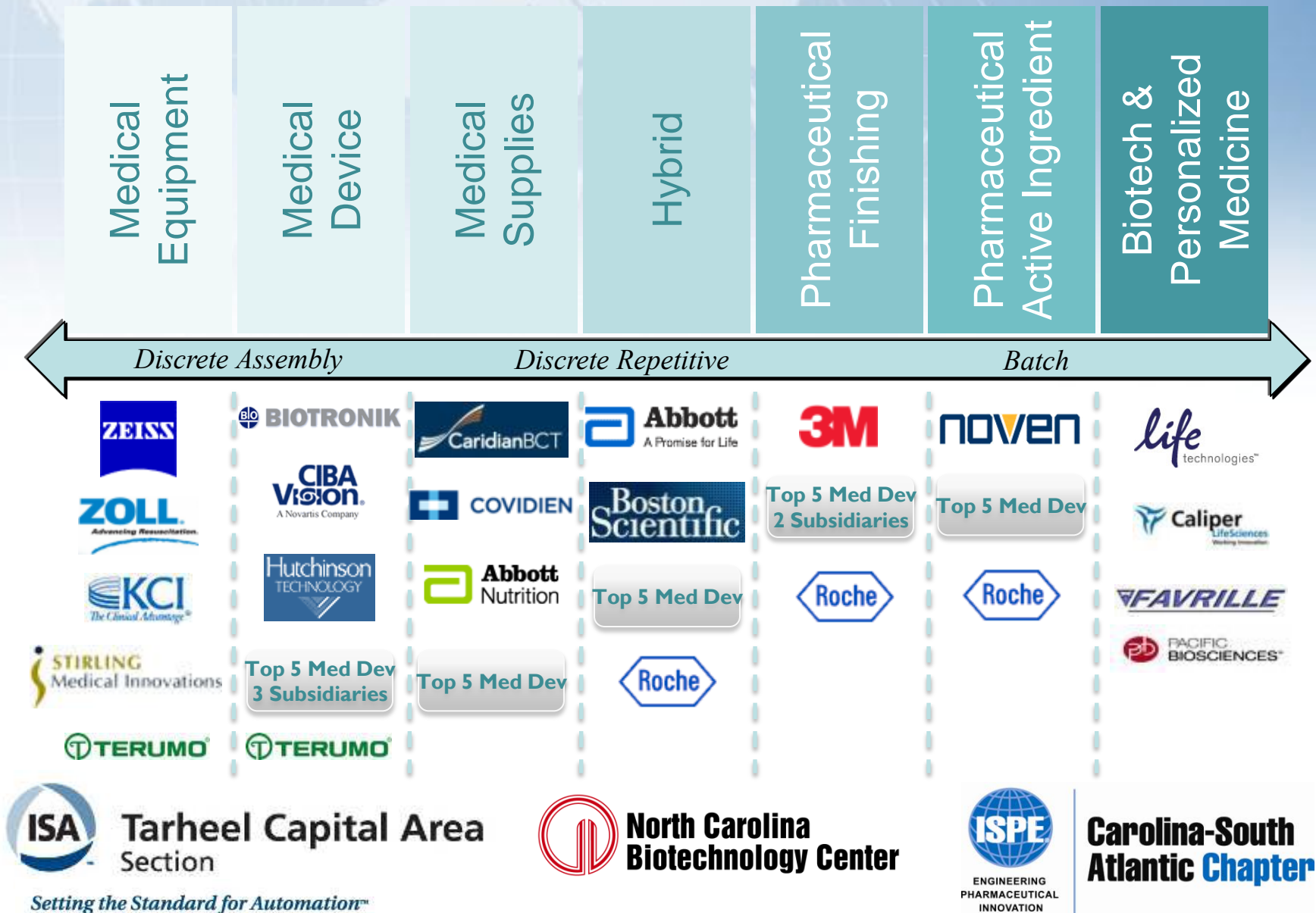
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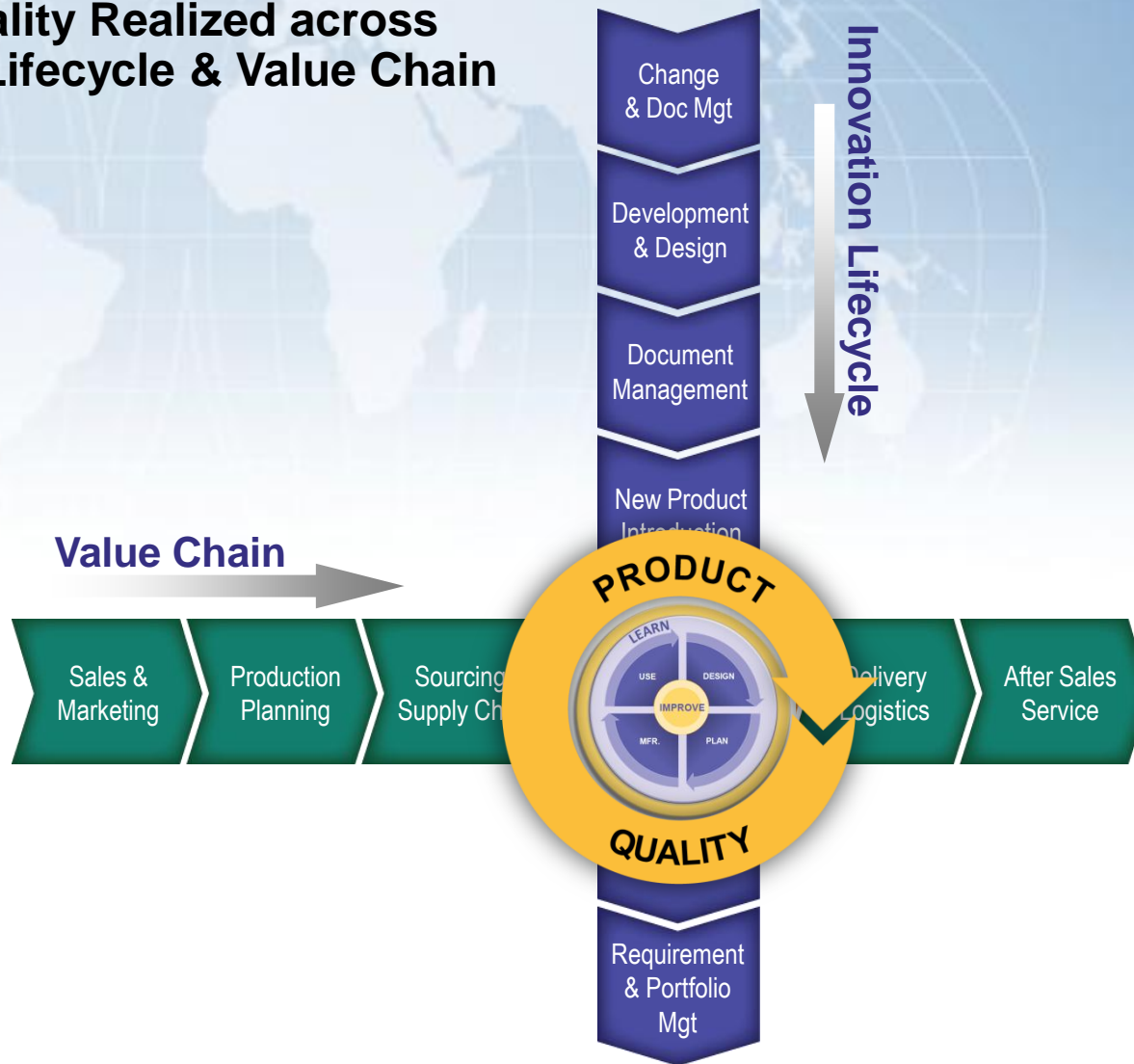
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Camstar Customers Across Life Sciences



