

TRACEABILITY

QUALITY



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Omnex provides training, consulting and software solutions to the international market with offices in the USA, Canada, Mexico, China (PRC), Germany, India, the Middle East, and SE Asia. Omnex offers over 400 standard and customized training courses in business, quality, environmental, food safety, laboratory and health & safety management systems worldwide.

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Contents

- Chapter 1 – Traceability
- Chapter 2 – System Application and benefits
- Chapter 3 – Internal, External, customer
- Chapter 4 – Design, verification and Validation Requirements
- Chapter 5 – Requirement linkage to PPAP (PFMEA and CP)
- Chapter 6 – Marking and identification
- Chapter 7 – 4M requirements
- Chapter 8 – ERP and other IT Systems
- Chapter 9 – IIOT Systems

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A BRIEF INTRODUCTION TO OMNEX

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Omnex Introduction

- International consulting, training and software development organization founded in 1985.
- Specialties:
 - Integrated management system solutions.
 - Elevating the performance of client organizations.
 - Consulting and training services in:
 - Quality Management Systems, e.g., ISO 9001, IATF 16949, AS9100, QOS
 - Environmental Management Systems, e.g., ISO 14001
 - Health and Safety Management Systems, e.g., ISO 45001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
 - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.



About Omnex

- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 700 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for ISO/TS 16949.
- Served on committees that wrote QOS, ISO 9001, QS-9000, ISO/TS 16949 and its Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Former member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).



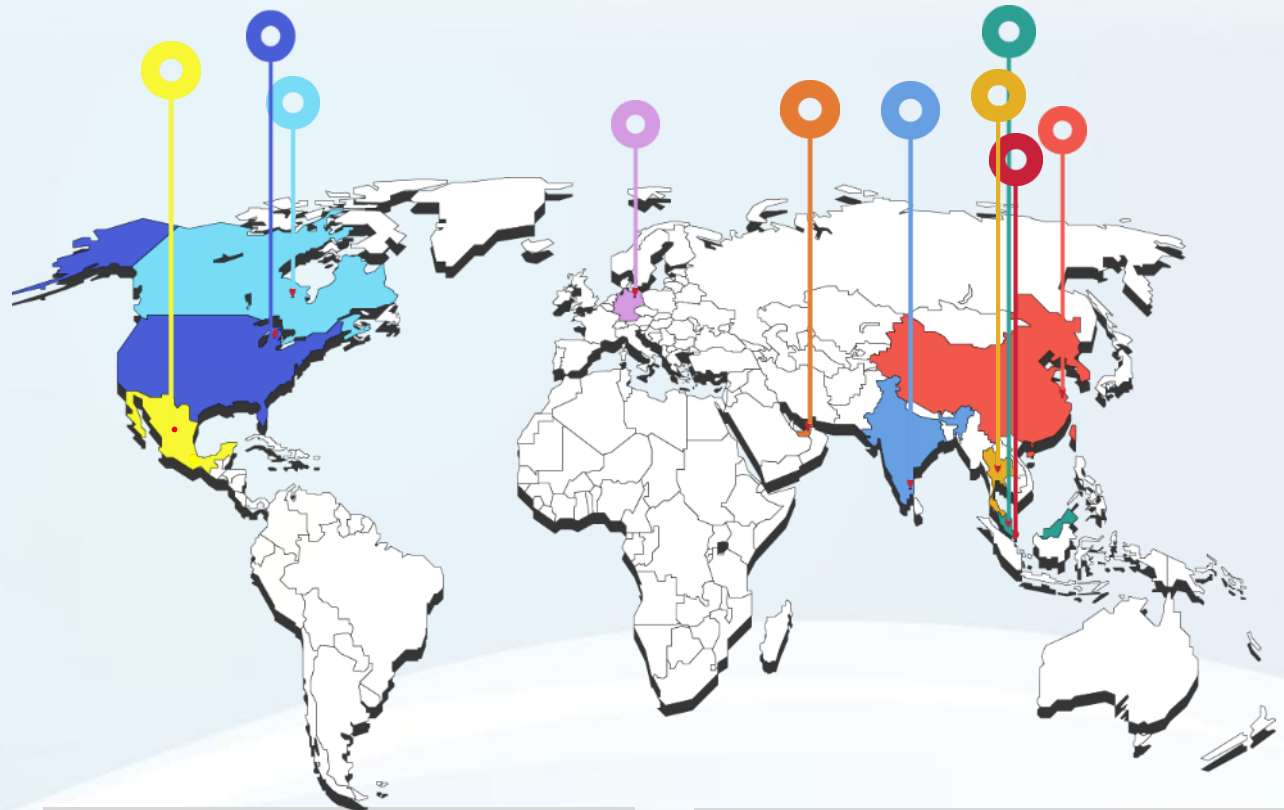
Omnex Worldwide Offices



Omnex is headquartered and operates from the United States through offices in Michigan.

The company maintains international operations in many countries to provide comprehensive services to clients throughout Western Europe, Latin America and the Pacific Rim.

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● Omnex Global Head Quarters (Michigan, USA)
West Coast Operations (San Jose, CA)

● Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)

● China (Shanghai, Guangzhou, Wuhan, Chengdu)

● Canada (Mississauga)

● Europe (Berlin, Germany)

● Middle East (Dubai, Saudi Arabia, Bahrain)

● Thailand (Bangkok)

● Mexico (Monterrey)

● Singapore

● Malaysia (Kuala Lumpur)



Rules of the Classroom

- ✓ Start and end on time
- ✓ Return from breaks and lunch on time
- ✓ All questions welcome
- ✓ Your input is valuable and is encouraged
- ✓ Don't interrupt others
- ✓ One meeting at a time
- ✓ Listen – and respect others' ideas
- ✓ No “buts” – keep an open mind
- ✓ Phones in Do Not Disturb (silent) mode
- ✓ No e-mails, texting or tweeting during class

If you must take a phone call or answer a text please leave the room for as short a period as possible

Icebreaker

- Instructor Information:
 - Name
 - Background
- Student Introductions:
 - Name
 - Position / Responsibilities
 - What is your involvement in the Quality Management System and the auditing process?
 - What do you expect to take away from this class?
 - Please share something unique and/or interesting about yourself.



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Chapter 1

Traceability

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Traceability

Traceability is the ability to trace all processes from procurement of **R**aw **M**aterials to **P**roduction, **C**onsumption and **D**isposal to clarify "when and where the product was produced by whom."

Due to improving product quality and the rise in safety awareness in recent years, traceability has been increasing in importance and spreading into a wide range of fields, such as automotive, electronics, food and pharmaceutical.

You may ask

Is it worth putting a traceability on each of the 10 - 20,000 parts or components that make up in an automobile

Answer is Yes

Traceability in Automotive industry

Traceability for the automotive industry is a process that documents the genealogy of the parts and sub-assemblies associated with a specific vehicle or range of vehicles. The type of information tracked will vary, but some of the more commonly collected information include –

- * Source Manufacturer
- * Place of origin
- * Lot number
- * Model number
- * Components used in assembly
- * Manufacturing or assembly facility
- * Production time and date
- * Part number / Serial number
- * Documents
- * Expiration date, etc.

All of this data can be accumulated and combined into a traceable code (barcode) and marked on the part. Barcode readers then decode the data through out the part's lifecycle and reliably transfer the information into an Enterprise Resource Planning (ERP) software system ensuring full traceability for each part of a finished vehicle.



While Setting Objective

- The objective of Traceability Standard is to assist organizations and industries in the design and implementation of traceability systems of standards.
- The objective must be intended to help organizations and industries to achieve global supply chain traceability
- Enabling lifetime imperishable communication across supply chains by providing consistent ways to identify traceability to parts or system
- At a strategic level, the standard shall aims to provide key insights and knowledge for organizations or industries that are developing long-term traceability goals.
- Providing a methodology for organizations while designing requirements of traceability systems
- Serving as the foundational stone

While Setting Scope

The scope of the traceability system of a part will depend on the role of the organization and the traceability questions that need to be addressed.

Some elements that define the scope of a traceability system are:

- How many tiers up and down your supply chains will you need to share data?
- Will you need to interact with only direct supply chain partners, or will your system require a broader scope?
- Will you track main ingredients only, or also packaging and indirect materials?
- Will your system need to integrate data sharing with final consumers / end customers?
- Will your system need to integrate data coming from supply chains
- Which process steps need to be captured?
- What is the most cost effective way to capture the data?

Why is “Traceability” Important

Minimizing Customer complaints, warranty, rejects and recalls

- How much it could cost to find the problem, fix it, and then find and fix all of the affected parts.
- If the part makes it further downstream to the assembly plant, it could cost exponentially more to fix, as well as damage the supplier’s quality rating with the automaker.
- Should the problem reach consumers while the automobile is in service, the total recall costs can be XX times that.
- With a solid traceability program in place, these costs remain at the minimums with the least disruption

Why is “Traceability” Important

- Monitoring process control, CC & SC characteristics
- Real-time tracking systems can help reduce lead times and optimize the supply chain by providing information about work movements from zone to zone. These tracking systems are based on work in process (WIP) identification and associates the data with other management and control systems.
- If, or when you find a bottleneck or problem, you will know
- what - it is as well as
- Where - it is within the process

Why is “Traceability” Important

- Implemented error proofing methods
- Traceability poka-yoke (an error proofing mechanism used in a lean manufacturing process) improves quality by ensuring that the appropriate processes are performed in the correct sequence on the right parts. In addition to eliminating manual part number data entry errors
- Code reading can also assist in data logging for safety, liability, and warranty issues, and satisfy regulatory requirements for permanently identifying high-value parts that are subject to theft or counterfeiting.

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Ice Breaker

- What do you check on the product when you go to a super market and bring it to your house?
- One thing we all know is Price and Discount. Based on the daily / weekly requirement what are the other check and activity you do?

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Ice Breaker

When we go to Store shelf?

- : we check for date of manufacturing, we pick the product with more time period
- : we check the batch number and with it we find where was the product manufactured
- : we check for ingredients and even Google for the preservative added
- : we check for certification number from legal body
- : we check for quantity, colors and flavors
- : we check for dosages requirement
- : we check the storage condition

When we go to Billing counter?

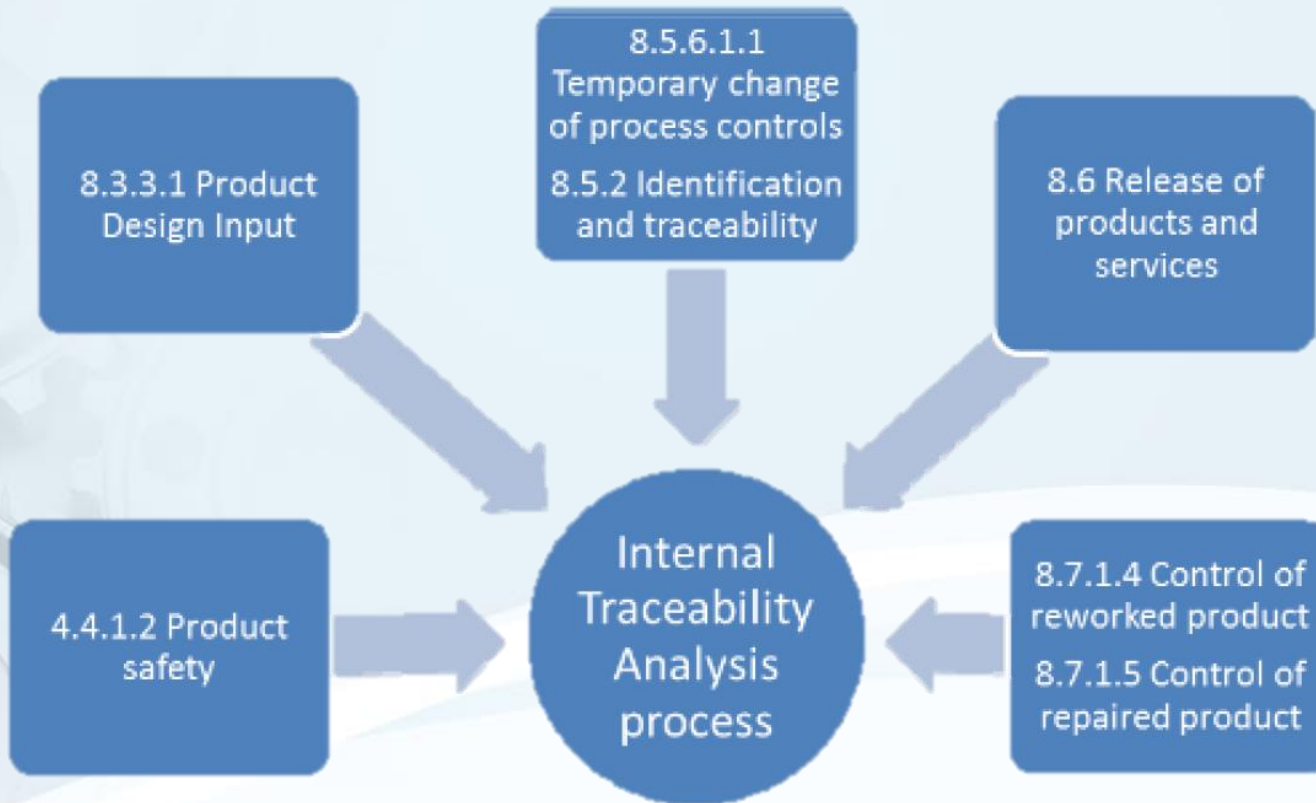
- : operator can operate the counter only if he keys his ID & password or scan his I card.
- : bill get generated only once all the items are entered.
- : we compare the price mentioned on the shelf and on the bill
- : we check the products purchased are placed properly in side our bag or baskets

When we store in our house?

- : we keep it at desired location
- : we keep new product below the old product or keep it alone until we use the old one
- : some houses have identification on the containers
- : we do not destroy the shelf life information till we consume the product



Requirements in IATF requirement 16949 - traceability



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Chapter 2

Traceability – System Application

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Traceability – System Application

- We all know manufacturing is becoming increasingly more efficient, customized, modular, and automated, but we and the manufacturers are slow in adopting the technology as it needs new investments.
- As industrial technology requires increasing auditability and digitization, the manufacturing industry will need to continue to embrace new technology.
- Even though there are different system and technologies in a manufacturing process, one of the answer to this is ‘Traceability’, lets go one by one to see how traceability is applied

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Traceability – System Application

Application where traceability can be applied

- Product R&D
- Supplier Management & Sourcing
- Operations Monitoring & Data
- People Management
- Maintenance Data
- Quality Assurance (QA)
- Warehousing
- Transport

**“If you always do what you always did, you’ll always get what you always got.”
Henry Ford**

Traceability – System Application

Product R&D

- The product development process has become a matter of managing complexity of the product development process.
- Traceability like the life of a product and its requirement is one key tool to manage the complexity challenge.
- When traceability is carried out correctly, teams can accurately assess
 - The impact of changes.
 - Track the full history of product development.
 - Keep everyone in sync in project and
 - Consistently improve the quality of the products being developed.



Traceability – System Application

Supplier Management & Sourcing

- Once a product design is finalized, the next step is planning how it will be made
- As there is continuous demand for flexibility, speed and seamless integration across multiple system a robust supplier management solution is a need for converging day-to-day requirements in the automotive industry.
- A Typical traceability involves all the activities followed by your company like
 - Suppliers and manufacturing location
 - Basic materials used
 - Performance on Development, Quality & Delivery against order
 - Real-time inventory
 - Packing and Transportation etc.

Traceability – System Application

Operations Monitoring & Machine Data

- Traceability in manufacturing ensures processes and product quality standards are met and give real-time information about production and equipment.
- Tracking production information back to the exact date, time, supplier components, operator and machines used will help organization
 - Increase customer satisfaction and safety
 - Improve product and process accuracy
 - Increase operational productivity
 - Reduce warranty claim costs and generate revenues
 - Protect your brand and bottom line

Traceability – System Application

People Management

- What manufacturing looks like has changed drastically in a short time, people on the plant floor also need to be much more skilled than they were in the past
- Tracking the efficiency and safety of manpower and availability of the workers will boost the operation productivity and skills of industrial worker & drastically reduce the physical toll of repetitive work
- Tracking also helps in predictive to intervene before risk of injury or incident where manpower is still needed for some hazardous and dangerous tasks

Traceability – System Application

Maintenance Data

- Customers expect manufacturers to provide excellent quality, reliable delivery and competitive pricing. This demands that the manufacturer's machines and processes are highly reliable.
- In order to possess highly reliable machines to make sure smooth manufacturing process, tracking organizations Maintenance will help enable the machine and tool to maximize the effectiveness of equipment
- By tracking maintaining the organization can optimize relationship between people and their machines with added advantage of reducing time delays, added costs, and waste

Traceability – System Application

Quality Assurance (QA)

- In mass production, checking whether every product is meeting specification is a very tiresome job and tracing / tracking any error in the product once it has left the station or plant is limited to human weakness
- Traceability in quality helps organization in tracing / tracking product, process as well as calibration of equipment's and instruments

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Traceability – System Application

Warehousing

- As computer based ERP along with IIOT planning, fewer people and display boards will be needed in sorting, standardizing, and arranging the material in wear house
- A computer based system will
 - Count the number of boxes in a pallet
 - Count the quality in each boxes
 - Identify the packing condition etc.

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Traceability – System Application

Transport

- In general, there is poor awareness about where items are in real time throughout the supply chain, once the product is packaged and palletized, getting it delivered to customer in an efficiently way is a daunting task
- With addition of IIOT and fleet telematics, organisation can track
 - The real time movement of the products
 - Route information used by the transporter
 - Pick up and deliver date and timings etc.

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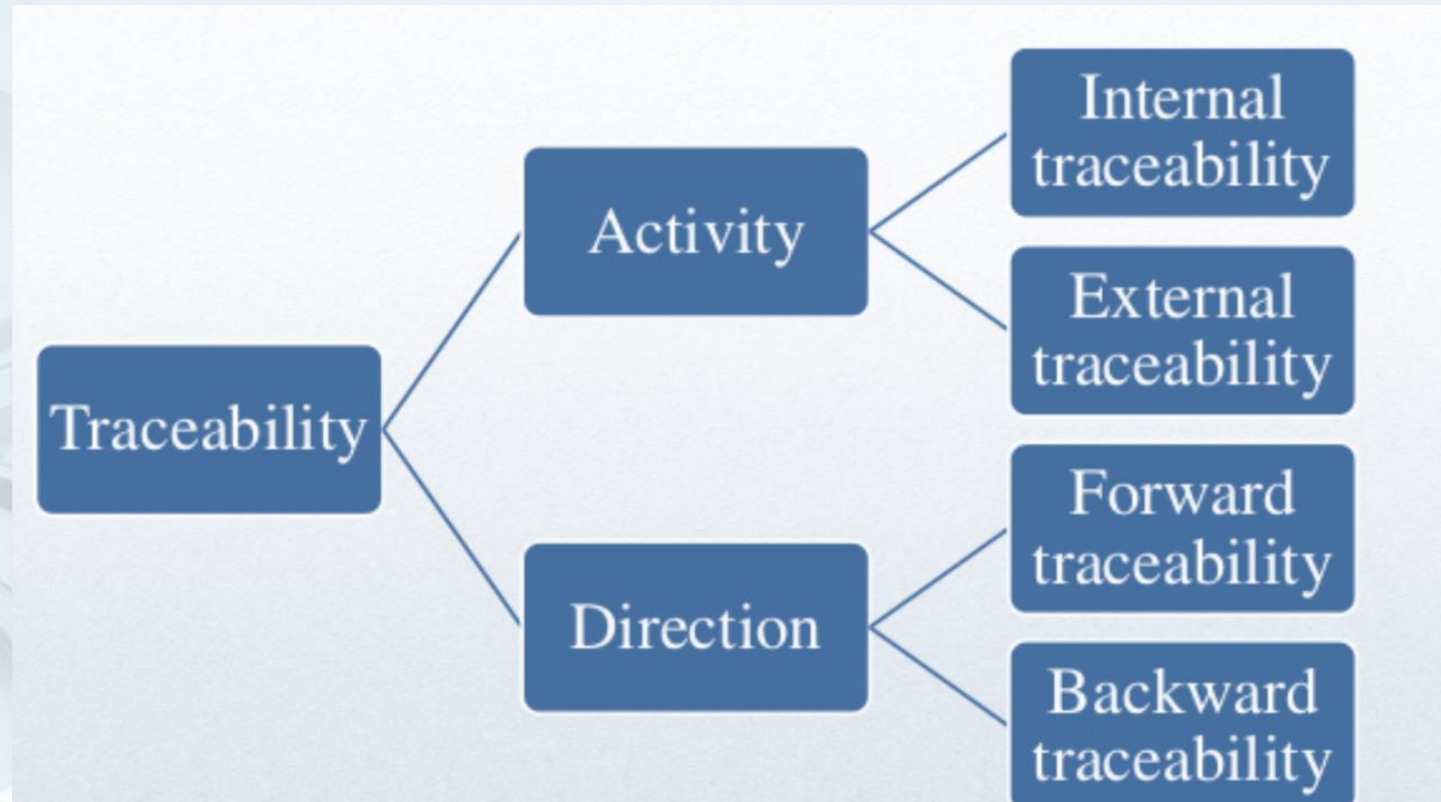


Chapter 3

**Traceability - Internal, External,
customer and supplier (tier 2,3..)
logistics**

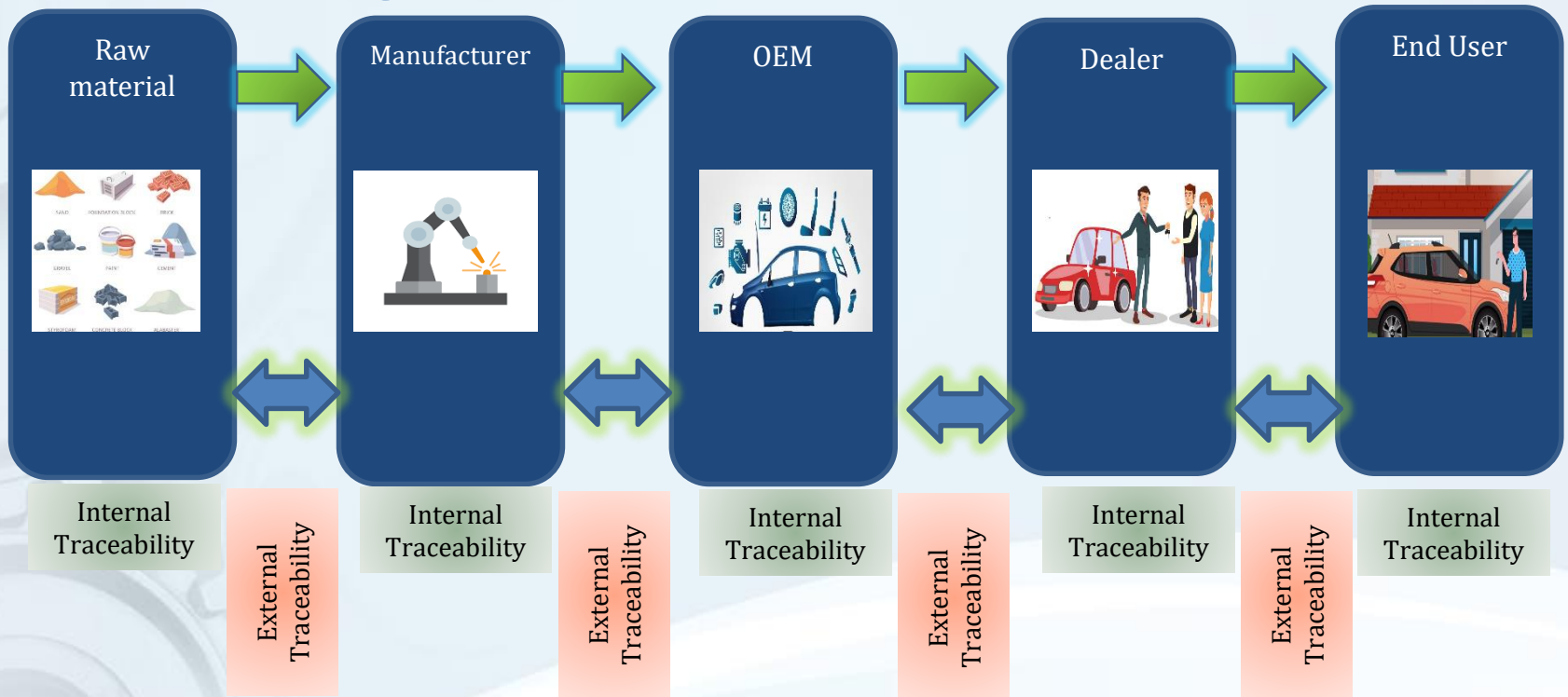


Traceability Type

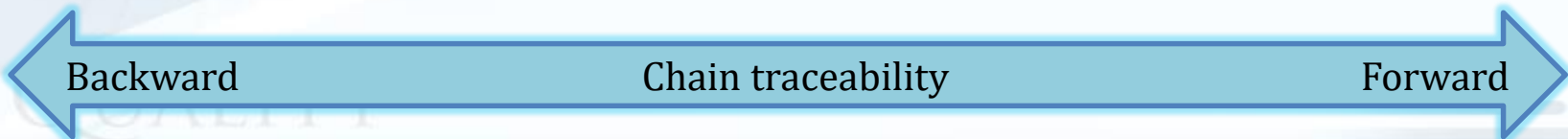


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Traceability Flow



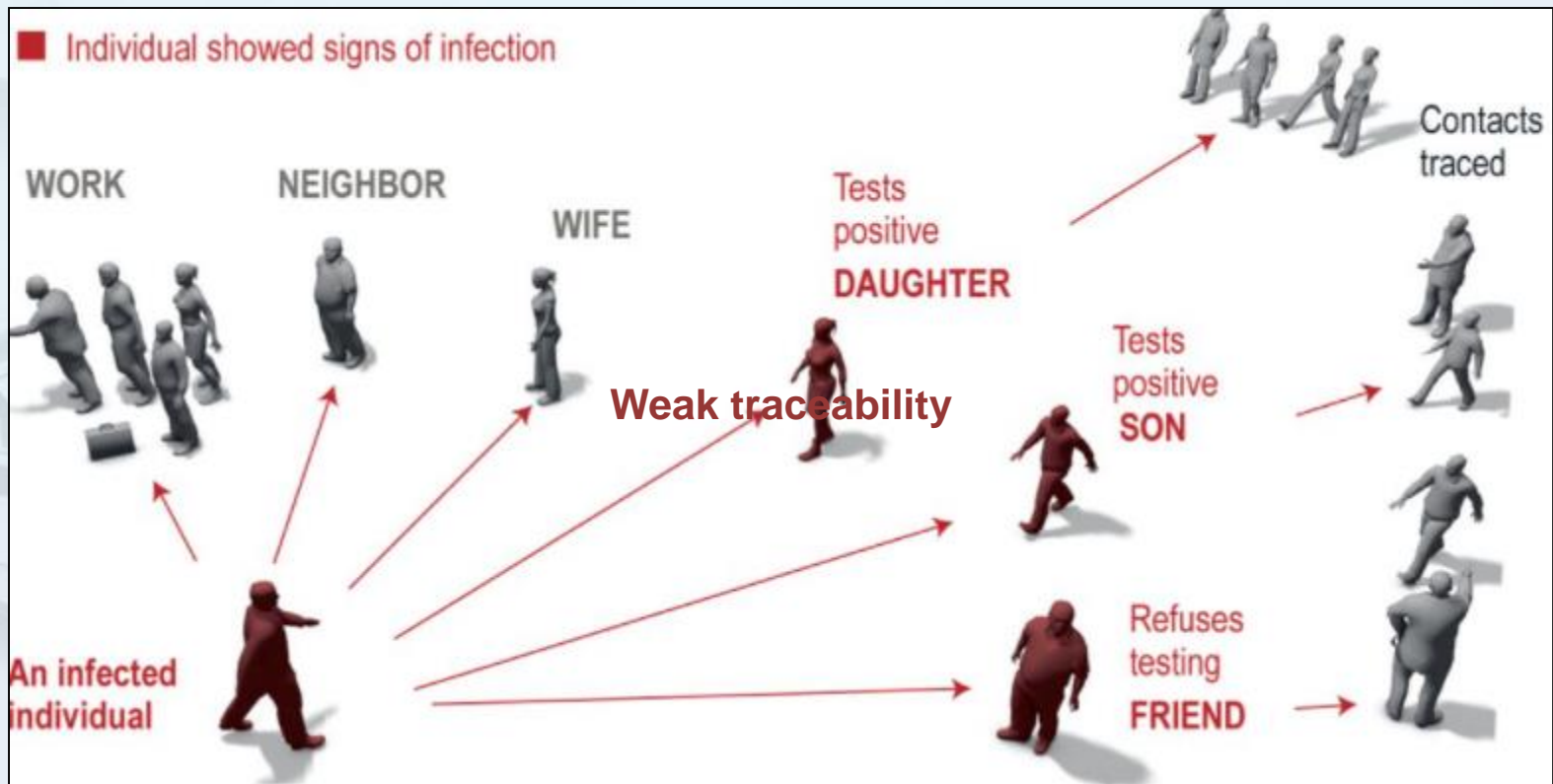
Tracing (Backward traceability)



Tracking (Forward traceability)



Looking at the present scenario



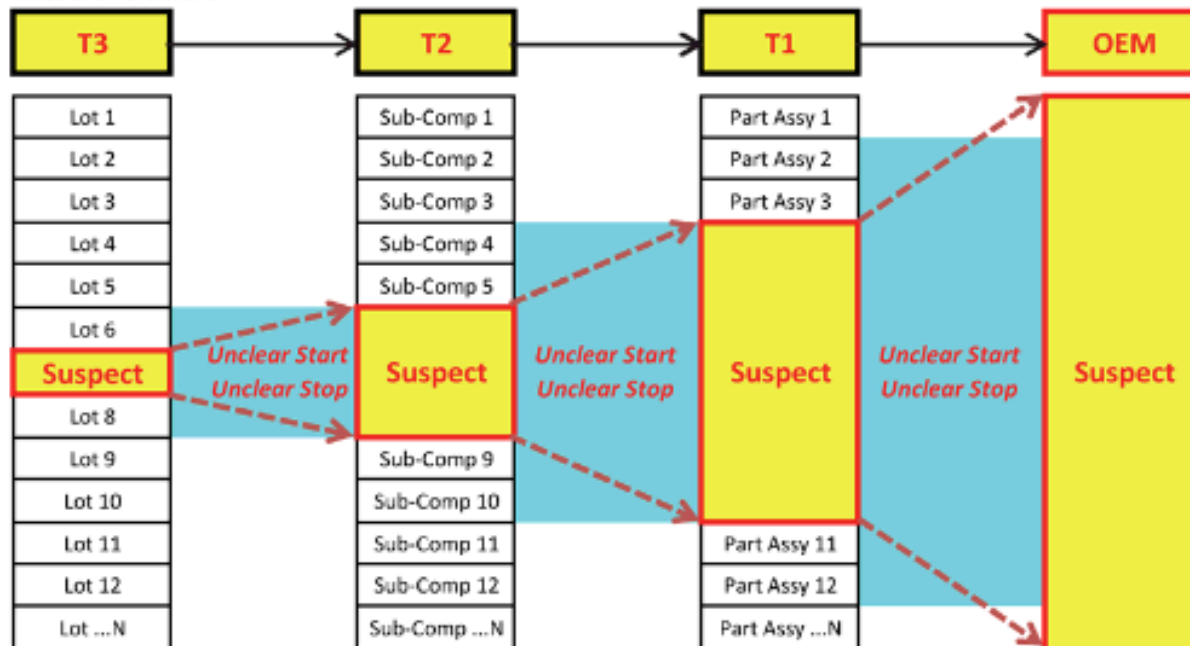
Weak Traceability

Similar

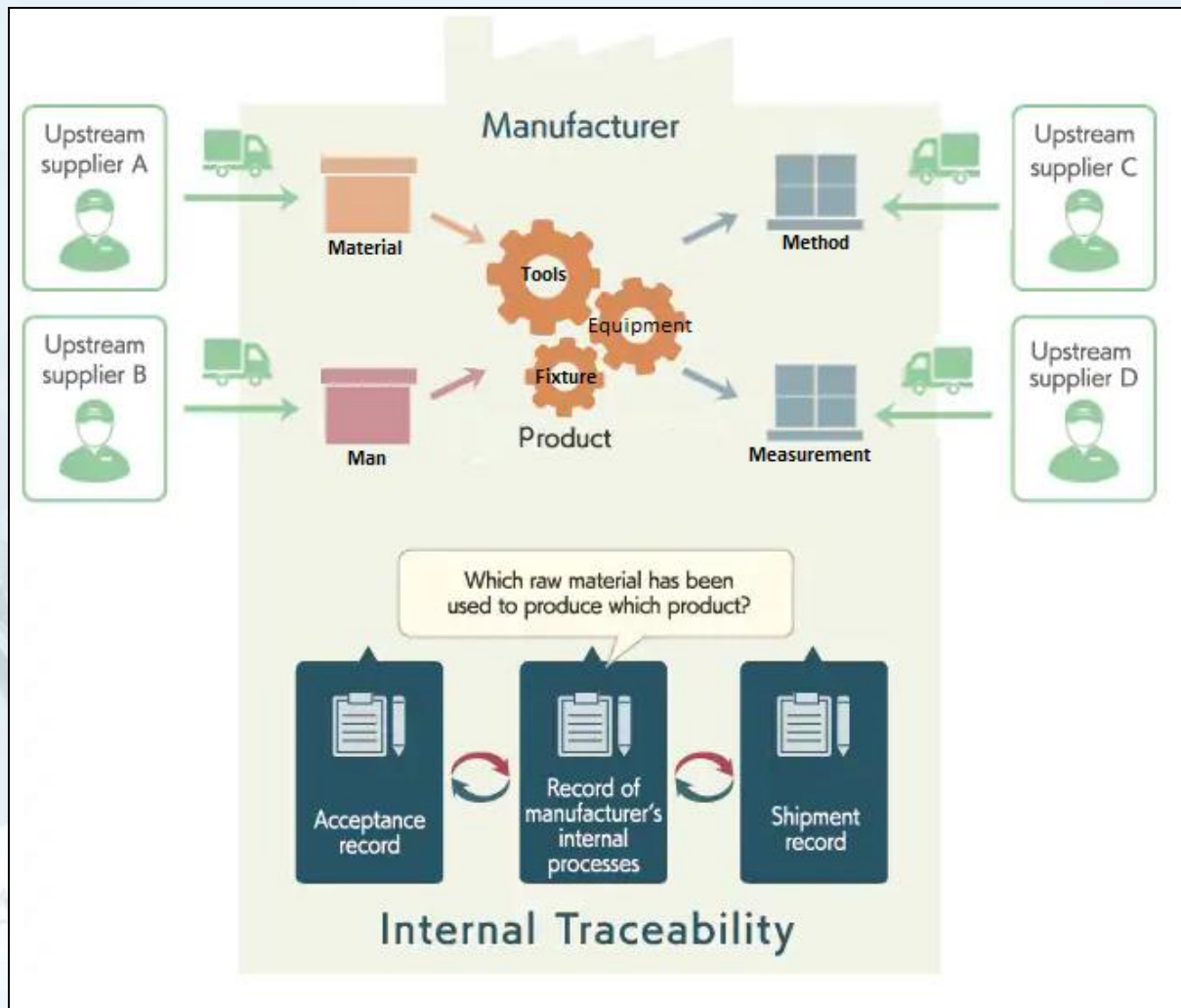
Case/Situation:

No Part S/N to VIN Traceability; Insufficient FIFO of T3-T1 Components

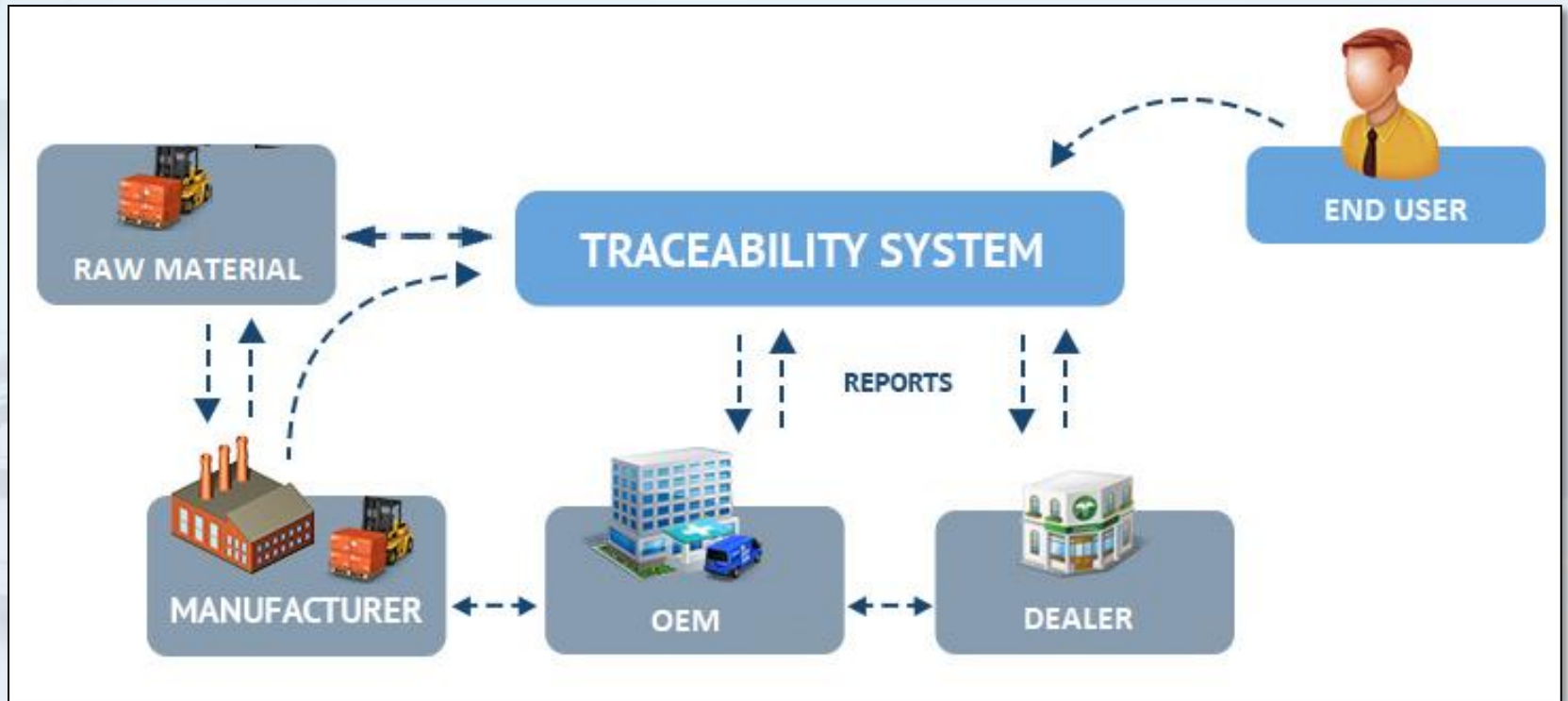
Illustration of Situation:



Internal Traceability



External Traceability



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What is Product Traceability

It used to be that auto manufacturers' success was based on their ability to DEVELOP efficient and profitably design, produce, sell and ship products.

But in a fast-changing world, with more complex engineering and the outsourcing of sub-components, manufacturers now have to consider the quality and safety of their products as well.

The automotive industry has been the most impacted by product recalls in recent years with insurance claims over US\$10 million per recall event. The impact of recalls can be far-reaching, causing not only financial but reputational damage.

With stringent inventory and regulations, automotive manufacturers need to have business systems in place that can trace back and forward, and detail of any modifications done to a product through its lifecycle. A solution should enable traceability of:

- Suppliers and their products that you use
- Items and processes used in your production process
- Products shipped to customers



What is Product Traceability

Traceability refers to the capability for tracking products along the distribution chain on a batch/lot number or series number basis capturing below details but not limited to -

- Raw material and sub part lot number used for each part
- 4M used for each part
- Change management start date and part ID number
- Supplier connected to the RM or sub part or assembly etc.

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What is Product Traceability

Why is it Important? – to give quick response when

- recall product(s) deemed as unsafe/adulterated
- Allow OEM to track product(s) back to the source
- Allows suppliers to track products during containment and analysis
- To identify the methods of disposal of product at the End Of Life

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Production Traceability

With a traceability system in place, manufacturers can not only verify the location, history and application of items moving through their production process, but information from the system can be used to improve efficiency and correct processes where needed.

To implement a robust traceability, collaboration is required among different teams in the organization to identify the materials and items that require traceability, and decide what information needs to be recorded during the manufacturing process, such as:

- what raw materials went into the product
- how long, where, and under what conditions items were stored in the warehouse,
- important documentation such as specifications, changes, certifications and quality records.

Production Traceability

- For full visibility and compliance, you need to have traceability from
 - Raw materials and parts to shipment, and the reverse.
 - Shipment to raw material or parts receipt.
- If the system is part of an integrated ERP solution, you can test that traceability works across all the departments and processes of your business.

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Production Traceability

- With the risk of product recalls on the rise, auto manufacturers should implement a recall management system -
 - To give access to all the critical information needed to track a suspect product through its lifecycle,
 - Supply the information needed to identify, isolate and action activities that occur within a predetermined recall time, and
 - Ensure that regulatory reporting requirements are met.

To prepare for recall events, a recall management system mock recall practice allow you to generate reports of mock and get ready for actual recalls and comply with legislative requirements

Shipment Traceability

Even after a product leaves the factory, you still need to be able to track the product.

In past, it was done by calling the driver or the security gate.

Now a days special scanning technology, advance shipment notice, shipments via barcodes and a smartphone camera can do the same work.

If you have a tracking solution that supports mobile devices it's much simpler and cheaper to track products anywhere in transit.

Your organization cannot manage customer shipment delays these days by phone calls.

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Shipment Traceability

An effective customer shipment delivery system not only supports the capturing, management and resolution of complaints, but also simplifies the process of reviewing and escalating service issues. The information can also help with quality control and enable you to improve the supply and manufacturing process.

With greater traceability in both the product lifecycle and supply chain, auto manufacturers can mitigate the impact of product.

Using an ERP system that includes full traceability and product shipment management, can give you a greater chance of avoiding customer dissatisfaction and processes to ensure the chance of such events re-occurring is reduced or eliminated.

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Shipment Traceability

AWB/ Consignment Number Reference Number

B78162725

Summary Results

Shipment Summary

[Raise your Query](#) [NotifyMe](#) [Mail Me](#) [Print](#)

Tracking No.	B78162725	Last Status Date	07 th jul'21
Reference No.	122336916624	Last Status	Out For Delivery
Booking Date.	06 th jul'21		

Shipment Details

Origin	Bangalore	Destination	Chennai	Destination Pincode	600097
No. of pieces	1	Service Type	Lite		
Package contents	Others2				

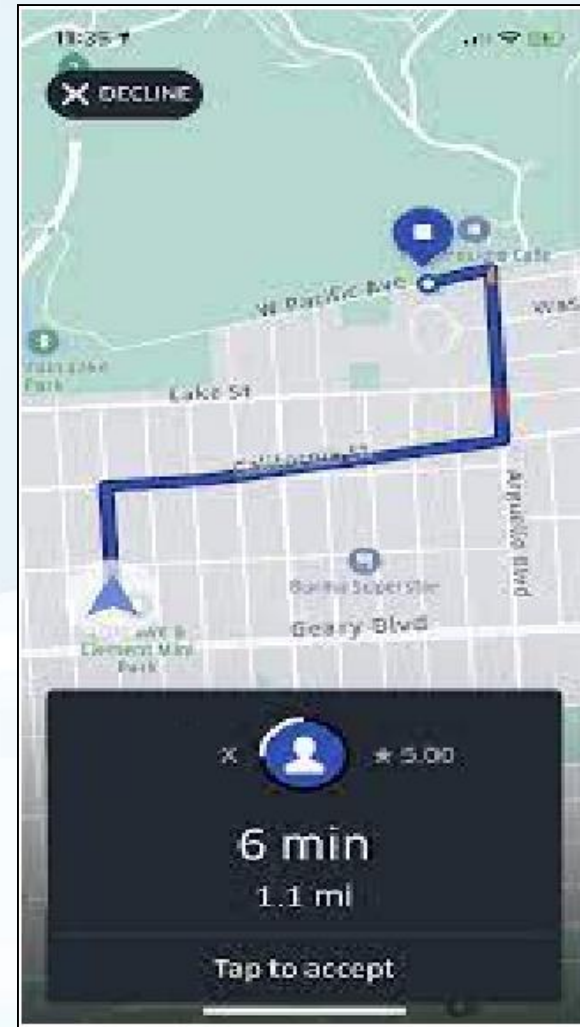
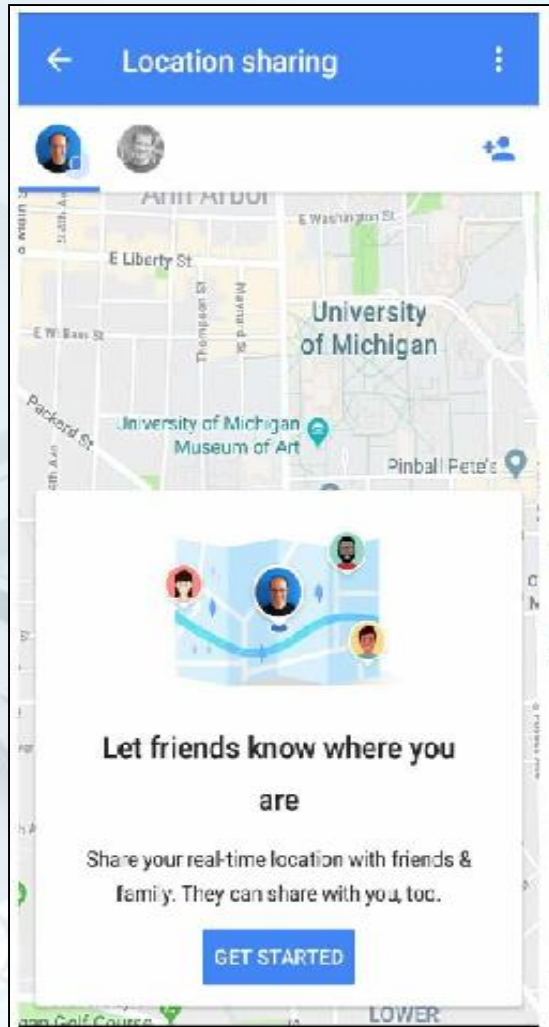
Shipment Tracking History

Pick Up
Booked & Dispatch
In Transit
At Destination
Out for Delivery
Delivered

Date	Activity	From	To
Wed,07 th Jul'21 14:20 Hrs	Out For Delivery	Pallikaranai Master Franchisee(THURAIPAKKAM)	
Wed,07 th Jul'21 13:35 Hrs	Received At Facility	Chennai Apex	Pallikaranai, Chennai
Wed,07 th Jul'21 13:31 Hrs	Received At Facility	Chennai Apex	Pallikaranai Master Franchisee
Wed,07 th Jul'21 13:30 Hrs	Received At Facility	Chennai Apex	Pallikaranai Master Franchisee
Wed,07 th Jul'21 12:35 Hrs	Processed & Forwarded From Hub	Chennai Apex	Pallikaranai Master Franchisee
Wed,07 th Jul'21 12:33 Hrs	Processed & Forwarded ToHub	Chennai Apex	Pallikaranai Master Franchisee
Wed,07 th Jul'21 12:33 Hrs	Processed & Forwarded To Hub	Chennai Apex	Pallikaranai, Chennai
Wed,07 th Jul'21 11:16 Hrs	Received At Hub	Domlur Branch	Chennai Hub
Wed,07 th Jul'21 11:12 Hrs	Received At Hub	Domlur Branch	Chennai Apex
Wed,07 th Jul'21 11:11 Hrs	Received At Hub	Chennai Apex	Chennai Apex
Tue,06 th Jul'21 21:32 Hrs	Received At Hub	Domlur Branch	Bangalore Yehalanka Apex
Tue,06 th Jul'21 20:07 Hrs	Processed & Forwarded From Facility	Domlur Branch	Bangalore Yehalanka Apex
Tue,06 th Jul'21 19:39 Hrs	Processed & Forwarded ToFacility	Domlur Branch	Chennai Apex
Tue,06 th Jul'21 19:37 Hrs	Processed & Forwarded To Facility	Domlur Branch	Chennai Hub
Tue,06 th Jul'21 18:26 Hrs	Booked At Facility	Domlur Branch	Booked To CHENNAI
Tue,06 th Jul'21 15:23 Hrs	Softdata Upload	First Mile	Booking Initiated



Shipment Traceability



Note: the data and case study is only for training purpose



Supplier Traceability

The trigger for a product quality issue, recall or return is usually an issue within raw materials to finished goods. Therefore it's important to have an efficient method to make sure defective items are identified, quarantined and returned to or repaired by a supplier.