Product Quality Realized across Innovation Lifecycle & Value Chain



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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.**



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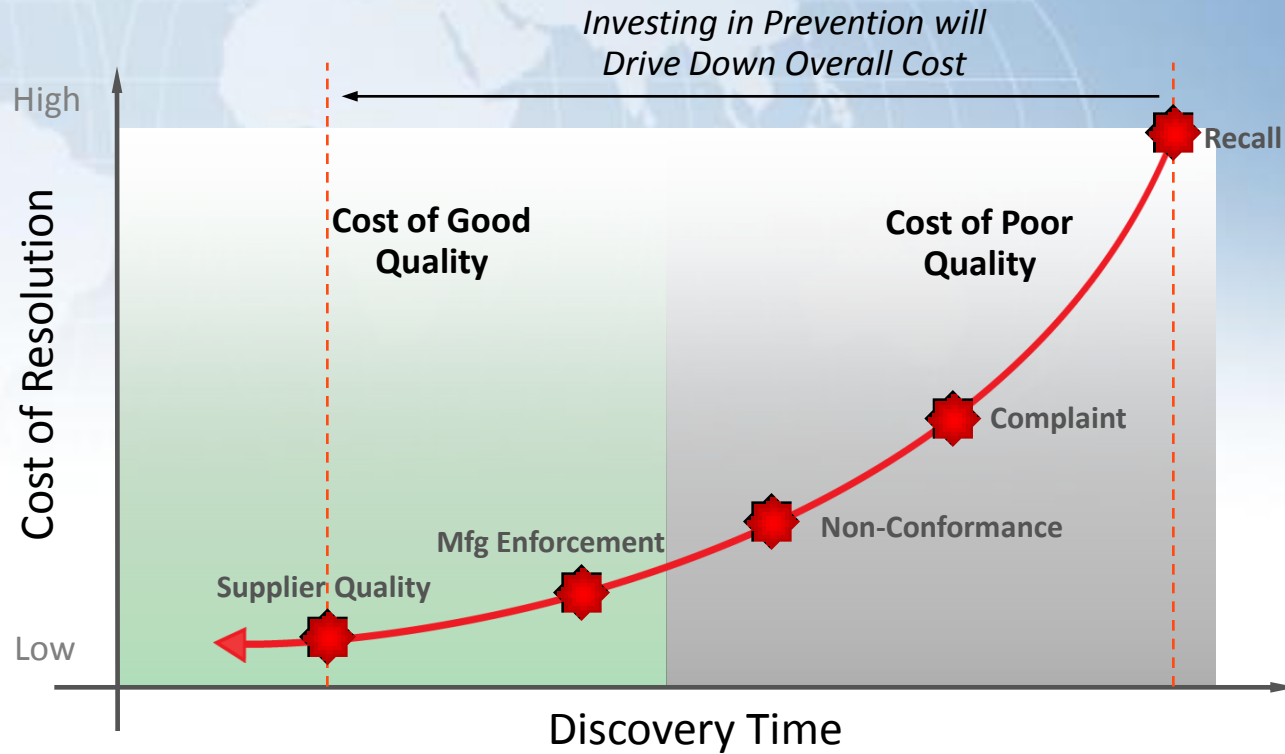
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Product Quality Realized across Innovation Lifecycle & Value Chain



Value Chain



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Recalls, Recalls Everywhere

InformationWeek

THE BUSINESS VALUE OF TECHNOLOGY

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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

CNNMoney.com™

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Toyota recall costs: \$2 billion

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

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

Toyota's market share plummets

Toyota's January recall and the subsequent halt it put on sales of top models caused its worst sales month in more than a decade. Its U.S. market share dropped by 3 points.



SOURCE: Motorintelligence.com | Tobey/The Washington Post - February 3, 2010



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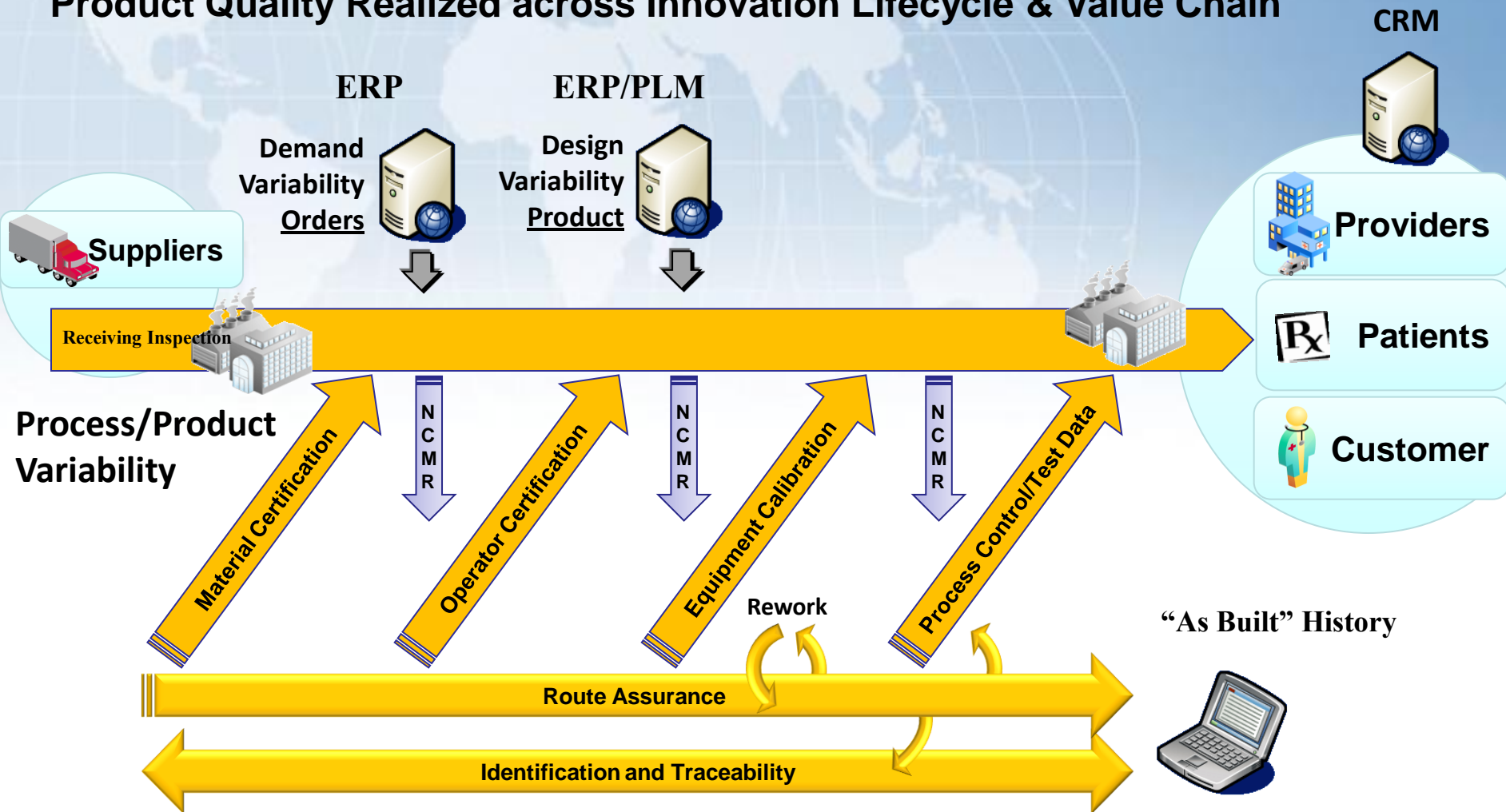
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Real-Time Enforcement - Material