There must be a full tracking of the item during process till End of Life of the product.

Manufacturers need to have full visibility of product when it comes to manufacturing, quality, issue of rework or repair activities and be assured that they are being handled correctly and efficiently. This is not only important for traceability but also to enable quality control in the procurement and supplier process.

With the availability of online systems organizations can look at automating the creation of requests to suppliers, scheduling, tracking product and process, controlling quality etc. via systems it self.

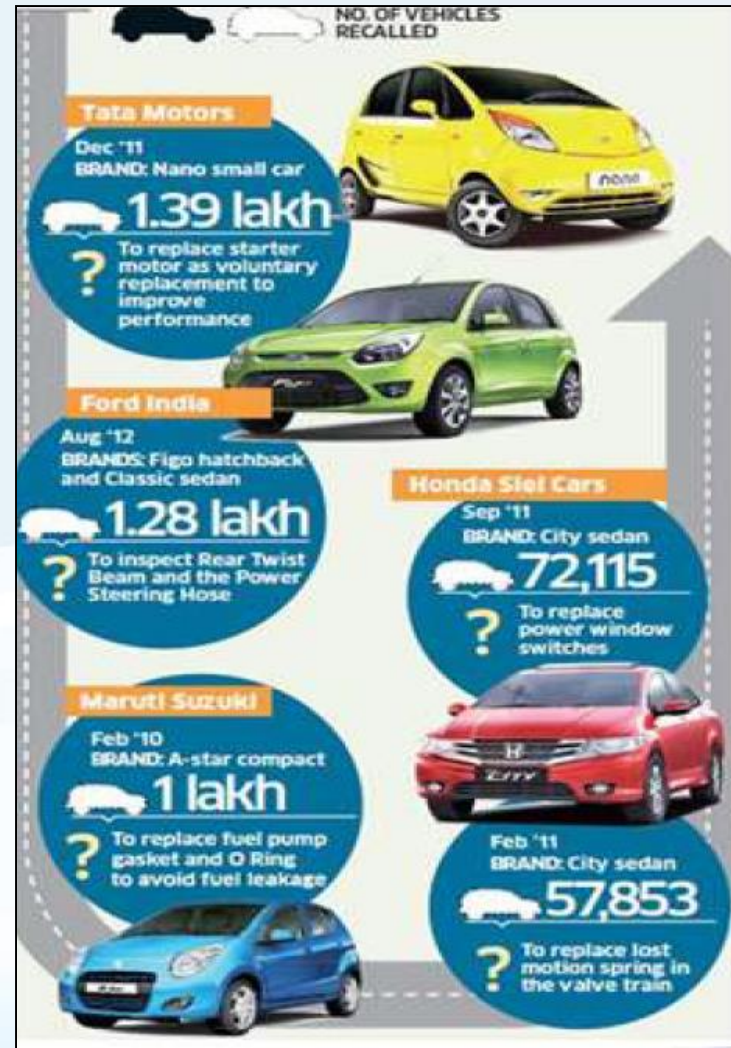


Supplier Traceability

Returns and recalls don't just impact the product and supply chains but also brand image and some times even call for action by legal team (Government or Regulatory authority)

The advantage of an integrated ERP system helps you to track & trace all the original order, so you have traceability of the product history, other accounting items, cost variances, goods received notes, credit notes, and purchase orders.

On the inventory side, you will need to ensure that returned goods are quarantined as they may have to be returned to the supplier. You will also need efficient traceability of stock by tracking serial numbers, lots and bins across warehouses so you can isolate any remaining defective stock.



Note: Data and case study is only for training purpose

Document and Record Traceability

Design Documents	Drawings
	Technical requirements
	Safety requirement SC / CC
	Change management

Verification & Validation Documents	DFMEA ,
	DVP&R
	Homologation
	Inspection report of test rigs

Incoming Documents	Supplier Inspection reports
	Material test certificate,
	Lot identification markings
	Sub supplier v/s QTY supplied

Document and Record Traceability

Process Documents	lot size / Quantity produced per day
	Individual part readings & markings
	Bill of material / parts used and their batch number
	Line, machine and fixture number used, operator and his shift etc.
	Record related to production period

Final inspection Documents	Inspector name and his shift
	Date & time of inspection for each product
	Test result including dimensions, fit and function during process and at final inspection area
	Process control charts for each individual lot/ batch or product and it markings

Document and Record Traceability

Dispatch Documents	Packing and labeling
	Invoice and it tracking to lot / batch number
	Quantity shipped and on which vehicle with its number
Product Markings	Identification on product that have passed all test in process and final inspection

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Case Study

Ford Kuga burning crisis

- In December 2015, one person was burnt to death in his 1.6-litre Eco Boost Ford Kuga in South Africa. Since then a recorded 51 Kugas have caught alight across the country, and two more in Swaziland and Botswana.
- One Year after the incident Ford recalled 4,556 1.6-litre Eco Boost Kugas in South Africa manufactured between December 2012 and February 2014.
- The fire is considered to have occurred by a lack of coolant circulation and the superheated surfaces which could lead to cracking of the cylinder head, exhaust manifold, the turbocharger and the catalytic converter resulting in an oil leak and subsequent fire in the engine compartment

Note: Data and case study is only for training purpose



Case Study

Toyota reaches \$1.2 billion settlement to end probe of accelerator problems

- It took the company eight years to recall 7.7 million vehicles after a number of crashes and deaths.
- It's therefore clear that the sooner a company reacts to a problem, the less of a negative impact there will be on customers, the brand and the bottom line. And, in addition, that if it makes a super effort to address the problem it can even build brand and customer loyalty like never before.

Note: Data and case study is only for training purpose



Exercise: Creating Requirements List

The traceability mandate demands efficient, demonstrable traceability one step forward to your finished product customers and one step backward to your sub assembly and raw material suppliers. Broadly speaking, this means maintaining comprehensive and accessible records on your sub assembly, child parts and raw material including suppliers, all sub assembly , parts and raw materials received, each step of the manufacturing process, rejects, repairs and rework, inventory and storage, dispatch and shipping to customers.

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Exercise: Creating Requirements List

Based on the above, team need to Brain storm and make a check list on what are the data which needs to be part of traceability from each department starting from development till dispatch, some examples are given below –

- Ingredient receiving records, unique ID and quantities used in the batch.
- Packaging records, unique ID and quantities used in the batch.
- Production batch sheet
- Rework or over-run added / created
- Waste
- Finished product Lot ID and quantities
- Storage and inventory records
- Current location of all quantities produced
- Dispatch and shipping records
- The test duration

Chapter 4

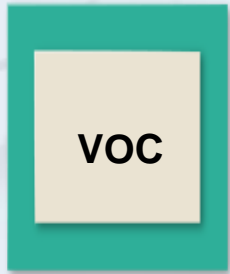
Traceability – Design, verification and Validation Requirements

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Traceability – Design Requirements

Voice of the Customer(VOC) to Testing Plan to PPAP



Inputs to design the product and its requirements

- Direct discussion and MOM,
- Market surveys,
- Customer specific requirements,
- Quality Issues, warranty data, field reports, etc.

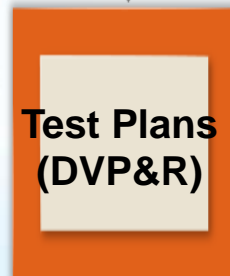
Requirement Flow Down



Tool used to identify causes of failure modes, or reduce their rate of Occurrence

- Identified Potential product failure modes.
- Identified Critical Characteristics and/or Significant Characteristics.
- Design actions to reduce severity or improved design
- Eliminate the causes of product failure modes etc

Prevention Controls and detection controls



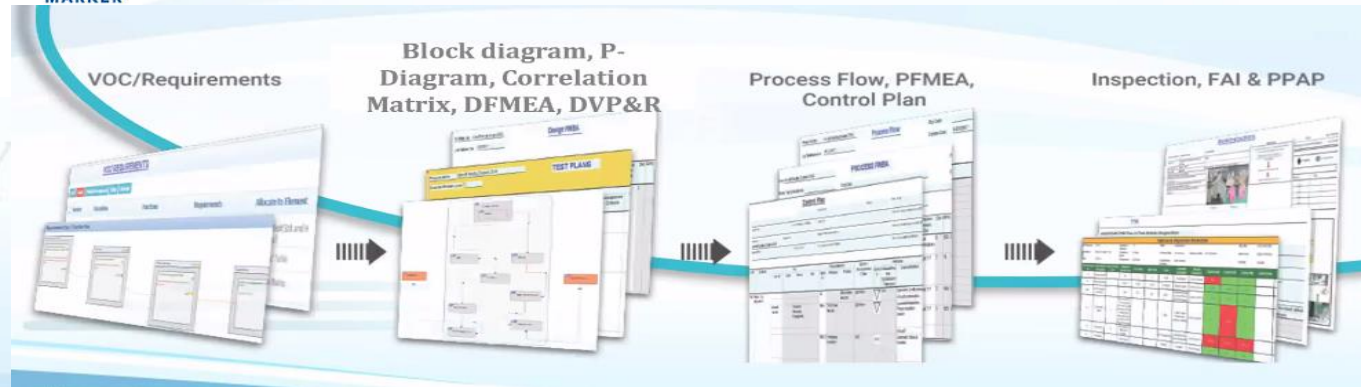
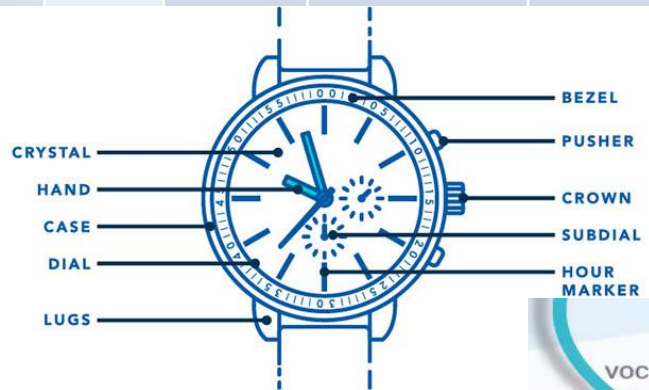
Tool is most often used in conjunction with DFMEA

- Performing tests as part of a problem solution or root cause analysis (RCA)
- Plan and document test information to validate product performance w.r.t design requirement
- Testing during NPD, recertification for regulatory requirements for change or improvement if any

Traceability – Design Requirements

Let us take an example of a Waterproof Watch

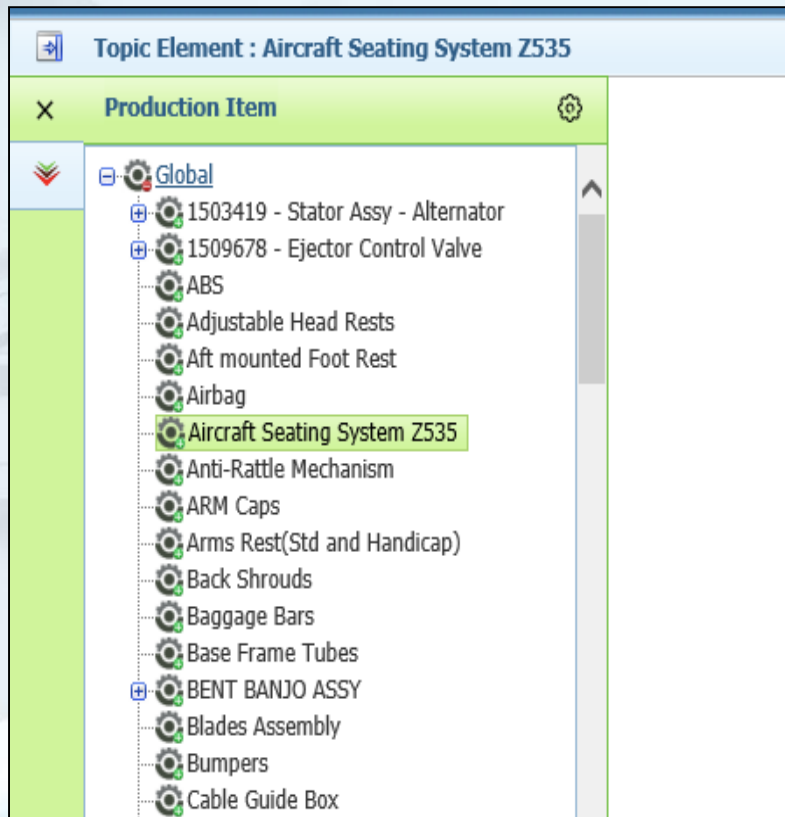
Requirement ID	System Function	Function requirement ID	System Requirement	Sub System Requirement ID	Sub System requirement	Component requirement ID	Component requirement
A	The watch must be water proof	A 1	The watch should function even if the user, uses for a prolonged time	A 1.1	Swims in cold water	A 1.1.1	Water entry from Bezel
						A 1.1.2	Water entry from Crown & Pusher
						A 1.1.3	Water entry from Back cover
				A 1.2	Bath in hot water	A 1.2.1	
						A 1.2.2	
						A 1.2.3	
				A 1.3	Work in hazardous environment	A 1.3.1	
						A 1.3.2	
						A 1.3.3	



Traceability – Design Requirements

To meet the Requirement Flow Down we need assembly and it's bill of material data

Part Structure View



Bill of Material Structure



Traceability – Design Requirements

VOC - System

Topic Element : Aircraft Seating System Z535 Active Document : Voice of the Customer

Voice of the Customer **VOC Flowdown Functions & Requirements (System to Sub-system)**

VOC – Sub System

Topic Element : Food Table Active Document : Voice of the Customer

Voice of the Customer

VOC Flowdown Functions & Requirements (Sub-system to Component)

Number	Description	Function	Requirement	Parent Element	Status
<input type="checkbox"/>	VOC-FT0001			Food Table	ⓘ
<input type="checkbox"/>	VOC-FT0002			Food Table	ⓘ
<input type="checkbox"/>	VOC-FT0003			Food Table	ⓘ
<input type="checkbox"/>	VOC-FT0004			Food Table	ⓘ
<input type="checkbox"/>	VOC-FT0005			Food Table	ⓘ
<input type="checkbox"/>	VOC-FT0006	Description of VOC-FT0006	Should be able to assemble very easily.	Foam Assy	ⓘ

Requirement Flows Down

<input type="checkbox"/>	Element	Food Table
<input type="checkbox"/>	Function	Pull and Push the food table
<input type="checkbox"/>	Requirement	Requirement of Pull and Push the food table.

+ F + R - D

- Cup Holder Assy
- Foam Assy
- Table Latch Assy
- F To deploy or engage the table.
- R Should withstand 16 G and work for 35K cycles.



Traceability – Design Requirements

Requirement Tree

Focus Element: Battery Management... Context Element: Battery Management... Active Document: Voice of the Customer

Default Select Select Search

Number	Description	Functions	Req Id	Requirements	Allocated	Req Status	Skip Review	Req Status	ASIL	Status
VOC-BMS0005		Interface Function of MBS Relay-BMS Mod2(P)	REQ-BMS0008	Interface Requirement of MBS Relay-BMS Mod2(P)		Draft	<input type="checkbox"/>	Architectural		
		Monitor for electrical isolation	REQ-BMS0010	Send isolation violation notification through auxilliary power	BMS Software BMS Hardware	Draft	<input type="checkbox"/>	Technical Safety		🟡
		Permit/Support Battery charging function	REQ-BMS0013	Charge from 0% to 80% within X-duration		Draft	<input type="checkbox"/>	Technical Safety		🟡
		Prevent risk of electric shorts by design	REQ-BMS0009	Follow SDR #3156 for line spacing requirements	BMS Hardware	Draft	<input type="checkbox"/>	Technical Safety		🟡
		Provide state of charge information to vehicle ECU	REQ-BMS0016	Provide state of Charge to vehicle ECU real-time with lag not more than x seconds		Draft	<input type="checkbox"/>	Technical Safety		
		Provide state of health information to		Provide state of health information	BMS Software	Draft	<input type="checkbox"/>	Technic		

+ Add Delete Publish for Approval Enable Review



Traceability – Design Requirements

Failure Tree

Focus Element: Battery Managemen... Context Element: Battery Managemen... Active Document: Failures Tree

Requirements Flowdown

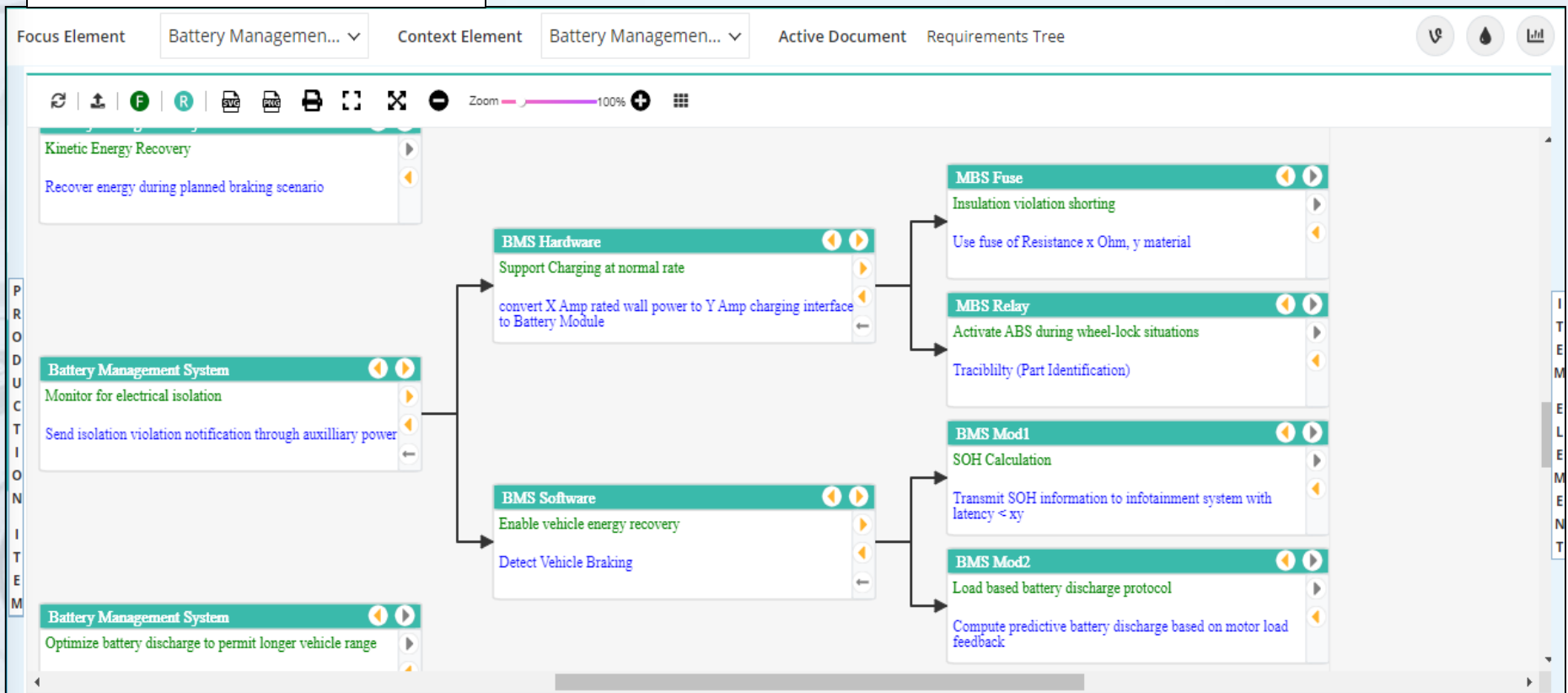
Element	Battery Management System
Function	Monitor for electrical isolation
Requirement	Send isolation violation notification through auxilliary power
Failure	Monitoring failed:Over discharge

+ F + R + F - D

- BMS Hardware
 - Accept variable energy profile
 - Function of BMS Software-MBS EMC Filter (flowDown from Battery Management System)(2)
 - Monitor for electrical isolation
 - Support Charging at normal rate
 - convert X Amp rated wall power to Y Amp charging interface to Battery Module
 - Electrical reading to SOH conversion logic does not follow table #11908
 - Thermal reading communication
 - BMS Software

Traceability – Design Requirements

Failure Flow down



Traceability – Design Requirements

DFMEA

Focus Element Battery Managemen... Context Element Battery Managemen... Active Document Design Failure Mode and ...

Product: Battery Management System
Design FMEA

Function Group	Function	Requirement ID	Requirement	Potential Failure Mode	Failure Mode Additional	Potential Effects of Failure: Sev	Sev	Design Requirement Review Status Name	Class	Potential Cause(s)/Mechanism(s) of Failure	Occ	Preventive Design Controls	Detective Design Controls: Det	Det	RPN	Recommended Actions	Responsibility
VOC-BMS0005:	Monitor for electrical isolation	RFQ BMS 001	Send isolation violation notification through auxiliary power	Monitoring failed: Over discharge		Fireball event:	10			BMS Hardware: Electrical reading to SOH conversion logic does not follow table #11908	6	Material Specifications For Oil And Refrigerant As Per DDS 6 05/02/2021 Completed-Inactive Alice Whitman	Millipore Test As Per DDS 1125 - III A3: 4 07/10/2021 Andrew Ethan Not implemented	4	240		
										BMS Software: L2 does not meet radiation	6	Provision Of Protection Cap In Design 6 04/05/2021 Decision pending Don Wright	To Provide Instructions In Drawings: 7 06/08/2021 Mary Rowzee Open	7	420		

PRODUCT INFORMATION

ITEM ELEMENT



Traceability – Design Requirements

DVP&R

Focus Element Battery Managemen... Context Element Battery Managemen... Active Document Design Verification Plan a...

Product: Battery Management System
DVP&R

Test Plan																				
Function Group	Function	Requirement	Design Control	Procedure/Standard	Acceptance Criteria	Test Number	Test Name	Test Case	Test Plan	Test Instance Status	Attachments	Design Test Category Name	Test Instance	Test Responsibility	Test Stage	Sample		Timing		Quantity
																Quantity	Type	Start	End	
PRODUCT INFORMATION	Battery pack voltage monitoring	Read battery voltage across pack terminal	Part Design As Per Vehicle CAD Data							Failed but, approved by management								04/10/2021	05/08/2021	
			Union Design As Per Industrial Standards							Failed									07/09/2021	10/05/2021
	Interface Function of BMS Hardware-BMS Software(P)	Interface Requirement of BMS Hardware-BMS Software(P)																		
	Monitor for electrical isolation	Send isolation violation notification through auxilliary power	Material Specifications For Oil And Refrigerant As Per DDS								Failed								07/05/2021	05/05/2021
Millipore Test As Per										Passed								09/02/2021	10/08/2021	

Verification and validation tests can be defined for any layer of requirements. Test scripts can include other tests and run external tools to collect automated test results. If a test step fails it can be linked to the system.



Traceability – Design Requirements

Requirements Manager

Focus Element : Mercury Battery Pack System Context Element : Mercury Battery Pack System Active Document: Voice of the Customer

Voice of the Customer

+Add Delete Publish for Approval Enable Review Select Release Info

Number	Description	Function	Requirements	Allocated To Element	Release Info	Requirement Review	Skip Review	Requirement Type
VOC-MBPS0014		Ensure Isolation			B.21	Draft	<input type="checkbox"/>	
VOC-MBPS0008		Interface Function of Element ABC-Battery Management System(P)	No movement	Element ABC	B.21	Draft	<input type="checkbox"/>	
VOC-MBPS0006		Interface Function of Element XYZ-BMS Hardware(P)	Interface Requirement of Element XYZ-BMS Hardware(P)-xyzchanges		B.21	Draft	<input type="checkbox"/>	
VOC-MBPS0006		Interface Function of Element XYZ-Battery Management System(P)	Interface Requirement of Element XYZ-Battery Management System(P)	Battery Module	C.31	Draft	<input type="checkbox"/>	Architec
VOC-MBPS0003		Interface Function of Module Balancing Unit-Mechanical Enclosure	Interface Requirement of Module Balancing Unit-Mechanical Enclosure	Mechanical Enclosure	C.42	Approved	<input type="checkbox"/>	Architectural
VOC-MBPS0001		Function of Battery Cell MX15-Richar	Requirement of Battery Cell MX15-Busbar	Battery Module	C.42	Draft	<input type="checkbox"/>	

- Requirements Traceability.
 - Requirement reviews
 - Flow down of requirements
 - Ensure all requirements are verified.
- more...

Case Study of 737 MAX Airplane

In October 2018, 189 passengers perished when Lion Air Flight 610 crashed a few minutes after taking off from Jakarta.

Initial Analysis mentioned :- human error and embarked on a process meant to update the online training software administered to pilots

A few months later, in March 2019, Ethiopian Airlines Flight 302, a second airplane of same type, the 737 MAX model, carrying 157 passengers.

Note: Data and case study is only for training purpose

Data as received from
Sustainability 2020, 12, 8994; doi:10.3390/su12218994 www.mdpi.com/journal/sustainability



Case Study of 737 MAX Airplane

Background

Company planned to design a brand-new airplane to substitute the aging fleet of 737 and due to competition in the market company mentioned the new model was simply a derivative of the traditional 737 aircraft.

But it was not the case

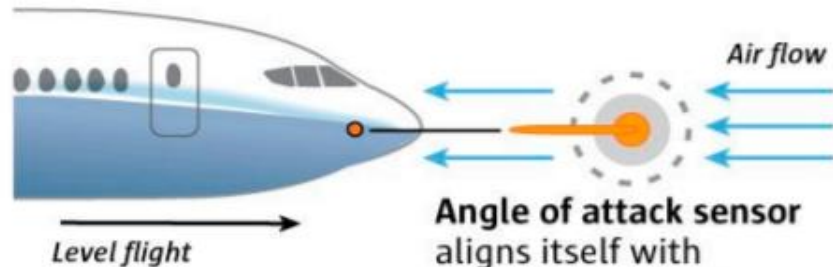
The new model were installed with larger engines and shifted their location forward, which disrupted the plane's aerodynamic structure, causing it to become susceptible to stalling under certain flight conditions

To obviate this problem, manufacturer developed the MCAS system, which pushed the plane's nose down to stabilize the aircraft. When needed, the system engaged automatically. The pilots could not deactivate, even if pilot was able to deactivate, the system would have reactivated by itself after few seconds.

Note: Data and case study is only for training purpose

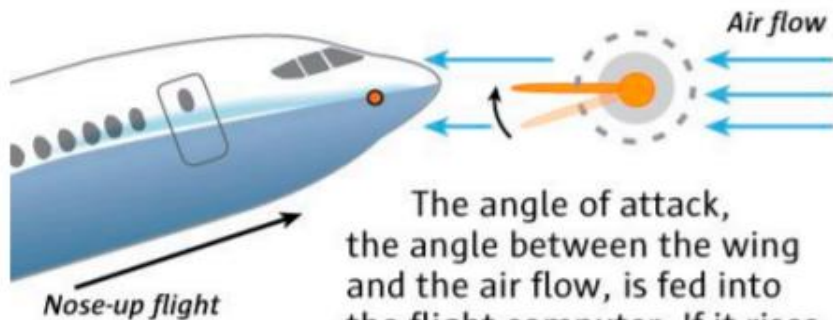


Case Study of 737 MAX Airplane



Level flight

Angle of attack sensor aligns itself with oncoming air flow.



Nose-up flight

The angle of attack, the angle between the wing and the air flow, is fed into the flight computer. If it rises too high, suggesting an approaching stall, the MCAS system activates.

MCAS (Maneuvering Characteristics Augmentation System)

The MCAS system automatically swivels the horizontal tail to move the nose down. In the Lion Air crash, the angle of attack sensor fed false information to the flight computer.



Sources: Boeing, FAA, Indonesia National Transportation Safety Committee, Leham.net, and The Air Current.

Reporting by DOMINIC GATES,
Graphic by MARK NOWLIN / THE SEATTLE TIMES

Company CEO replied: "I think about that decision over and over again. If we knew everything back then that we know now, we would have made a different decision"

Note: Data and case study is only for training purpose



Case Study of 737 MAX Airplane

Findings

Work Pressure

Due to intense competition in the aviation industry and enormous pressure on the manufacturer to produce a new plane as quickly and inexpensively as possible. The company decided to update an outmoded design without properly testing a prototype.

Safety System

In order to meet the requirement for the 737 aircraft to be fuel-efficient, several technical changes were needed. The manufacturer shifted the engines forward which changed the aerodynamics.

Management and Supervision

The third antecedent of the plane disasters was the ignoring of pilots' warnings. A search of the Aviation Safety Reporting System [30] reveals that the MAX anti-stall system was activated on at least two prior incidents as quoted.

Note: Data and case study is only for training purpose



Case Study of 737 MAX Airplane

Findings

Competence

Lack of training for the pilots on the new modifications to the 737 MAX. When the MAX jet was under design, the company engineers concluded that pilots could fly the plane without new training, because it was an upgrade of the previous 737 model and decided that the 737's new features could be learned from an iPad orientation.

Risk

Both flights lacked safety features that were offered to the manufacturer for an additional price. Safety features include communication and navigation systems that are necessary for the plane's cruise control.

Procedures and Rules

The crash was due to the accelerated certification that the FAA awarded to the 737 MAX without due accuracy.

Note: Data and case study is only for training purpose



Exercise : Tracking Documents

During the last decade products have become more and more complex. In order to master these challenges manufacturing companies have provided approaches for reusability, adaptability, and variety of product and partial design solutions. Fundamental problems of such approaches are lack of design solutions understanding and the danger of mistakes during solution adaptation and integration. The problems are mostly caused by insufficient design documentation, and inadequate support to the tracing of design evolution.

Collect all the SOP, Document and Records from all departments involved in New Product Development. Team shall report which are the document which are incomplete or not available.

QUALITY

Exercise : Tracking Documents

Team connected -

- Product design
- Process design (ME)
- Purchase and SQA
- Logistics, Store and Packing
- New Product Development
- Quality and validation
- Production
- Maintenance and line set up team etc.

Based on the findings, fine tune your question created during brain storming.

QUALITY

Chapter 5

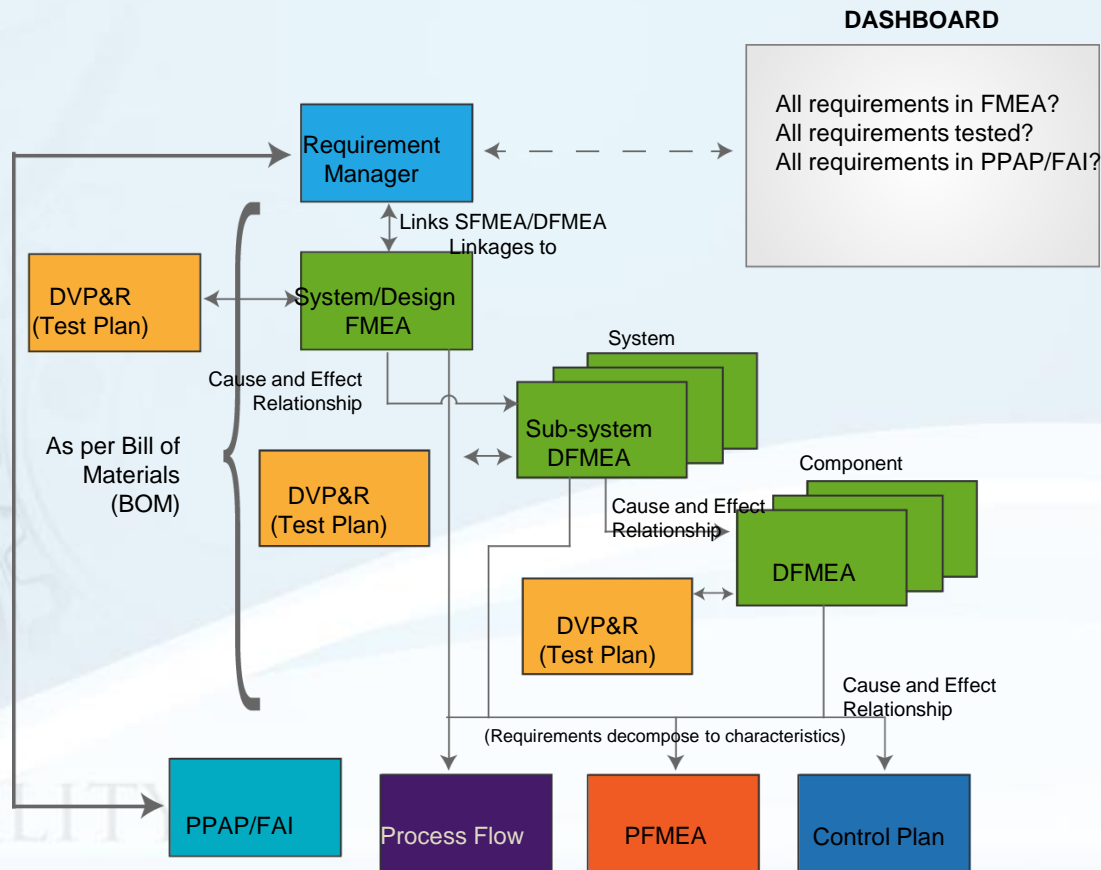
Traceability – Requirement linkage to PPAP (PFMEA and CP)

QUALITY



Requirement traceability

Flow Down to PFMEA, Control Plan and Inspection report



Requirement traceability

Requirements traceability

Requirements traceability is the tracking of requirements throughout the product development lifecycle.

It is a documented thread that provides forward and backward visibility into all activity surrounding each requirement (including design, development, testing, and support).

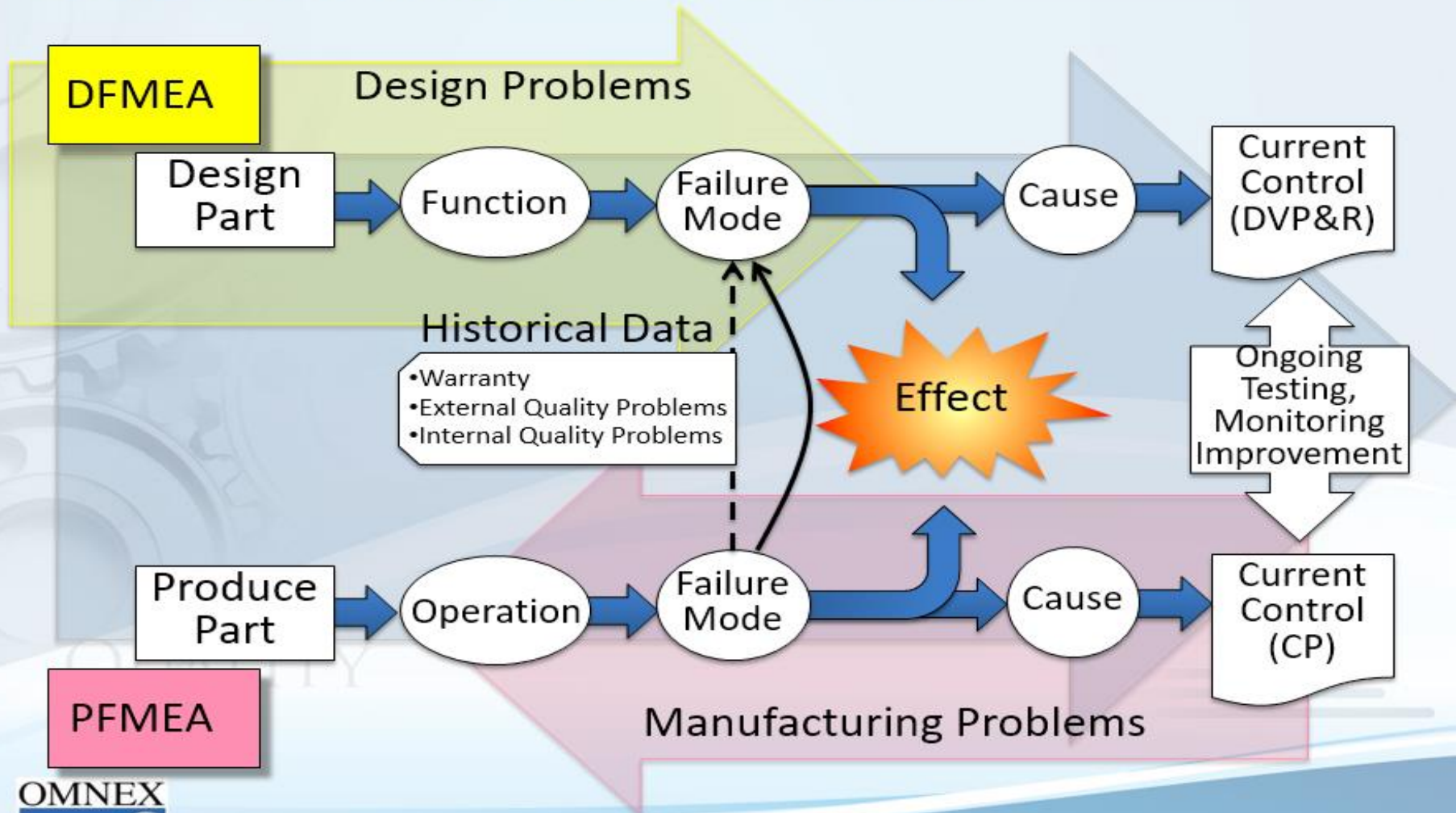
Requirements traceability helps minimize the risk of negative outcomes and maximize productivity. Its benefits include greater team efficiency, easier regulatory compliance, and higher-quality products.

QUALITY



Requirement traceability






Design and Process FMEA Links



Requirement traceability

Process Flow Document

Product: Battery Management System
Process Flow

Op. Grp. Sequence	Operation		Process Flow Symbol	Process Flow Diagram	PC ID	Symbol	Product Characteristic Description	Process
	Num	Description						
1	10	Obtain permission to start work	Decision (hexagon)		BM-10-045PR		The material must have high mechanical strength so that it carries the tension and weight of the conductors.	
					BM-10-047PR		The material is highly resistive for preventing the flow of leakage current from the conductor to earth.	
					PD\RC\101		Tube length	
					PD\RC\102		Tube diameter	
					PD\RC\103		Tube I.D.	
					PD\SM\100		Spacer I.D.	
					PD\SM\101		OAL	
					PD\SM\102		Chamfer degree	
					PD\SM\103		Chamfer length	
	20	Identify the source(s) of supply using an approved voltage indicator or test lamp	Operator					
	30	Prove that the approved voltage indicator or test lamp is functioning correctly	Operation		PC\WS\100		Wash acid content	Wash acid content
					PD\WS\100		Free of machine oil	
	40	Isolate the supply(s)	Decision (diamond)		PC\GR\100		Machine speeds and feeds	Machine speeds and feeds
					PD\GR\100		Finished diameter	

Requirement traceability

Process FMEA Document

SPPC

- ADC
- ASEC
- Battery MX1
- Battery Cell MX15
- Battery Management System
- Battery Module
- BMS Hardware
- BMS Mod1
- BMS Mod2
- BMS Software
- BMS Unit1
- BMS Unit2
- BMS Unit3
- BMS Unit4
- BMS Unit5

- Process Flow
- Process FMEA
- Control Plan
- Dynamic Control Plan
- Bill of Material
- Checksheet #1
- Checksheet #2
- Checksheet #3

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

Item: Battery Management System Process Responsibility: _____


FMEA Number: _____

Model Year(s)/Vehicle(s): _____ Key Date: _____

Prepared By: _____

Core Team: _____

FMEA Date (Orig.): _____ (Rev.): _____

Op. Grp. Sequence	Operation Number	Operation Description	Requirements				Potential Failure Mode	Potential Effects of Failure: Sev	Sev	Potential Causes of Failure	Preventive Controls	Occ
			PC ID	Product	Characteristic Class Symbol	Process						
1	10	Obtain permission to start work	BM-10-045PR	The material must have high mechanical strength so that it carries the tension and weight of the conductors.			A second short-circuit to earth has occurred PE (2) creating a short-circuit current through the modules and wiring. This will increase the risk of fire.	Monitoring failed: Over discharge Fire ball event: 8	8	Improperly maintained switches and circuit breakers.	Use safe work practices every time electrical equipment is used. 3	3
			BM-10-047PR	The material is highly resistive for preventing the flow of leakage current from the conductor to earth.			Touching the modules may lead to severe physical injuries.	Leak Fluid (Does not contain fluid) Fuel leakages out of pipe: 2: 8	8	Obstructed disconnect panels.	Multi-plug adapters must have circuit breakers or fuses 4	4
								Water or liquid near electrical equipment.			Know the location and how to operate shut-off	4

Requirement traceability

Control Plan Document

- ADC
- ASEC
- Battery MX1
- Battery Cell MX15
- Battery Management System**
- Battery Module
- BMS Hardware
- BMS Mod1
- BMS Mod2
- BMS Software
- BMS Unit1
- BMS Unit2
- BMS Unit3
- BMS Unit4
- BMS Units

- Process Flow
- Process FMEA
- Control Plan**
- Dynamic Control Plan
- Bill of Material
- Checksheet #1
- Checksheet #2
- Checksheet #3

CONTROL PLAN

Control Plan Number		Key Contact		Phone		Date (Orig.)		Date (Rev.)		
Part Number			Latest Change Level/Date			Core Team		Customer Engineering Approval/Date (If Req'd.)		
Part Name		Description		Supplier/Plant Approval/Date			Customer Quality Approval/Date (If Req'd.)			
Battery Management System		BM-6264HDG3435								
Supplier/Plant		Supplier Code		Other Approval/Date (If Req'd.)			Other Approval/Date (If Req'd.)			