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



Suppliers

Receiving Inspection



Providers



Patients



Customer

Process/Product
Variability

Material Certification

NCMR

Operator Certification

NCMR

Equipment Calibration

NCMR

Process Control/Test Data

Route Assurance

Identification and Traceability

“As Built” History



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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



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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



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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”



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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



Suppliers

Receiving Inspection



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Process Control/Test Data

Rework

Route Assurance

Identification and Traceability

“As Built” History



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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



Suppliers

Receiving Inspection



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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

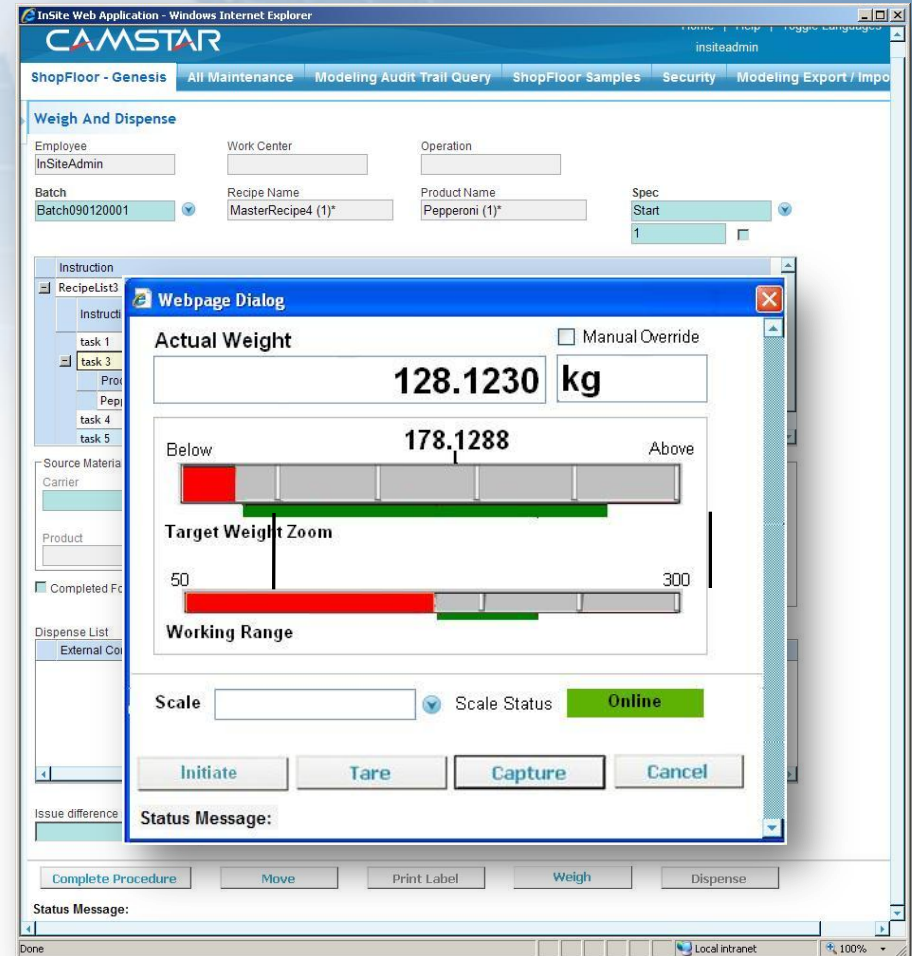
- Automate downloading of machine settings, without the need for human decision