Op. Grp. Sequence	Op#	Op Name	num ,machine, device, jig, tools, for manufacturing		Characteristics			Special Characteristic Class	Methods		Gage Number	Evaluation Measure Techn
			No	Name	S.No	Process	Product		Product/Process Specification/ Tolerance	Control Method		
1	10	Obtain permission to start work			1		The material is highly resistive for preventing the flow of leakage current from the conductor to earth.	@Critical	3mm	Inside storage and visual inspection Know the location and how to operate shut-off switches and/or circuit breaker panels. Material Specification As Per DDS Multi-plug adapters must have circuit breakers or fuses Operator instructions for handling Supplier certification and auditing	G-004	Pressu
					2		The material must have high mechanical strength so that it carries the tension and weight of the	@Fit/Function	0.1 mm - 0.5mm	Fixture to ensure cell stack height within tolerance: Use safe work	G-002	Go/No

Requirement traceability

FAI- Form 1: Part Number Accountability

ADC

ASEC

Battery MX1

Battery Cell MX15

Battery Management System

Battery Module

BMS Hardware

BMS Mod1

BMS Mod2

BMS Software

BMS Unit1

BMS Unit2

BMS Unit3

BMS Unit4

BMS Unit5

AS9102 Form1

AS9102 Form2 - Materials

AS9102 Form2 - Special Operation

AS9102 Form2 - Test Procedures

AS9102 Form2 - All Sections

AS9102 Form3

AS/EN/SJAC9102 Rev A First Article Inspection

Form 1: Part Number Accountability

1. Part Number Battery Management System	2. Part Name BM-6264HDG3435	3. Serial Number	4. FAI Report Number
5. Part Revision Level	6. Drawing Number	7. Drawing Revision Level	8. Additional Changes
9. Manufacturing Process Reference	10. Organization Name	11. Supplier Code	12. P.O. Number
13. Detail FAI <input type="checkbox"/>	14. Full FAI <input type="checkbox"/>	Baseline Part Number including revision level	
Assembly FAI <input type="checkbox"/>	Partial FAI <input type="checkbox"/>		
Reason for Partial FAI: _____			

a) if above part number is a detail part only, go to Field 19

INDEX of part numbers or sub-assembly numbers required to make the assembly noted above

15. Part Number	16. Part Name	17. Part Serial Number	18. FAI Report Number
Battery Module	The battery module, part of a battery pack supplies electrical energy for the electric powertrain through it's terminals. Battery modules are daisy chained in nS-mP configuration (n-series; m-parallel) to collectively provide the required output.		
BMS Hardware			
BMS Software			
DW Perception Module	ECU that contains integration of info from sensor fusion and path planning		

1) Signature indicates that all characteristics are accounted for; meet drawing requirements or are properly documented for disposition.

2) Also indicate if the FAI is complete per section 5.4: FAI Complete FAI Not Complete

19. Signature _____	20. Date _____
21. Reviewed By _____	22. Date _____
23. Customer Approval _____	24. Date _____

Requirement traceability

FAI - Form 2: Material

AS/EN/SJAC9102 Rev A First Article Inspection
 Form 2: Product Accountability - Raw Material, Specifications and Special Process(es), Functional Testing

1. Part Number: Battery Management System 2. Part Name: BM-6264HDG3435 3. Serial Number: 4. FAI Report Number:

5. Material Name	Requirements			7. Code	8. Special Process Supplier Code	9. Customer Approval Verification	10. Certificate of Conformance Number
	6A. Id	6B. Description	6C. Specification Number				
Obtain permission to start work	BM-10-045PR	The material must have high mechanical strength so that it carries the tension and weight of the conductors.	0.1mm - 0.5mm	TR-541	SUP-00548	YES	CN-76YTB979
	BM-10-047PR	The material is highly resistive for preventing the flow of leakage current from the conductor to earth.	3mm	TR-838	SUP-489YT54	N/A	CN-76YTB979
	BM-10-049PR	They must have high dielectric strength.	0.22mm	TR-U766	SUP-00548	NO	CN-76YTB979

13. Comments

14. Prepared By: 15. Date:

Requirement traceability

FAI - Form 2: Special Operations

- ADC
- ASEC
- Battery MX1
- Battery Cell MX15
- Battery Management System
- Battery Module
- BMS Hardware
- BMS Mod1
- BMS Mod2
- BMS Software
- BMS Unit1
- BMS Unit2
- BMS Unit3
- BMS Unit4
- BMS Unit5

- AS9102 Form1
- AS9102 Form2 - Materials
- AS9102 Form2 - Special Operation
- AS9102 Form2 - Test Procedures
- AS9102 Form2 - All Sections
- AS9102 Form3

AS/EN/SJAC9102 Rev A First Article Inspection

Form 2: Product Accountability - Raw Material, Specifications and Special Process(es), Functional Testing

1. Part Number Battery Management System	2. Part Name BM-6264HDG3435	3. Serial Number	4. FAI Report Number
---	--------------------------------	------------------	----------------------

5. Process Name	Requirements			7. Code	8. Special Process Supplier Code	9. Customer Approval Verification	10. Certificate of Conformance Number
	6A. Id	6B. Description	6C. Specification Number				
Obtain permission to start work	BM-10-045PR	The material must have high mechanical strength so that it carries the tension and weight of the conductors.	0.1mm - 0.5mm	TR-541	SUP-00548	YES	CN-76YTB979
	BM-10-047PR	The material is highly resistive for preventing the flow of leakage current from the conductor to earth.	3mm	TR-838	SUP-489YT54	N/A	CN-76YTB979
	BM-10-049PR	They must have high dielectric strength.	0.22mm	TR-U766	SUP-00548	NO	CN-76YTB979

13. Comments

14. Prepared By _____ 15. Date _____

Requirement traceability

FAI – Form 2: Test Procedures

AS/EN/SJAC9102 Rev A First Article Inspection
Form 2: Product Accountability - Raw Material, Specifications and Special Process(es), Functional Testing

1. Part Number Battery Management System	2. Part Name BM-6264HDG3435	3. Serial Number	4. FAI Report Number
---	--------------------------------	------------------	----------------------

11. Functional Test Procedure Number FTP-879HG7346	12. Acceptance Report Number, if applicable GD-73743TE
---	---

13. Comments

14. Prepared By	15. Date
-----------------	----------

Requirement traceability

FAI – Form 2: All Sections

AS/EN/SJAC9102 Rev A First Article Inspection							
Form 2: Product Accountability - Raw Material, Specification and Special Process(es), Function Testing							
1. Part Number		2. Part Name		3. Serial Number		4. FAI Report Number	
Battery Management System		BM-6264HDG3435					
5. Material or Process Name	Requirements			7. Code	8. Special Process Supplier Code	9. Customer Approval Verification	10. Certificate of Conformance Number
	6A. Id	6B. Description	6c. Specification Number				
Obtain permission to start work	BM-10-045PR	The material must have high mechanical strength so that it carries the tension and weight of the conductors.	0.1mm - 0.5mm	TR-541	SUP-00548	YES	CN-76YTB979
	BM-10-049PR	They must have high dielectric strength.	0.22mm		SUP-00548		
	BM-10-047PR	The material is highly resistive for preventing the flow of leakage current from the conductor to earth.	3mm		SUP-489YT54		
Obtain permission to start work	BM-10-045PR	The material must have high mechanical strength so that it carries the tension and weight of the conductors.	0.1mm - 0.5mm	TR-541	SUP-00548	YES	CN-76YTB979
	BM-10-049PR	They must have high dielectric strength.	0.22mm		SUP-00548		
	BM-10-047PR	The material is highly resistive for preventing the flow of leakage current from the conductor to earth.	3mm		SUP-489YT54		
11. Functional Test Procedure Number				12. Acceptance Report Number, if applicable			
FTP-879HG7346				GD-73743TE			



Requirement traceability

FAI – Form 3: Characteristic Accountability, Verification and Compatibility Evaluation

- ADC
- ASEC
- Battery MX1
- Battery Cell MX15
- Battery Management System
- Battery Module
- BMS Hardware
- BMS Mod1
- BMS Mod2
- BMS Software
- BMS Unit1
- BMS Unit2
- BMS Unit3
- BMS Unit4
- BMS Unit5

AS/EN/SJAC9102 Rev A First Article Inspection

Form 3: Characteristic Accountability, Verification and Compatibility Evaluation

1. Part Number Battery Management System	2. Part Name BM-6264HDG3435	3. Serial Number	4. FAI Report Number
---	--------------------------------	------------------	----------------------

O p e r a t i o n	#	Name	Characteristic Accountability			Inspection / Test Results			14. Remarks
			5. Char No.	6. Reference Location	7. Characteristic Designator	8. Requirement	9. Results	10. Designed Tooling	
1	10	Obtain permission to start work	BM-10-045PR		@Fit/Function	0.1mm - 0.5mm	OK	G-001	NC-245YTD873
			BM-10-047PR		@Critical	3mm	OK	G-003	
		PD\RC \101				N/A	G-003	NC-654TER83	
		PD\RC \103		@Fit/Function	2.15mm	OK	G-003		
20		Identify the source(s) of	PD\SM \100				N/A	G-001	

The signature indicates that all characteristics are accounted for; meet drawing requirements or are properly documented for disposition.

12. Prepared By	13. Date
-----------------	----------

Case Study : Weak Requirement Traceability

Observation during an improvement audit at a supplier works.
The final length in drawing is 741.0 mm +0/ -1 mm.

Drawing calls for
741.0 +0 / -1mm



Note: Data and case study is only for training purpose

Case Study : Weak Requirement Traceability

The final length in drawing it is 741.0 mm +0/ -1 mm

Process Flow Diagram						
PART NUMBER	2840100109-35		REV DATE	0.00.00.00	APPROVED BY	APPROVED DATE
OPER TEAM	Shresh Rishi Naresh Ramesh					
SUB PART NO		PFD NO	PT.PFDIACM0109		PAGE NO	1 of 1
SUB PART NAME		TRANSPORT	STORAGE	INSPECTION		
		OPERATION	OPN & INSP TOGETHER	INCOMING PARTS		
OP NO	WORK STN. NO / MACHINE NO	OPERATION DESCRIPTION	INCOMING SOURCE OF VARIATION	PROCESS FLOW	PRODUCT CHARACTERISTICS	PROCESS CHARACTERISTICS
38	Grinding Machine	Assembly	Previous operation of child part	38	1. Length - 380 2. Width - 52 3. No Burr 4. No Wrinkle 5. Product Shape	1. Stopper Setting 2. Sharpness of Blade 3. Clearance between Blade
39	FINAL INSPECTION & DISPATCH AREA	FINAL INSPECTION	variation from previous operations.	39	1. Dent & Scratch 2. SCRATCH	Inspector's Knowledge

2020' 2

Dimension 380.0 tolerance is missing

Note: Data and case study is only for training purpose



Case Study : Weak Requirement Traceability

The final length in drawing it is 741.0 mm +0/ -1 mm

2020-2-27 2

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

MODEL YEAR / VEHICLE												LPK 3516 BS-II		APPROVE :				
Sl No	Process / Function	Potential Failure Mode	Potential Effect of failure	S	Class	Potential Causes / Mechanisms of Failure	Current Process Control Prevention	O	Current Process Control Detection	D	N	Recommend Action	Responsibility & Targeted Completion Date	ACTION RESULTS				
														TAKEN	S	O	O	N
10	Asy / Riveting	If any defect found	Fitment problem / Visually	6		If any process by pass	Riveting	5	100% QA checked before used material	4	120							
20	Rework	If any defect found	Length Variation 741-1/+0	5		Spring back	Restriking	4	Pressing	6	120							
30	Final Inspection	Non Conformance to Specification & if any operation Fault	Major fitment Problem Customer End			Inspector's improper H Improper id Wrong Specification Form preparation	Inspector's inspection report. job setup approval Report. PDI report. Calibration of	2	Inspection as per QP. Use of calibrated instrument's and gauges.	4	56		PDI					

Dimension 741.0 +0 / -1mm

Note: Data and case study is only for training purpose



Case Study : Weak Requirement Traceability

The final length in drawing it is 741.0 mm +0/ -1 mm

CONTROL PLAN																
PROTOTYPE		PRE-LUNCH		PRODUCTION		KEY CONTACT / PH :		DATE (ORIGINAL)		20.11.17		DATE REVISED				
SUPPLIER / PLANT		PTPL	SUPPLIER CODE			Other approval date (if req.):			OTHER APPROVAL/ DATE (IF REQ.) :		N/A					
Part Process No.	Process name Operation Description	Machine device / Tools / Jig for Mfg	CHARACTERISTICS				S.C.C	METHODS		Sample Size Fre		Control Method	Error Proofing	Responsibility	Reaction Plan	Corrective Action
			No	BD No.	Product	Process		Product/Proc.Spec / Tolerance	Measurement Technique	operator	Inspector					
10	Reveting	Reveting Machine Mic	1		1. Rivet Head	1. Rivet mc Load setting	Head as per gauge		5%	First & last pc	F.P Inspection & process insp					
			2		2. Length											
			3		3. Width											
20	Rework	Hydraulic Power Pack	1		1. Length	Load setting	841.1+0	Gauge Gauge/M Tap	5%	First & last pc	1st piece & Last Piece Inspection report , set-up approval					
			2					Visual								
			3													
30	Final Inspection	Gauge	1		Rivet Head	Instrument and Gauge	As per gauge		5%	First & last pc	F.P Inspection & process insp					
			2		Length		841.1+0									
			3		Visual		No die mark									
			4				No crack/Burrs									

Dimension 841.0 +0 / -1mm

Note: Data and case study is only for training purpose



Case Study : Weak Requirement Traceability

Final inspection

- Just says OK or Not OK
- Standard check list is not available
- Actual measurement is missing
- Instrument used is missing
- Date, Shift, Lot or batch number is missing
- Part marking reference w.r.t the sample taken is seen missing

Dimension 741.0
+0 / -1mm

PVT. LTD.

**FINAL INSPECTION REPORT
CHECKLIST**

Part No..... 3120 Description..... Assy.....
 Challan No..... Date..... Lot Qty..... 30.....

Raw Material :

1. Phosphated	5. Oiled
2. Primer Painted	6. Welded
3. Finished Painted	7. Epoxy Primer
4. Zinc Plated	8. Powder Coating

Metallurgical Parameters

Specified Dimension	Tolerance	Actual Dimension					Remarks
		1	2	3	4	5	
length 741.0	+0 -1	OK	OK	OK	OK	OK	
H.D. 90	±0.5	OK	OK	OK	OK	OK	
Rivet Dia 18	±1.0	OK	OK	OK	OK	OK	
Rivet ht 7	±1.0	OK	OK	OK	OK	OK	
gap zero		OK	OK	OK	OK	OK	

Accepted/
Not Accepted

Signature of inspector

Note: Data and case study is only for training purpose



Case Study : Weak Requirement Traceability

Gauge Validation and Verification

There are 2 final gauges available at supplier and one has to be given to customer, when we check the parts in both the fixture some part which gets rejected in the 1st fixture is passing in the 2nd one and visa versa.

Parts which are failing in CMM are passing the final checking gauge and visa versa.

There are some SC dimensions which are not meeting the drawing specification and action plan from supplier is that they check the fitment of part on fixture which is mentioned in drawing, but some part are failing in the fixture also.

Note: Data and case study is only for training purpose



Case Study : Weak Requirement Traceability

Operator and Inspector Skill

Instruction for inspector on how to hold the part and method of inspecting the parts is not available due to which inspection was taking more time and Inspector was regularly looking for instruction from the in-charge.

Drawing, Control Plan and Inspection report is not inline to each other

Requirement in final length in drawing it is $741.0 +0/ - 1$

- PFD it is 380 mm
- PFMEA it is $741 .0 +0/ - 1$
- CP it is $841.0 +0/ - 1$
- Final inspection says only Ok / Not Ok
- There are multiple instrument mentioned on CP to check the dimension
- Instrument used to check is not mentioned on Inspection report
- Gauge used for measurement is not validated and calibrated
- Operators and inspectors are not skilled on the requirement

WHAT WILL BE THE IMPLICATION WHEN IN ANY ISSUE

Exercise : Checking Linkages

Based on the collected VOC, SOP, Document and Records from all departments involved in New Product Development, Check for the flow and linkage of all the documents.

Are the process been followed at shop floor?

Process connected

- Product design
- Process design (ME)
- In coming and its quality along with Sub Supplier PPAP
- Logistics, Store and Packing
- New Product Development
- Quality and validation
- Production
- Maintenance and line set up team etc.

Based on the findings, fine tune your question created during brain storming

DIGITALIZATION OF QUALITY : Powered by EwQIMS

APQP/PPAP MANAGER

Risk Management, Program management, APQP/PPAP Internal use, PPAP management suppliers, Change management

Document pro

document management software

Managing Quality, environmental and HS management system (documentation management)

BOSS

continual improvement

Top management in implementing customer-focused continual improvement and tracking performance

HR pro

performance objectives

Manages employee training and competencies, and aligns business objectives with employee objectives.

TPM pro

equipment maintenance

Manages Total Productivity Maintenance of your plant(s). Address all TPM requirements.

Audit pro

audit management software

Allows you to plan, schedule, conduct and close audits online, making a truly paper-less Audit Management tool.

MSA pro

measurement system analysis

Manages your gages and performs all MSA Studies - Bias, Calibration, GR&R, and Stability Studies for variable and Attribute gages

Requirement Flowdown

requirement flowdown

Involves establishing and maintaining agreement between customer and developer on both technical and non-technical requirements.

Functional Safety

functional safety

Manufacturing Controls and Traceability of ASILs to Control Plan, Inspection Plans, and Inspection sheets

AQuA pro

product realization software

Manages your APQP process and documents including DFMEA, DVPR/Test Plans, Process Flow, PFMEA, Control Plans, Check sheets, Work Instruction, PSWs

Inspection Control

quality control inspection

Manage your In-Process, Incoming & Outgoing inspections

Problem solver

manage your problems and incidents

Manage and solve problems through the use of integrated Problem solving tools.



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Chapter 6

Traceability – Marking and Identification

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Traceability - Marking and Identification

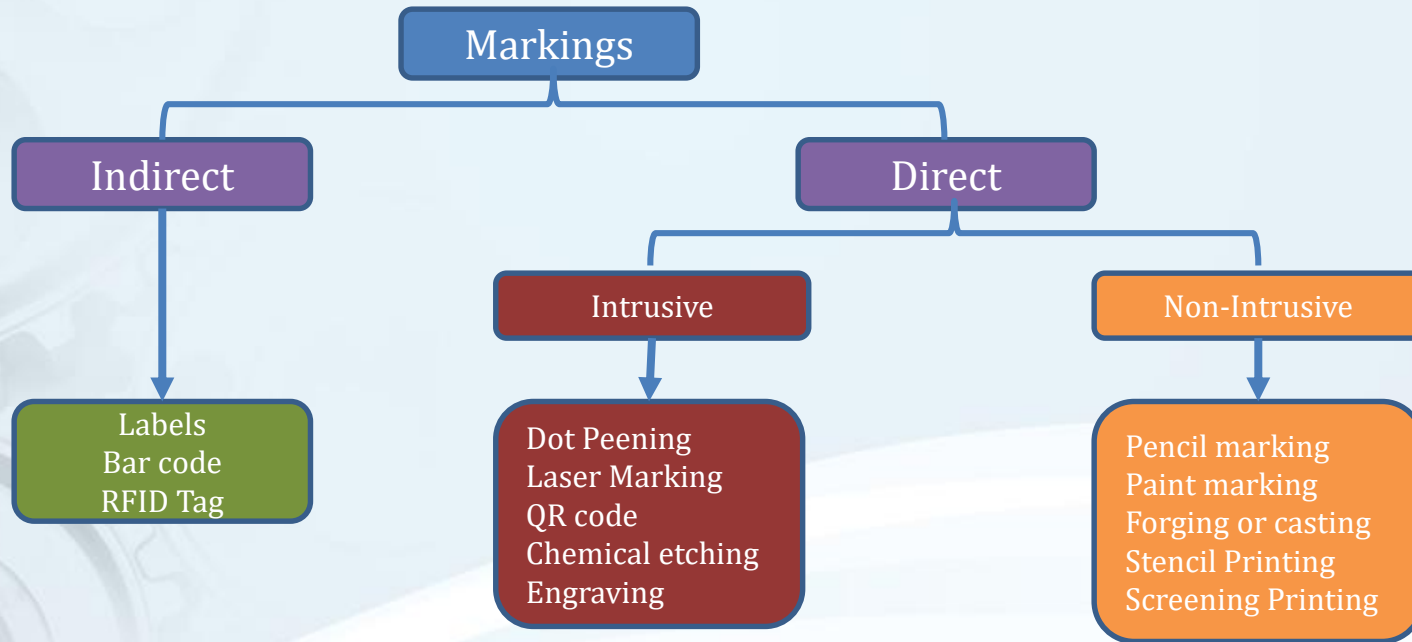
Part Marking

Part marking is a reliable way to provide lifetime traceability of parts that are exposed to harsh environments, tracking and improving product quality and production processes, improve supplier compliance to quality standards, and better manage product recalls. In the automotive sector, part marking has helped manufacturers improve production and quality, while also providing a way to better manage recalls. With more industries focusing on end-to-end tracking and anti-counterfeiting efforts, part marking is proving just as valuable as other process.



Traceability - Marking and Identification

The heart of any traceability system is the identification of that particular physical or digital object. For any tracking or tracing we need markings



Intrusive Marking Methods

Intrusive marking methods alter a parts surface (abrade, cut, burn, vaporize, etc.) and are considered to be controlled defects. If not done properly, they can degrade material properties beyond a point of acceptability. Consequently, some intrusive markings, especially laser, are generally not used in safety critical applications without appropriate metallurgical testing

Non-intrusive Marking Methods

Marking methods that are non-intrusive to the material are produced as part of the manufacturing process or by adding a layer of material to the surface using methods that have no adverse effect on material properties

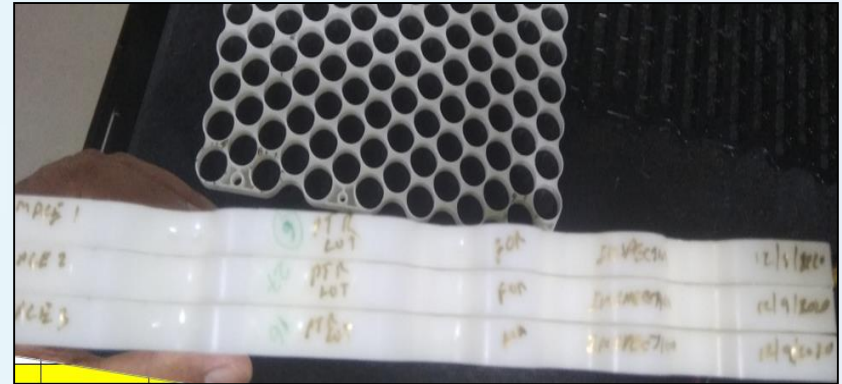
Non-Intrusive - Part Marking

Pencil / Paint / Chalk marking

This is traditional method still been used

Example usage

Injection moulded part, rubber compound and components etc.

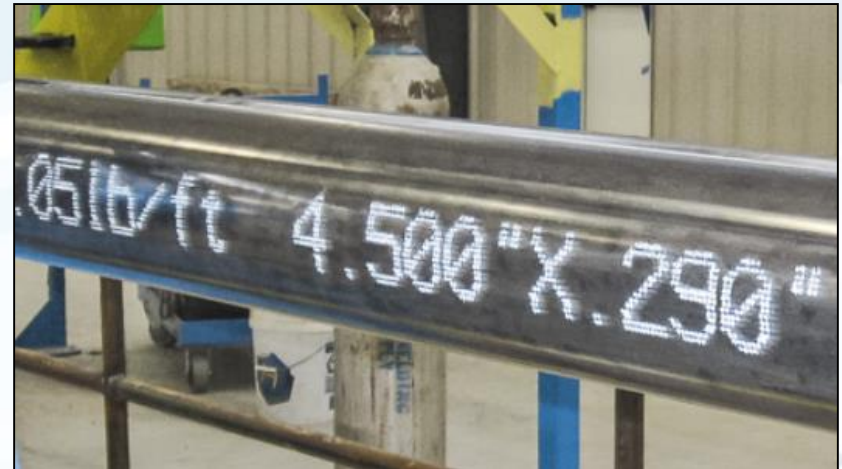


Stencil Printing

Which create the pattern or image by only allowing the pigment to reach some parts of the surface

Example usage

Metal tubes, extrusion pipes etc.



Intrusive - Part Marking

Dot peening

Dot Peen marking is a marking application that allows manufacturers to make deep, permanent impressions in a variety of materials for identification and traceability. Also known as "pin marking" or "pin stamping."



Laser marking

laser marking is a permanent process that uses a beam of concentrated light to create a lasting mark on a surface. Typically performed with pulsed, continuous wave, UV laser machine. Laser marking encompasses a wide variety of applications



Intrusive - Part Marking

Engraving

Engraving is one of the oldest and most important techniques in making. It also make deep, permanent impressions in a variety of materials for identification and traceability.



Chemical etching

Chemical etching is traditionally the process of using strong acid or mordant to cut into the unprotected parts of a metal surface to create a markings in the metal.

Different types of chemicals may be used on different types of material as a method of making.



Intrusive - Part Marking

QR Code

The Quick Response system is become popular in the automotive industry due to its fast readability and greater storage capacity compared to standard UPC barcodes. Applications include product tracking, item identification, time tracking, document management, and general marketing.



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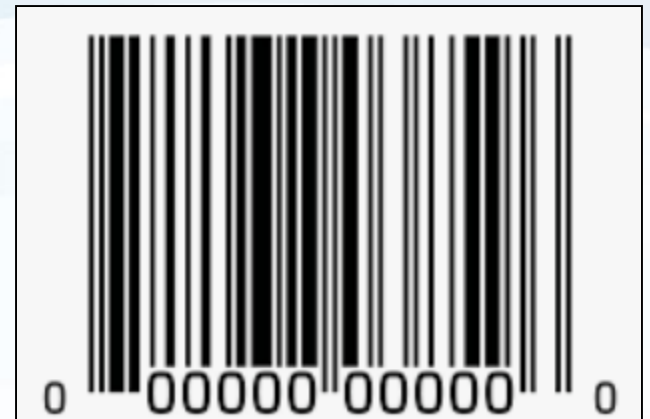
Indirect - Part Marking

Labels



Bar Code

A **barcode** or **bar code** is a method of representing data in a machine-readable form, barcodes represented data by varying the widths and spacing's of parallel lines. These barcodes, now commonly referred to as linear or one-dimensional (1D), can be scanned by special optical scanners, called barcode readers.



Indirect - Part Marking

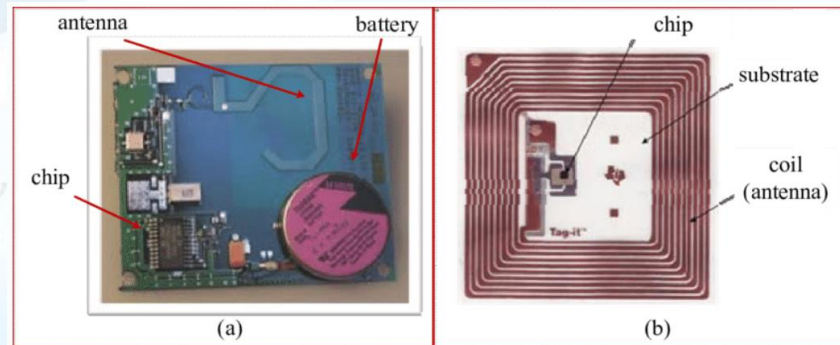
RFID (Radio Frequency Identification)

RFID is a technology that enables the electronic and wireless labeling and identification of objects, humans and animals.

HISTORY

Invented in 1948 by Harry Stockman. But initial application was during World War II-when the United Kingdom used RFID devices to distinguish returning English airplanes from inbound German ones. RADAR was only able to signal the presence of a plane, not the kind of plane it was..

It came into commercial use only in 1990s.

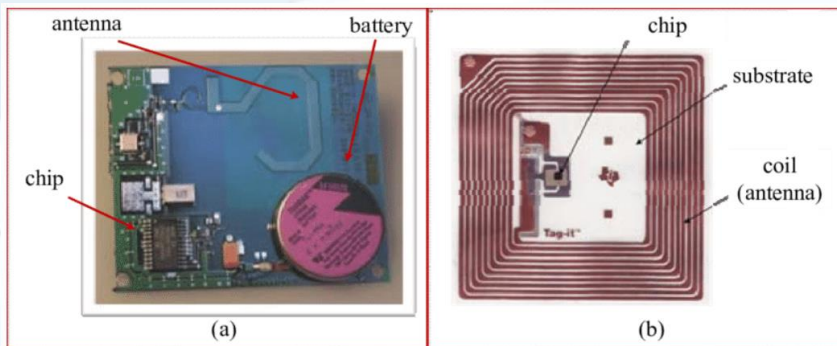


Indirect - Part Marking

RFID (Radio Frequency Identification)

Active tags – Powered by an internal battery – Finite lifetime (because of battery) – Greater range – Better noise immunity – Higher data transmission rates

Passive tags – Operate without battery – Derive power from the field generate by the reader – Less expensive – Unlimited life – Subject to noise – Require more powerful readers

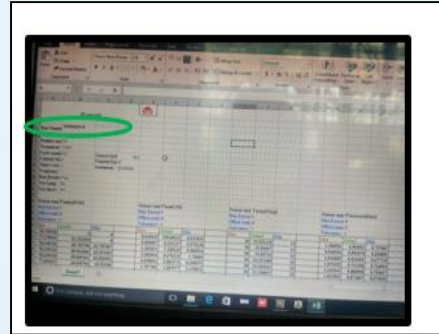


Traceability Use - Part Marking – Case Study

Capturing data and Real time Monitoring – during a Hardening process at Supplier



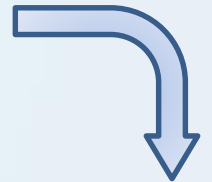
Supplier



Real Time Monitoring



Inhouse - Dashboard



OEM

Benefits:-

1. End to End traceability.
2. Online Tracking of machine and process performance.
3. Utilisation of resources efficiently.
4. Minimisation of Human Efforts.
5. Enhanced Data Collection and reduce paper work and errors.
6. Identification of hidden losses for continuous improvement.



Traceability – Part Marking

Markings : an identification number helps in an activity of collecting and managing information like -

- What has been done in manufacturing processes from acceptance of raw materials and parts to shipment of products
- Information such as work details, inspection results, and test result are linked to this identification number
- Contributes in improvement of production/work efficiency and quality.
- Increased stock visibility and availability.
- Reduces theft in the supply chain.
- Facilitates product selection during production, Line of sight is not required
- Easier Identification on recalls , repairs and rework

Exercise: Linking Requirements to Markings

To meet growing customer demands, the XYZ Group needed a solution that would uniquely identify each of its individual bearings to protect against warranty issue, counterfeiting parts and efficiently provide maintenance services for installed bearings around the world.

XYZ Group decided to use a serialized Item Number for protecting the product

XYZ Group now needs to send RFQ to the service provider for embedding the system for which now XYZ Group need to map what are the data they need to collect and what will be the benefits which it will get from the marking system



Exercise: Linking Requirements to Markings

Data to be collected

Information about Incoming part status	Information about manufacturing process and maintenance	Information about shipment
<ul style="list-style-type: none"> • Quantity Arrived • Date and Time of arrival • Lot and serial number • Supplier details and location • Inspection status • Storage area and qty • Any rejection / rework and segregation details date and time • etc 	<ul style="list-style-type: none"> • Manufacture Quantity from store to final product • Date and time for each stage of production • 4M tracing • Lot / batch number w.r.t each part • SPC value for CC / SC parameters • EOL testing data • Final inspection history • Employee details • etc 	<ul style="list-style-type: none"> • Packing condition and quantity • Shipment quantity • Shipment date and time • Customer and location history • Shipment delivery date and time • Transported name and vehicle details • etc

Exercise: Linking Requirements to Markings

The benefits of part marking for applications include:

- The ability to track items in high-temperatures and other harsh environments
- Providing more accurate and reliable part identification
- Preventing errors in just-in-sequence production
- Eliminating manual data collection approaches for inspections, inventories, and maintenance reports
- Ensuring the lifetime traceability of each part
- Enabling track-and-trace initiatives that provide chain-of-custody tracking and protect against product diversion
- Reducing or eliminating counterfeit parts by providing end-to-end traceability using a method that is difficult to duplicate, and doesn't rely on package marking
- Enabling more comprehensive inventory management

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Chapter 7

Traceability – 4M Requirements

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Traceability – 4M Method

Continuous processes / manufacturing are usually afflicted with a larger variation in process and product. In such type of processes, the products are progressively operated with minimal interruptions refined through a series of operations [1, 2].

Improvement initiatives are been regularly updated or changed including new process technology and automation to control in processes / manufacturing
In processes / manufacturing the variance in key product and process parameters has often remained unchanged, though large investments in automated process control systems has been made to reduce variance

However, to reduce the affect we need systems and tools for studying the impact of changes in the processes as it is vital for reducing the variation.

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Traceability – 4M Method

Today's production environment has substantially increased the number of issues that need to be managed in real time prompting the evolution traceability for tracking and tracing covering nearly every issue of shop floor management.

These issues include:

- **Method** : like equipment, fixtures, tools etc. are identified, used in production and maintained
- **Man** : production monitoring and control of man orientated process and measurement control including rework and repair management visibility is available at real time bases
- **Materials** : in WIP to assure correct production batch, FIFO etc. are followed
- **Measurement** : to monitor and improve key performance and to reduce causes

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Traceability – 4M Method

There are frequent processes found to have too many steps which needs too many sign off and integral activities that does not create values and for which a customer wouldn't pay.

Machine, tools, equipment's, procedure etc. with their underline support system are -

- Frequently mismanaged to achieve output
- Misaligned due to technical error
- Deviated due to inability to meet the desired intended output

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Traceability – 4M Method

Process traceability enables manufacturers to provide traceability for specific production events including part and process changes introduced on the shop floor.

This includes any defects captured and the associated repair processes along with operator activity.

Method traceability together with man, material, and measurement traceability allows manufacturers to achieve full traceability thereby significantly reducing the scope of potential recalls while meeting nearly every possible traceability requirement.

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Traceability – 4M Method

As the method is one of the key factor for any method traceability, we need to have -

- Supports free assembly by distinguishing between key and non key components.
- Assuring that the correct components are allocated to the correct process and by providing post-production traceability as demanded
- Manages and tracks material locations in the event of an alert, including material purging when appropriate
- Tracking changes on the shop floor, including introduction of BOM revisions, new parts

Traceability – 4M Method

Continued...

- Events including capture of defects at the board level with repair routes undertaken such as rework or replaced components and operator activity
- Capturing machine events, (including machine/feeders used during mounting process), errors during mounting,
- Inspection and Verification that process is performed as planned and tracking components mounted to the reference assembly and tested

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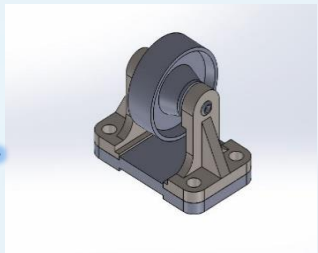
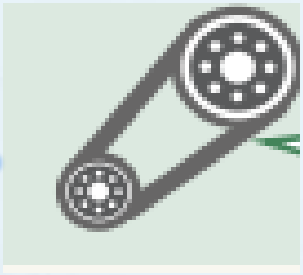
Traceability – 4M Method

Work Piece / Operator

Tools and Fixture

Machining / Assembly

Product Inspection



Serial No :
2021251821MAOM
Part 1 : 243
Part 2 : 890
Part 3 : 613

Part	Lot Code
243	SA1 - 5566
890	SA2 - 4444
613	SB1 - 3399

Serial No	2021251821MAOM
Operator	2021MAXOP
Inspector	2021RCINSP
Supervisor	2021MINSPV
Line no	01

Serial No	2021251821MAOM
Operator	2021MAXOP
Inspector	2021RCINSP
Supervisor	2021MINSPV
Line no	01
Tool	103725
Fixture	1821MA
Test Rig	MATR71

Serial No	2021251821MAOM
Operator	2021MAXOP
Inspector	2021RCINSP
Supervisor	2021MINSPV
Line no	01
Tool	103725
Fixture	1821MA
Test Rig	MATR71
Date/Time MFG	4/1/2021/ 12:24:56
Pressure	2 KPa
Temp	27° C

Serial No	2021251821MAOM
Operator	2021MAXOP
Inspector	2021RCINSP
Supervisor	2021MINSPV
Line no	01
Tool	103725
Fixture	1821MA
Test Rig	MATR71
Date/Time MFG	4/1/2021/ 12:24:56
Pressure	2 KPa
Temp	27° C
Date/Time INP	4/1/2021 12:27:12
Inspection result	125.5 mm
Pressure result	0.5 N/m
EOL	No wear and tear of belt and found ok
Status	OK

Note: Data and case study is only for training purpose



Traceability – 4M – Man

Why **Man** should be the first choice for your shop-floor execution system needs?

- The only manufacturing execution system designed with flexibility in mind
- Integrates with your ERP, MRP, and EDI systems
- Allows your organization to strategically implement and rapidly increase capabilities
- Can be fully integrated into your production environment in minimum days
- Most flexible solution for your production needs

But he also is the most volatile resource in a manufacturing industry



Traceability – 4M – Man

As the man power is the most dependable service and support you expect the most in any manufacturing process, we need to have traceability to trace and track the activity performed.

- An automated / biometric data collection, lot traceability, and product & process sequencing followed.
- Integration to Manufacturing Information system to bridge the gap between the manufacturing shop floor and its ERP/IOT solution.
- The production information and product acceptance necessary to enable your management team to meet the customer demands.
- To adapt to customer driven changes in the manufacturing place.
- Understands training needs and skill mapping that provides successful opportunities to improve their internal manufacturing processes.

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Traceability – 4M – Material

Ability to identify a materials used in a part assembly or in a product and throughout the life of the structure, When it come to material traceability is classify it self in to two levels -

- **Lot traceability**

Means that the materials used in a part can be traced to the set of MTR

- **Piece-mark traceability**

Means that the heat number can be correlated for each piece mark, of which there can be many individual pieces

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Traceability – 4M – Material

Lot identification is most common type of traceability while Piece-mark traceability is often specified as main members in bridges gaps during traceability

traceability of material in manufacturing provides quality assurance, protect customer and end user from delivering defective products

By tracking each piece material, quality problems or product failures can be narrowed to a specific batch or production process. This will help isolate and reduce further issues with an individual heat (lot) or process, while improving performance evaluation and quality control measures.

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Traceability – 4M – Material

Key benefits of Material traceability –

- Minimizes scope and size of product recalls
- Improves material management process
- Accurately tracks manufacturing events by capturing all assembly and inspection points
- Improves flexibility in issuing parts to the shop with the ability to track locations against specific work orders
- Automatically associates specific suppliers > lots > date codes to serial number thereby avoiding all guesswork
- Eliminates mounting errors associated with wrong part placements by verifying kitting and machine setup
- Gives instant visibility to material levels in WIP, allowing improved inventory planning
- Wins more business by complying with core traceability requirements



Traceability – 4M – Measurement

Measurement Traceability is important for providing assurance and accuracy to both customer and in-house manufacturer team for a given process.

Establishing a traceability in measurement that is accurately traceable to a higher standard gives credibility for manufacturers for their results to their customers.

One common misconception with measurement traceability is that the result of the measurement or the value of a standard is actually traceable which is not the only understanding it also provides measuring equipment is traceable and accuracy.

Measurement traceability ensures that a manufactured part dimensions, material or testing and even instrument calibration is accurate and will meet the desired specifications for the application.



Traceability – 4M – Measurement

Result records are documents that give an account of the results at manufacturing, testing and inspection.

Examples:

- Alterations in the manufacturing / measurement process.
- Results of tests and inspections
- Marking between parts and/or lots.
- Reports and investigations on nonconformities
- Certificate of parts / lot w.r.t SC and CC characteristics

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Traceability – 4M – Measurement

Key benefits of Measurement traceability -

- Assure that correct components are allocated to the next processes or customer
- Improves & enables contaminated and noncompliant materials to be located and purged
- Provides comprehensive part inspection history including test results, repair and rework
- Improves product and process defects tracking including which repair activities were undertaken, such as replaced parts and operator activity.

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Traceability – 4M – Measurement

Continued.....

- Normally trace possible root causes – particularly if the cause is a component failure from a specific vendor or production lot
- Tracks operator certification and skill confirming that only certified operators with the appropriate skill and training performed the necessary measurement
- Ensures calibrated equipment & instrument are used in production and track the best before date for calibration of equipment and instrument used for manufacturing and measurement.

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Traceability – 4M – Documents


Bin card

Bin card is the record maintained under the inventory system by the stores department and shows the quantities of materials received, issued and balance in hand after each receipt and issue. It is also known as stock card or bin tag.








It is the statement of records only quantity of materials not the value. It is updated when receipts and issues are made in the store department.

Bin Card is maintained for each item in the stock, in this way it facilitates individual record keeping. It also provides information about the minimum level or maximum level of stock. Bin Card is flexible to use as its format is not standard or rigidly specified. Control over stock can be more effective due to continuous updating. It reduces counting errors.

Traceability – 4M – Documents

Bin Card						
Material Code:			Maximum Level:			
Material Description:			Minimum Level:			
Location:			Reorder Level:			
Unit of Measurement:						
Date	Doc No.	Received from/Issued to	Receipt	Issue	Balance	Verification with SL Date & Verified by

Real Time Data

Date	Raw Material Name	Particulars	Bin Card #	Quantity
1 st Jan 2017	Air Mesh	Receipts		5,000
4 th Jan 2017	C4 Cartons	Receipts		10,000
7 th Jan 2017	C2 Cartons	Receipts		12,000
15 th Jan 2017	C4 Cartons	Issues		4,000
20 th Jan 2017	Air Mesh	Issues		1,000
23 rd Jan 2017	C2 Cartons	Issues		8,000
27 th Jan 2017	Air Mesh	Issues		2,100

Traceability – 4M – Documents

Route Card

Production route card is used for planning the material flow for the production with step by step process and sequence required for the product, this planning sheet is used in all the manufacturing industry that basic requirement for the process sequence and interaction between all the processes and product requirements. Production route card is information sheet for the order wise / customer wise product progress and route tracker and to monitor.

Process route card must have the all information that required to manufacturer the product as per customer requirement and also to consider the quality requirements for the product as per customer expectation.

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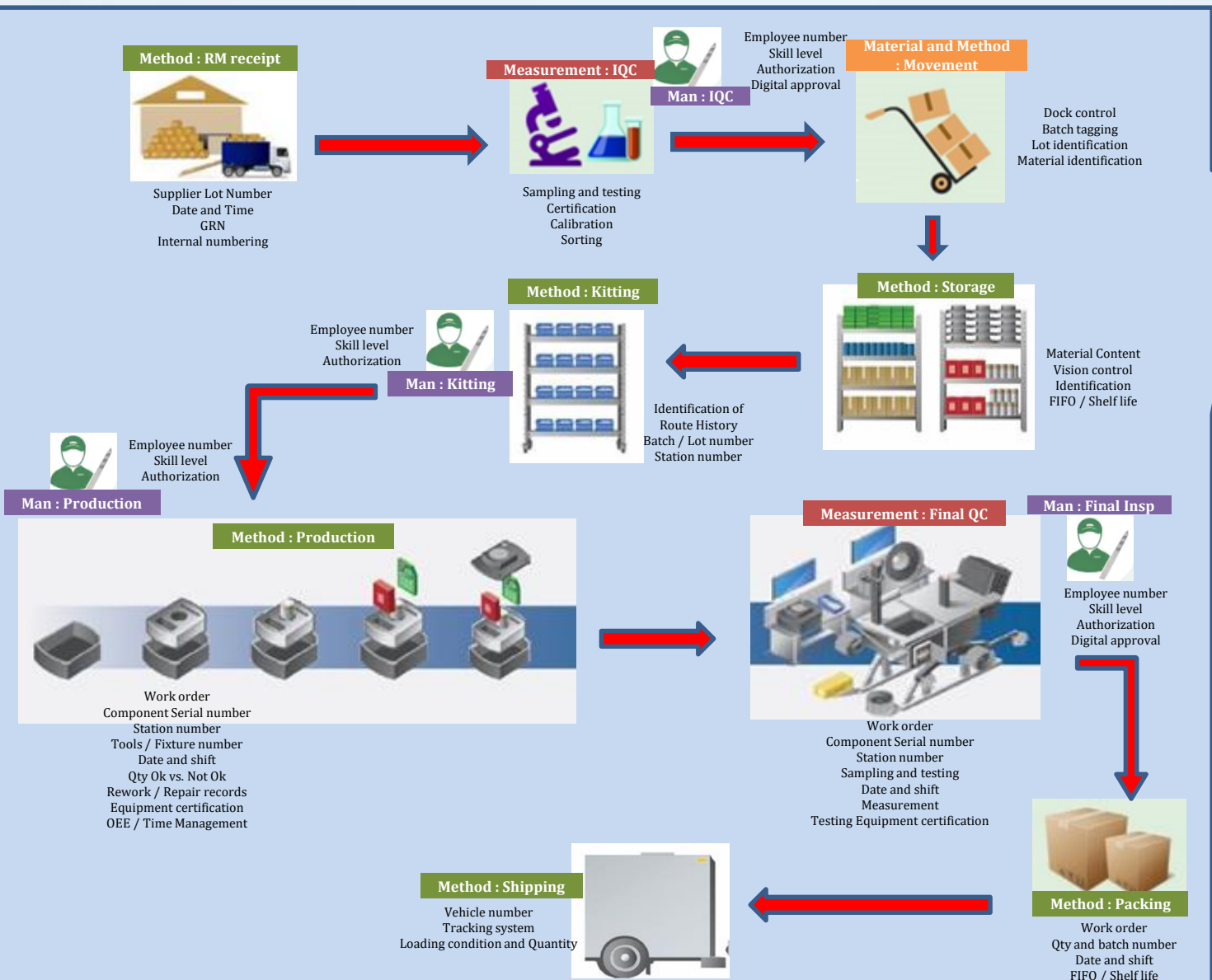
Traceability – 4M – Documents

Some basic following fields are used for the production route card:

- Customer Name
- Product ID and Product Name and quantity to be produced
- Generate date – this production route card generated date
- Process sequences & production -
 - Process name
 - Start and end date
 - Production unit that is quantity
 - Reason form reject if any
 - Accepted unit
 - Remarks

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Traceability – 4M – Summary



Data Reporting and traceability (ERP or other IT system)



- Purchase Order
- Production History
- Productive Reports
- Process Controls
- Machine Events
- Measurements
- Change History
- Deviation Records
- Chemical Presence
- Certification
- Packing and Dispatch
- Invoicing etc

Exercise – Backward Traceability

Backwards traceability

Select a finished product from the material ready to be dispatched. All team will collect record stored may be throughout the different process or department.