■ Error Proof Execution

■ Transform “islands of automation”

- As-manufactured history is complete for correlation and root cause analysis

➤ Reduces Variability



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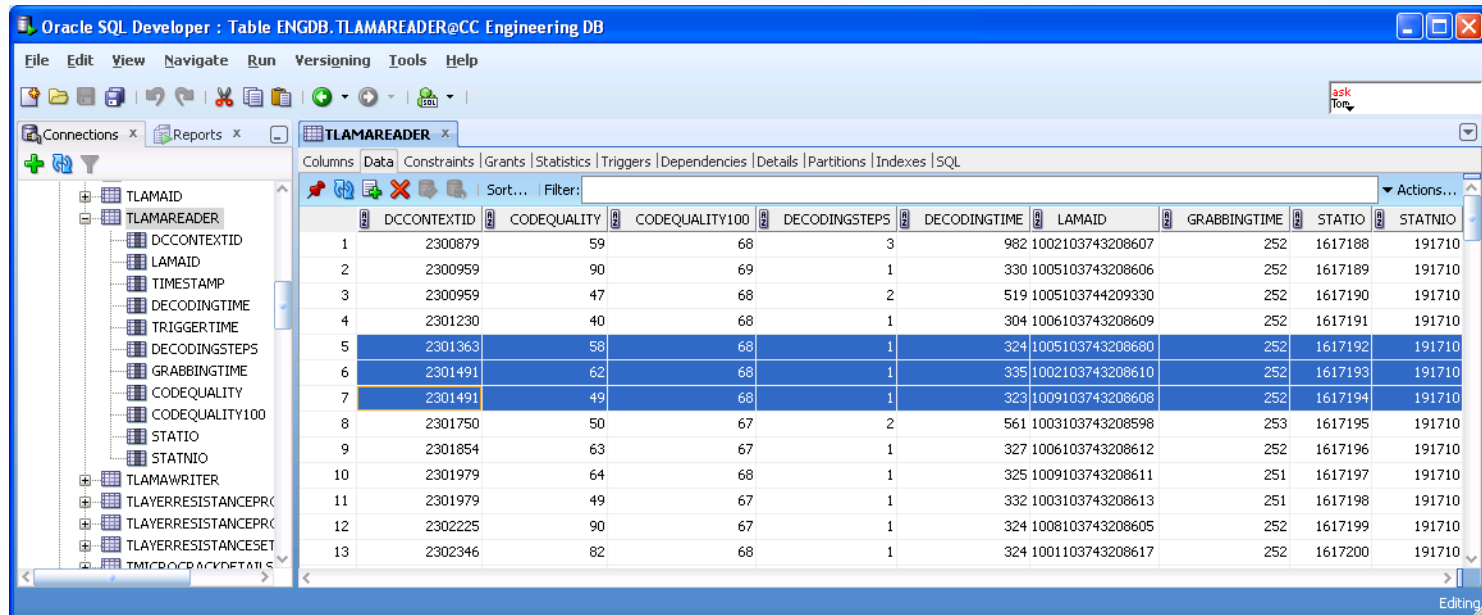
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How Can Automation Advance Product Quality?

- **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**



Oracle SQL Developer : Table ENGDB.TLAMAREADER@CC Engineering DB

File Edit View Navigate Run Versigning Tools Help

Connections x Reports x

TLAMAREADER

Columns Data Constraints Grants Statistics Triggers Dependencies Details Partitions Indexes SQL

	DCCONTEXTID	CODEQUALITY	CODEQUALITY100	DECODINGSTEPS	DECODINGTIME	LAMAID	GRABBINGTIME	STATIO	STATNIO
1	2300879	59	68	3	982	1002103743208607	252	1617188	191710
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How Do You Measure the Impact of a Quality Solution Over Time?



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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**



Learning Organizations

*Improved Product
Performance (ADAPT)*

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



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Questions?

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Camstar Systems, Inc.



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Thank You



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