Team will present there finings along with photocopy of relevant records based on the data at receiving, at incoming inspection, manufacturing, packaging and shipping of the finished product. **Do not write on or use highlighters on original records.**

Complete a physical inspection and document the results based on the traceability completed. Add as much as photocopies of all related records used during the traceability exercise e.g., material description, lot numbers, quantities, production records, shipping records etc.

Based on the recovery or tracking done Identify areas of improvement to increase efficiency.

The team has to collect the documents from different department / process mentioned based on the exercise completed for markings



Exercise – Backward Traceability

Record	Relevant Information for Traceability (be sure the information can answer the question in parentheses)	Location
Receiving Log	<ul style="list-style-type: none"> Product description Date received Supplier Supplier invoice number and amount Quantity received Batch/Lot number 	
Incoming inspection records Instrument calibration records	<ul style="list-style-type: none"> Inspection ranges identified on IPR or inspection Lab / NABL inspection records Methods used, rework or scrapped Calibration records and history Calibration and acceptance criteria Causes of variation and updating to latest design change. Calibration traceability to International std. The labs used must be NABL accredited 	
Product Storage Log Shelf life Storage Log Cold Storage Log etc.	<ul style="list-style-type: none"> Product description Product code Storage date (in/out) Quantity Location of storage w.r.t quantity traceability to ERP system 	

Exercise – Backward Traceability

Record	Relevant Information for Traceability (be sure the information can answer the question in parentheses)	Location
<p>Production Record</p> <p>Packaging Material Usage Record</p>	<p>Ingredients, packaging materials, and equipment</p> <p>Date of the part production</p> <ul style="list-style-type: none"> ▶ Raw lot numbers and date of movement (change to production) ▶ Records of Manufacturing and Inspection Parameters ▶ Product lot number, operator, and inspector <p>Finished product</p> <ul style="list-style-type: none"> ▶ Product description ▶ Product code (lot code) ▶ Quantity produced <p>(How much of the lot code was used in production?)</p> <p>(How much product was produced?)</p> <p>(How much was rework? OA Hold? Waste/Damage?)</p>	
<p>Shipping Log</p>	<p>Date shipped</p> <p>Customer and its location</p> <p>Finished product lot code</p> <p>Quantities shipped</p> <p>Packing condition</p> <p>(What customers received the product, when and how much?)</p>	



Chapter 8

Traceability – Data elements linkage to ERP / Other IT systems

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OMNEX



Traceability - ERP

ENTERPRISE RESOURCE PLANNING(ERP)

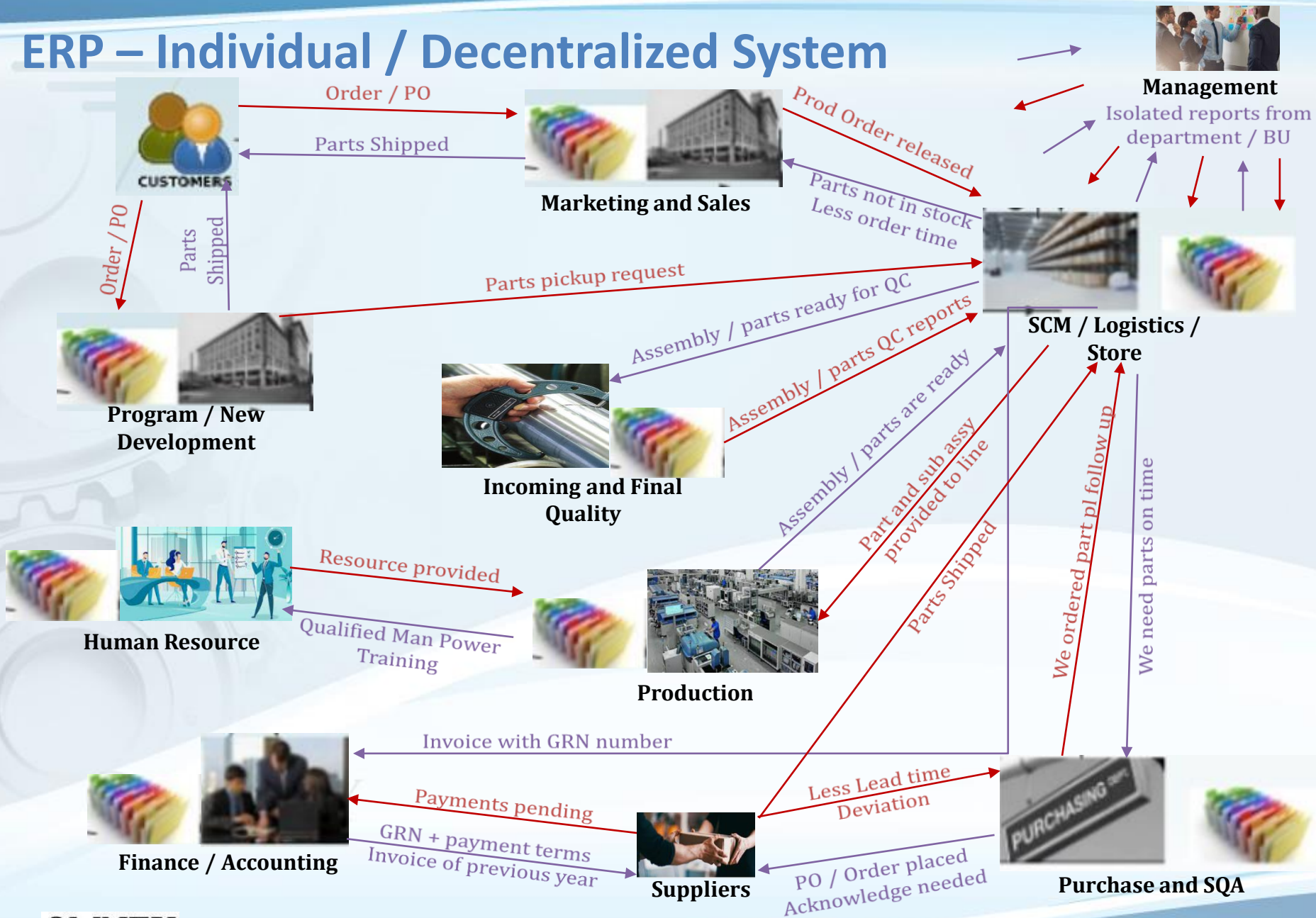
ERP is a cross- functional enterprise system driven by an integrated suite of software modules that supports the basic internal business processes of a company

A traditional company has many departments/ business units(BU), these departments/ BU continuously communicate and exchange data with each other when ever needed, but ERP combines all databases across departments into a single database that can be accessed by all employees

By combining all databases across departments into a single database that can be accessed by all employees and also automates the tasks involved in performing a business process interlink

The success of any organization lie's in effective communication and data exchange between the departments/ BU as well as associated third party such as suppliers, outsourcers and customers.

ERP – Individual / Decentralized System



Note: Data and case study is only for training purpose

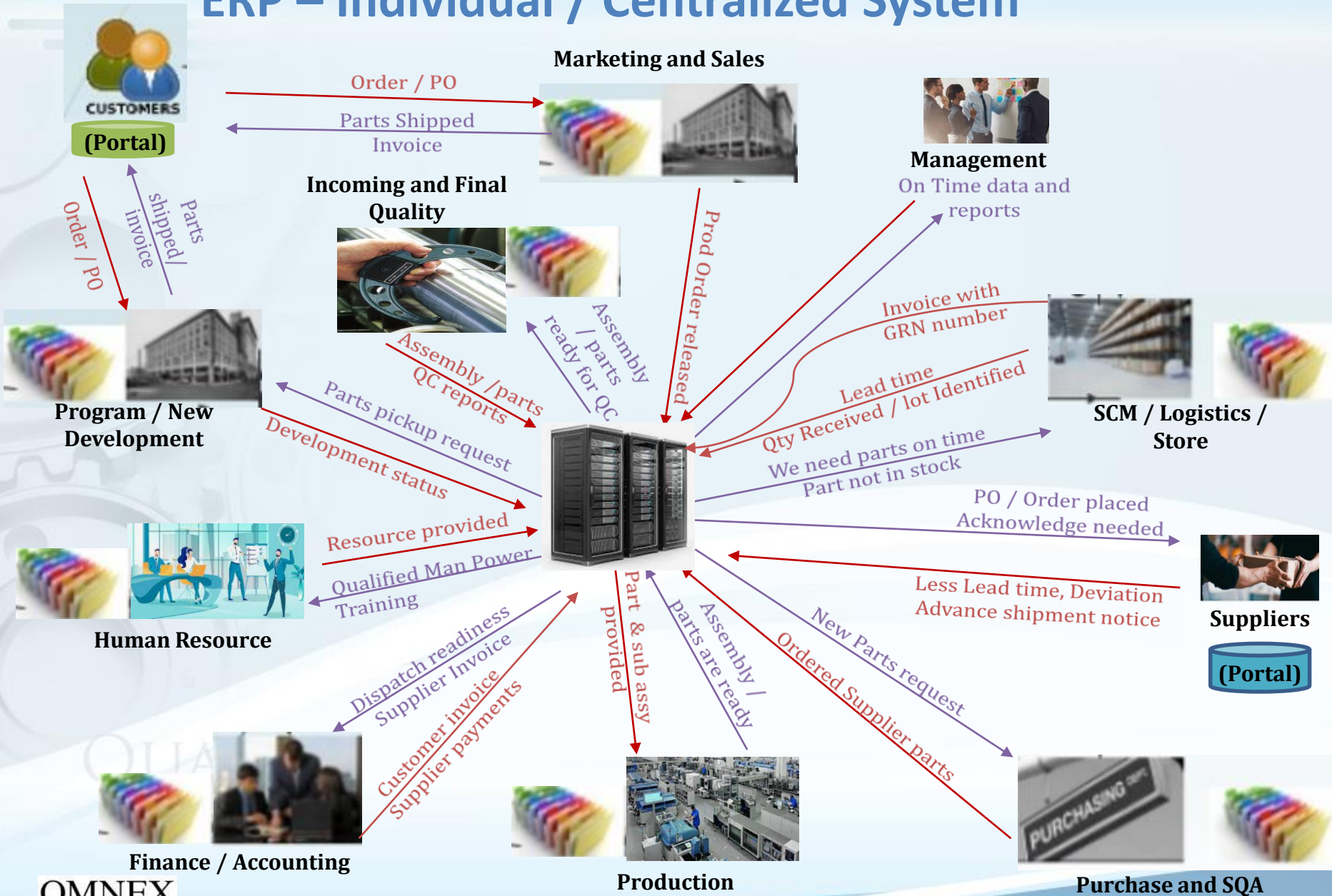
ERP – Individual / Decentralized System

Problems with ERP - Decentralized System -

- Numerous disparate information system are developed individually over the time.
- Integrating the data becomes time and money consuming.
- Inconsistences and duplication of data.
- High inventory, material and human resource cost.

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ERP – Individual / Centralized System



Note: Data and case study is only for training purpose



Benefits of traceability with ERP Integration

Management

- Provides on time reports, spreadsheet and analysis on all BU processes including KPI
- Ability to modify, add and share new requirements and build plans for new models.
- Reduce the time taken and risk associated with managing issues, assets, non moving stock etc.
- Adapt quickly to changes in the business while continually improving operational effectiveness

Benefits of traceability with ERP Integration

Customer

- Facilitate on-time communication and ordering from customers through a portal and self-service ERP.
- Manage, Track and Trace all aspects of the product lifecycle, including quotes, orders, pricing, changes, validation and verification, requirement fulfillment, quality issues, returns, repairs, campaign and service
- Automatically turn a customer-specific feature requirement into a set of requirements to be validated as well as buildable manufacturing requirements to the shop floor.
- Streamline customer order which is faster, more accurate for make-to-order with fewer errors in manufacturing and shipping
- Provide visibility and tracking of product inventory and Improves equipment management and inventory of spare parts
- Manages and Tracks all modes of transportation w.r.t shipments control.



Benefits of traceability with ERP Integration

Manufacturing

- Digitalizes manufacturing by integrating planning, scheduling, quality, cost management, material movement and shop floor control
- Gains visibility across plans, accurately track manufacturing performance, tracks and provides information on waste.
- Capture material and production data w.r.t markings according to manufacturer, supplier and/or customer formats to improve effectiveness e.g. material transaction
- Optimize manufacturing performance, facilitate risk management analysis on planned and unplanned equipment and machine maintenance, including calibrations

Benefits of traceability with ERP Integration

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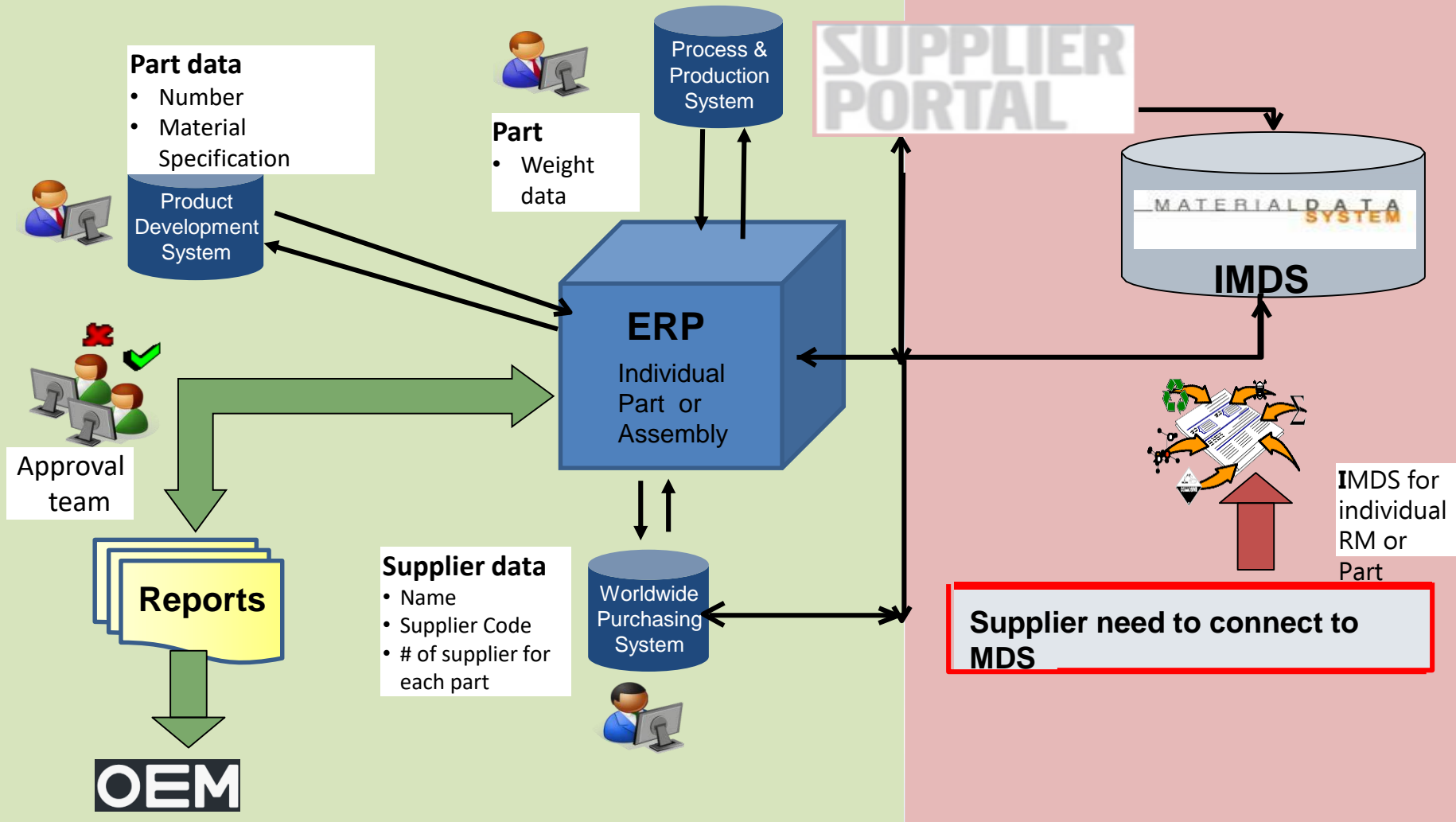
Benefits of traceability with ERP Integration

Supply Chain

- Facilitate real-time communication about RFQ and development including product and process requirement
- Synchronization operation and traceability between supplier and manufacturer
- Capture inbound receiving data w.r.t. supplier labeled markings
- Ensure quality standards compliance with suppliers
- Track corrective actions and support continuous quality improvement

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ERP with Internal System and IMDS Linking Application



Chapter 9

Traceability – Industrial Internet of Things

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Industrial Internet of Things (IIoT)

Stronger demand for customization, increasing customer expectations, the complexity of the global supply chain – these and many other challenges encourage manufacturers to find new, more innovative ways to remain competitive. In an attempt to gain productivity improvements and uncover new ways of enhancing manufacturing and supply chain operations, businesses resort to digital transformation.

Industrial Internet of Things (IIoT) is a way of digital transformation in manufacturing. Industrial IoT employs a network of sensors to collect critical production data and uses cloud software to turn this data into valuable insights about the efficiency of the manufacturing operations and services they provide.

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Industrial Internet of Things (IIoT)

The Industrial IoT helps organization achieve and enhance customer experience by -

- Predicting product failures and service problems in after sales
- Evaluate product performance
- Maximize productivity through maintaining production uptime and efficiency
- Reducing costs and eliminating waste.
- Optimize supply chain processes, improve demand forecasting,

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IIoT – After Market / Sales

Aftermarket service is the new focus to address the revenue, profitability in today companies as they are looking for new way to increase their revenue and customer loyalty along with increasing competition along with tougher and dynamic sales of new products, equipment and technology.

Profitability through services has always had a higher contribution to company's profit which further emphasizes the need for better service and a connected IIoT acts as a key enabler to monitor, control & optimize services throughout the life cycle of the product.

IIoT Enables -

- Remote service
- Analytics through systems
- Reduce Warranty costs / return



IIoT – After Market / Sales

Remote service - this provides a rapid ROI without immediately changing the entire value chain. Like -

- Monitor health & performance of product and provide much needed information to customer service agents and field technicians.
- Provide accurate solution at a faster rate and reducing the equipment downtime
- Tracks product and its performance against standard expected metrics.

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IIoT – After Market / Sales

Analytics through systems - helps make informed data-driven decisions which includes -

- Predictive maintenance – including service visits, potential failure, alerts
- Real-time information on product usage
- Scope for business optimization – an opportunity to integrate business systems is made possible through IIoT and can help in automating processes like parts ordering, warranty claim management , customer support, asset tracking and fleet management.
- An ability to transform customer experience – additional product value can lower cost through software upgrade of the connected systems which can focus on the usability thereby increasing the life of the product.

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IIoT – After Market / Sales

- Reduce Warranty costs
- Arrest false claims – the operating conditions can be monitored to help establish genuine warranty claims
- Improve design – Manufacturers can get better insight into the performance of the equipment thereby bringing in better features and functionalities with quicker and better design
- Reduce inventory costs – with insight into potential failures manufacturers can better plan their inventory levels and increase sales of their high margin parts
- Reduce service cost – by equipping the field technician with information on the equipment configuration, performance, usage, etc. he/she can provide better service enhancing
- Enable remote servicing – decreasing unplanned equipment downtime and reducing travel cost

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Case Study : 2 Wheeler OEM

Built an intelligent electric scooter, featuring route optimization and predictive maintenance with Cloud IoT which enables instant data crunching for thousands of scooters.

Breakthrough of project

- A small engineering team to invent a unique IoT mobility system
- Facilitates platform updates every month
- Qualifies deployment of 43 IoT sensors on each vehicle for granular data on driver experience
- Delivers data insights that keep down costs for both the company and the consumer

They linked their big idea to Google Cloud, confident that Cloud IoT Core and Big Query



Case Study : 2 Wheeler OEM

The synergies between customer and Cloud IoT solutions resulted in a unique mobility platform and Google Maps Platform-enabled navigation as a core feature, 2 wheeler capabilities are amplified.

The 2 wheeler -

- Performs predictive maintenance to fix problems before they happen,
- Structures electricity use for big cost savings,
- Analyzes traffic and road conditions for optimal route options,
- Alerts riders to unoccupied electricity stations in the grid and many much more.

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Case Study : 2 Wheeler OEM

The aggregated data from all scooters on the road is providing key intelligence to develop future models based on customer habits and requirements, for example,

- Can read exactly how far customers are riding every day to inform decisions regarding driving range
- Innovative updates such as "guide-me-home" lights and real-time ride/energy efficient indicators help bolster Ather Energy's competitive position
- Rolling out an update every month. And that means our focus has to be on application development too

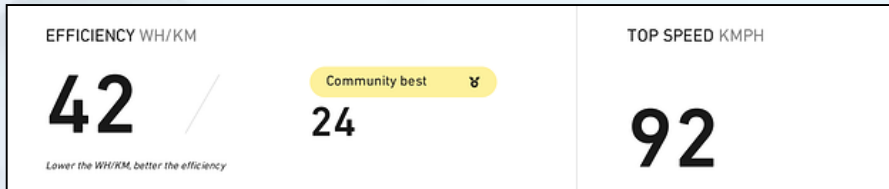
With data insights the company makes a small tweak into some of the firmware and fix issues with no cost impact on the customer as well as for OEM

QUALITY



Case Study : 2 Wheeler OEM

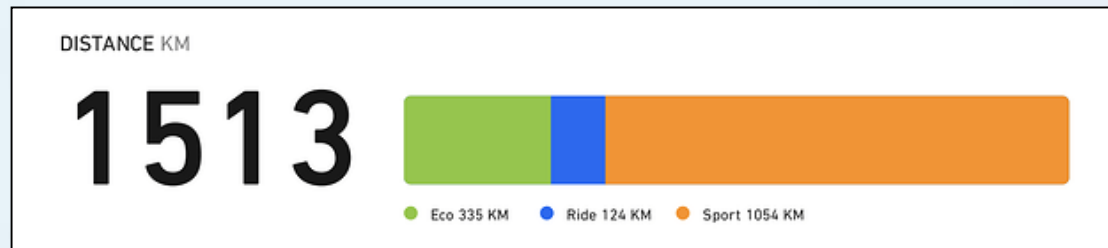
Ride efficient



How did you ride?



Mode of ride Sport vs Ride vs Eco

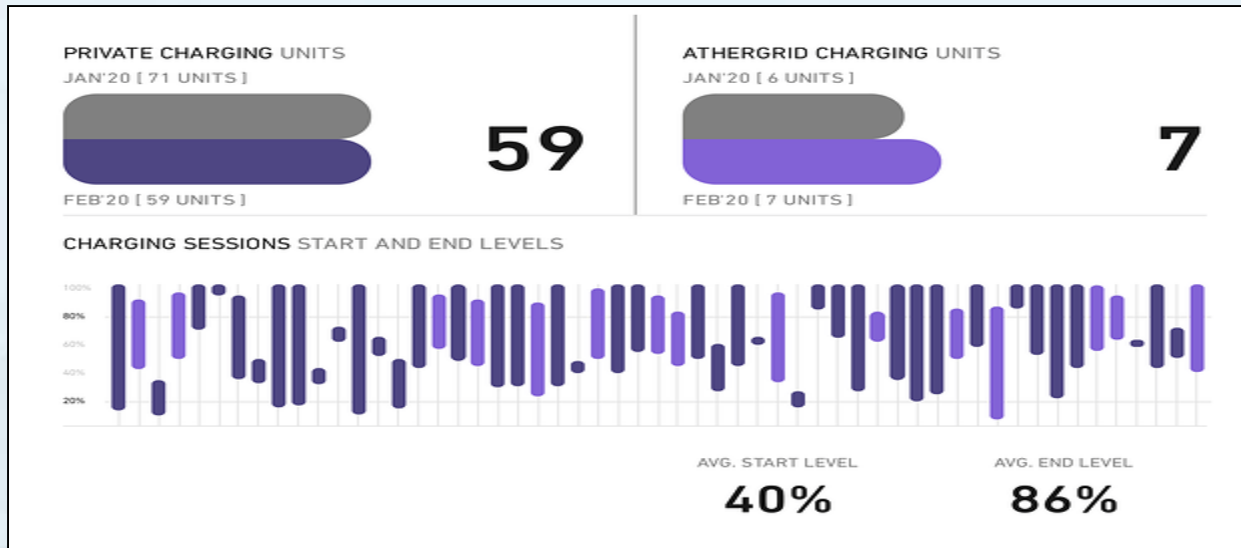


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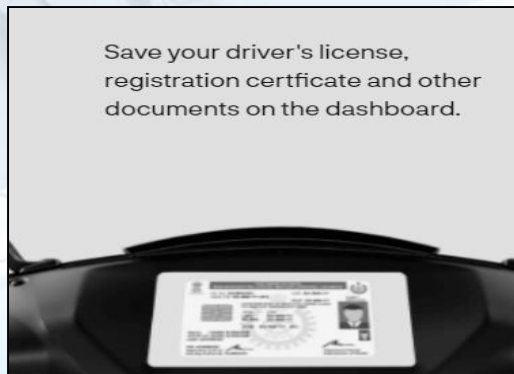


Case Study : 2 Wheeler OEM After Market

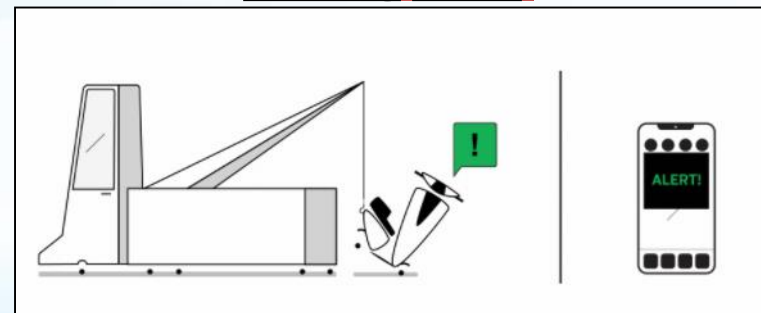
Charging behaviour



Personal and Vehicle documents



Towing Alert



IIoT Adoption in Manufacturing

The main adoption drivers for the Industrial IoT solutions include:

- **Cost reduction.** inventory management, reduced machine downtime, efficient energy use.
- **Shorter time-to-market.** Faster and more efficient manufacturing and supply chain operations, allow reducing product cycle time.
- **Mass customization.** A dramatic increase in the variety of produced increases manufacturing operations get more complex. Tracking the inventory and the manufacturing operations becomes burdensome and, in some cases, not feasible. IIoT facilitates mass customization by becoming a source of real-time data required for *thoughtful forecasting, shop floor scheduling and routing*.
- **Improved safety.** IIoT helps to ensure a safer workplace. Paired with wearable devices, IIoT allows *monitoring workers' health state and risky activities* that can lead to injuries. Along with ensuring workers' safety, IIoT addresses safety problems in potentially hazardous environments. For instance, in oil and gas industry, IIoT is applied to monitor gas leakages as it travels through the pipe network.

Three Visibility of IIoT's in Manufacturing

IIoT technologies are transforming the way production systems are built and run, driving improvements across manufacturing in digital transformation:

- Visibility into shop floor and field operations
- Visibility into the manufacturing supply chain
- Visibility into remote and outsourced operations.

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Three Visibility of IIoT's in Manufacturing

Visibility into the shop floor and field operations

The Industrial IIoT offers the innovative level of visibility into the shop floor and operations, as well as the control over resources. IIoT technologies fill the gaps created by that lead systems like ERP which has their own limitations eg the dependence on manual data input or the inability to work with detailed information By providing manufacturers with second-by-second shop floor data, IIoT allows businesses to -

- Track real-time equipment status
- Manufacturing process productivity and records
- Inventory and its location

The IIoT applications allow manufacturers to gain a higher level of visibility in -

- Supporting manufacturing operations
- Facilitating industrial asset management.

Three Visibility of IIoT's in Manufacturing

Manufacturing Operations

IoT applications for manufacturing deal with operations as monitoring and optimizing equipment performance, production quality control, and human-to-machine interaction.

Monitoring equipment utilization

IoT applications for monitoring machine utilization can increase manufacturing productivity by up to 10% to 25%.

IoT solutions for monitoring machine utilization provide businesses with real-time equipment utilization metrics, eg. what is occurring at every point of the production process.

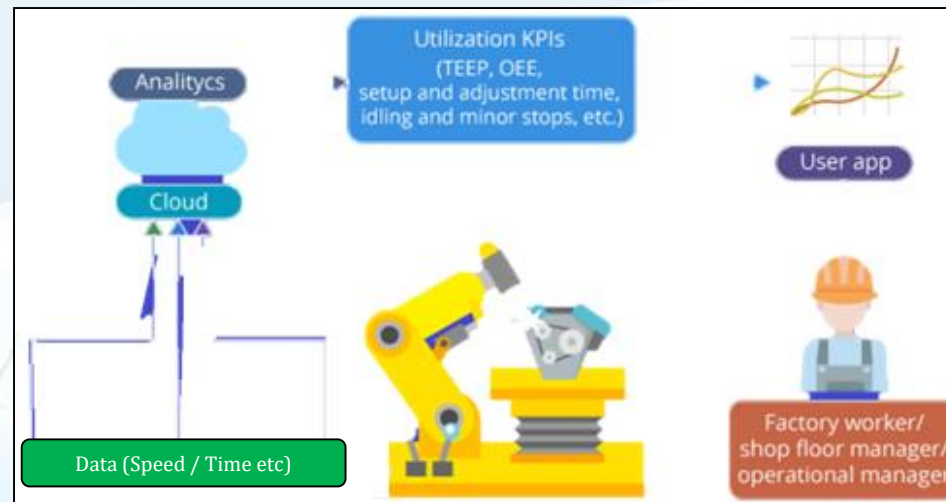
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Three Visibility of IIoT's in Manufacturing

Monitoring machine utilization starts with pulling relevant data about machine operating parameters, e.g., run time, actual operating speed, product output, etc. IIoT gathers data in real time and transmit it to the cloud for processing. The cloud aggregates the data and develops it into informative insights about equipment utilization KPIs.

Based on the data collected the results are visualized and displayed to user either web or mobile.



Three Visibility of IIoT's in Manufacturing

Manufacturing Operations

Quality monitoring

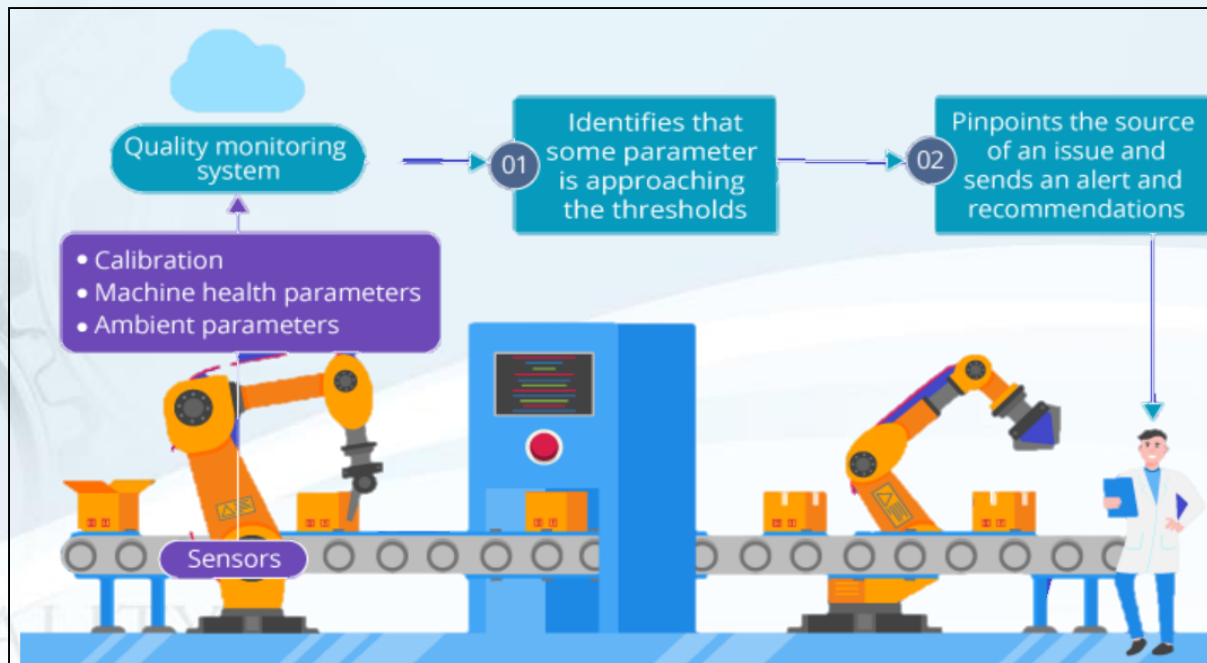
An IIoT Monitoring the quality is done jointly by capturing 3 activities and linking it to that individual product -

- Monitoring product quality like inspecting a WIP (work in progress) or produced goods as it moves through the production cycle. e.g. possibility to inspect every WIP, finish goods, statistical method etc.
- Monitoring the condition and calibration of machines/ equipment / instrument etc. on which a product is measured or manufactured. e.g. it helps to detect bottlenecks in the manufacturing operations, identify badly tuned and/or underperforming machines, timely prevent machine damages, and more.
- Monitoring the quality of the production process, such parameters as equipment, machine parameters (speed, vibration, etc.) and environmental conditions (temperature, humidity, etc.) are monitored to identify when they go beyond the normal thresholds and give trigger for correction.



Three Visibility of IIoT's in Manufacturing

A IIoT quality monitoring solution pinpoints the source of an issue, triggers an alert to take recommend action to fix or tune the machine and minimize the process of producing low-quality products.

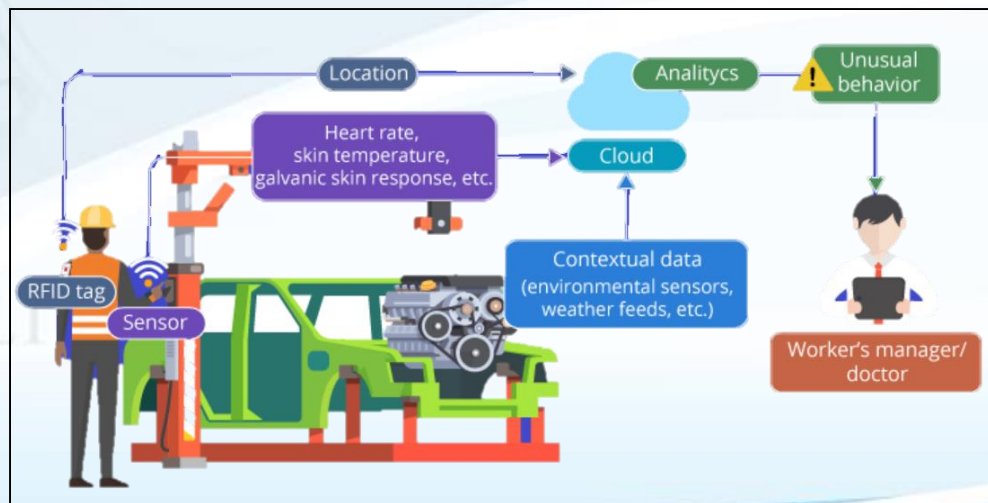


Three Visibility of IIoT's in Manufacturing

Manufacturing Operations

Monitoring safety

In various industrial sectors, including mining, oil & gas, transport, etc., workers receive RFID tags that gather data on their location and wearable sensors collecting data about their heart rate, blood pressure, skin temperature, and other parameters. The sensor data is relayed to the cloud where it is analyzed against data (e.g. from environmental sensors, legacy work planning systems, weather feeds, etc.) to detect unusual behavior patterns (say, sudden vertical movements, unusual heart rates, etc.), and prevent workers from falls, overexertion, and other injuries and timely report a safety threat.



Case Study : Tyre Industry (Manufacturing)

A Tyre Industries Ltd listed among the top 25 tire manufacturers in the world, with a wide range of products.

Caters to diverse different business segments in the automobile industry and with a global presence in 100 countries.

The companies has 12 manufacturing plants and produces over 35 million tires per year and they needed to check and drive all their performance.

The critical manufacturing processes included mixing, calendaring, extrusion, cutting, winding and curing and capturing the data and creating report manually was a challenging task.

To over come the constrain the company opted for drive IoT-enabled digital transformation by connecting critical processes in tyre manufacturing. Some challenges faced

- Integration with a fully-functional line and existing IT systems
- Support variety of machines with a variety of connectivity protocols
- Provided extreme accuracy and reliability so as to be used as point of reference

Case Study : Tyre Industry (Manufacturing)

The process and manufacturing data was integrated with ERP to bring visibility and predictability into the manufacturing value chain.

The resulting manufacturing process data was used for deeper analysis into improving process quality and predicting failure of product additional it was also used to monitor machine condition, and accuracy.

Machine	< 19-06-20 	Shift A							
<div style="display: flex; justify-content: space-between;"> MACHINE 02 REPORTS ▾ ACTIONS ▾ CONFIGURATIONS ▾ Jun 20th, 2019 Thu, 02:21:53 CDT </div>									
Parameter	05:00 - 06:00	06:00 - 07:00	07:00 - 08:00	08:00 - 09:00	09:00 - 10:00	10:00 - 11:00	11:00 - 12:00		
Back Pressure	218	49	45	203	32	49	191		
Cavity Pressure	549	137	137	595	135	139	608		
Injection Pressure	0	0	0	0	0	0	0		
Alerts									
Time	Message	Workcenter	Parameter	LCL	LWL	UWL	UCL	Warnings	Critical
13:00:00	⚠ Warning lim	MACHINE 02	Back Pressure	7	8	14	15	47	0
13:00:00	⚠ Control limi	MACHINE 02	Cavity Pressure	65	68	82	85	0	138
13:00:00	⚠ Control limi	MACHINE 01	Rear Zone Temp...	150	160	195	200	164	64

Case Study : Tyre Industry (Manufacturing)

Benefits

- **Traceability:** Mockup trail gave 98% accurate traceability through its manufacturing cycle and derive insights around critical quality, condition and production data at every stage.
- **Quality:** Reduced manufacturing rejection to only 0.05% as the data helped in performing root cause analysis of parameters that govern process quality using statistical and machine learning techniques.
- **Productivity Improvement:** Get an insight into parameters that impact line productivity, such as line rates, loss and quality analysis at multiple levels.

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Case Study : Tyre Industry (Manufacturing)

Benefits

- **Machine Condition Monitoring:** improved machine availability unto 97% through monitor and analyze parameters that are critical to machine health. Optimize machine downtime by predicting failure before it occurs.
- **Automated Bookings:** with ITOT integration with ERP, automatically book production that helped in better visibility and unblocking the inventory.
- **Energy and Consumables:** Analyze energy and other consumables that are part of the production process and discover ways to optimize their utilization.

Look forward to scaling further as the single source of truth for monitoring our operational KPIs and continuous improvement initiatives : MD Tyre Limited

Three Visibility of IIoT's in Manufacturing

Industrial asset management

Along with improving the effectiveness of manufacturing operations, the IIoT is applied to ensure proper asset usage, extend equipment service life, improve reliability, and provide the best return on assets like.

- Industrial asset tracking
- Inventory management
- Predictive maintenance (based on condition monitoring)

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Three Visibility of IIoT's in Manufacturing

Industrial asset tracking

IIoT provides -

- accurate real-time data about enterprise's assets,
- their statuses,
- locations and movements.

IoT-based asset management solutions remove the tracking burden and eliminate errors bound to the manual methods of data input.

Be it a mold, tool or fixture gets labeled with an tag, which serves as an asset identifier. Each tag has a unique ID, which is linked to the data about a particular asset. Both the ID and the corresponding asset data is stored in the cloud. The asset data may include the asset's physical parameters, cost, serial number, model, assigned line, area of use, etc.



Three Visibility of IIoT's in Manufacturing

Industrial asset tracking

Once an asset, say, a mold, leaves an equipment storage yard, a tag reader installed at the store entrance, scans the tag attached and saves the record about the asset leaving the store to an in-cloud database.

Similarly, when the mold enters, say, a molding machine, a tag reader at the machine scans the tag and updates the data in the database. Logging such data throughout the asset's journey allows all to see the movements of the assets.

A tag reader along with GPS tracking can be used to state the location of the movable assets outside your manufacturing location like supplier

QUALITY



Three Visibility of IIoT's in Manufacturing

Industrial asset management

Enterprise inventory management

IIoT-driven inventory management solutions help manufacturers

- Automate inventory tracking and reporting
- Ensure constant visibility into the statuses and
- locations of individual inventory items
- Optimize lead time (the time between an inventory order and its delivery).

Inventory management solutions applied in the manufacturing settings are based on IIoT and RFID technologies. Each inventory item gets labeled with a passive tag. Each tag has a unique ID that carries the data about the item the tag is attached to. To fetch the data from the tags, readers are used. A reader catches tags' IDs and relays them to the cloud for storing and processing. To establish the location and the movements of the scanned tags, along with the tags' IDs, the data about the location of the tag and the time of the reading are relayed to the cloud. The cloud pinpoints the location and the status of each item, visualizes the findings and displays them to the users.



Three Visibility of IIoT's in Manufacturing

Industrial asset management

Predictive maintenance, condition monitoring

Predictive maintenance relies on the insights gained with *continuous equipment condition monitoring*.

A equipment with sensors collect data on a wide range of parameters determining its health and performance, e.g. temperature, pressure, vibration frequency, etc.

Once collected, the real-time data from multiple sensors is transmitted to the cloud, where sensor readings are combined with data (equipment's model, configuration, operational settings, etc.), equipment usage history and maintenance data fetched from ERP, maintenance systems and other sources. The whole of data is analyzed, visualized, and presented to shop floor workers and management on a dashboard or in a mobile app.

Visibility across the manufacturing supply chain

Currently end-to-end supply chain visibility still seems far-off. However the adoption of IIoT-driven manufacturing supply chain management solutions are quite positive. Smart supply chain management solutions provide manufacturers with real-time insights into the location, status, and condition of every part (be it an individual inventory item on a warehouse shelf or a truck delivering supplies) at any segment of the manufacturing supply chain.

For instance, with the traditional supply chain management methods, the manufacturers could only get general data about the availability of an product.

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Visibility across the manufacturing supply chain

With IIoT in the manufacturing supply chain, organization get the data about both the location and the properties (e.g. production date, shelf life, etc.) of each individual product.

Along with monitoring the location and the properties of the product, IIoT is applied to monitor the conditions, under which the objects are stored and delivered. Before IIoT came into play, the condition of goods could only be monitored once they arrived at the delivery point. Now, the condition of materials, components and goods can be monitored during transportation, which is especially relevant for the manufacturers of breakable and perishable items (e.g. adhesive, glassware, modern nanomaterial's, etc.).

Consider an example of a adhesive company shipping an order to a customer via a third-party logistics service provider. Sensors attached to the containers monitor the temperature inside the containers, suppose, because of a cooling system failure, the temperature inside the containers is starting to rise. A temperature sensor attached to the inner side of the container 'detects' the deviation from the recommended threshold and alerts both the supplier and customer. The IIoT solution notifies the driver too that the delivery conditions have been violated and immediate action have to be taken.

Visibility into remote and outsourced operations

When an enterprise builds or buys a manufacturing or storage facility in a different city, state or country it still has to maintain its manufacturing and production standards (material testing, industrial automation, predictive maintenance, and other) which is difficult with traditional methods of monitoring.

IoT-based system given timely prediction of potential failures, allows scheduling, maintenance activities in advance and eliminates the need to keep a local maintenance team. Similarly, IoT-driven utilization monitoring solutions help manufacturers keep an eye on the efficiency of manufacturing operations (by providing real-time equipment efficiency metrics) without direct access to the shop floor.

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IIOT

The challenges of IIoT adoption

The toughest challenges faced for starting IIoT-enabled digital transformation initiatives include -

Investment needs and ROI - IIoT initiates spending on hardware (sensors, gateways), connectivity, cloud storage, administrative labor, and technical support. Businesses have to consider how quickly they can roll out new solutions and how fast it will take for a solution to start generating revenue.

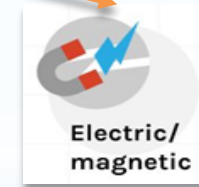
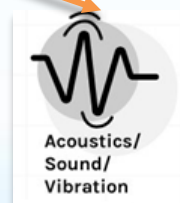
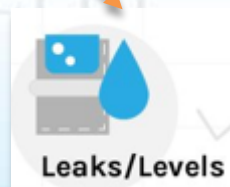
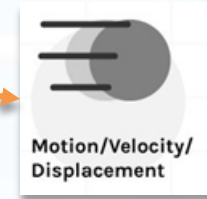
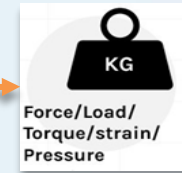
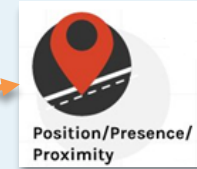
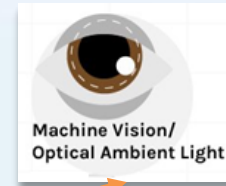
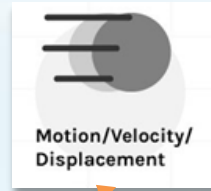
Data security issues - IIoT adopters believe IIoT is increasing the risk of cyber attacks as they do not have a plan to prevent losses from possible security threats. As most of IIoT system and sensor are driven through 3rd party

Lack of qualified employees - Have a shortage knowledge or trained people at the management and deployment level with experience in IIoT. Other specific skills that are lacking, which include analytics expertise and experience in big data, embedded software development, embedded electronics, IT security and artificial intelligence.

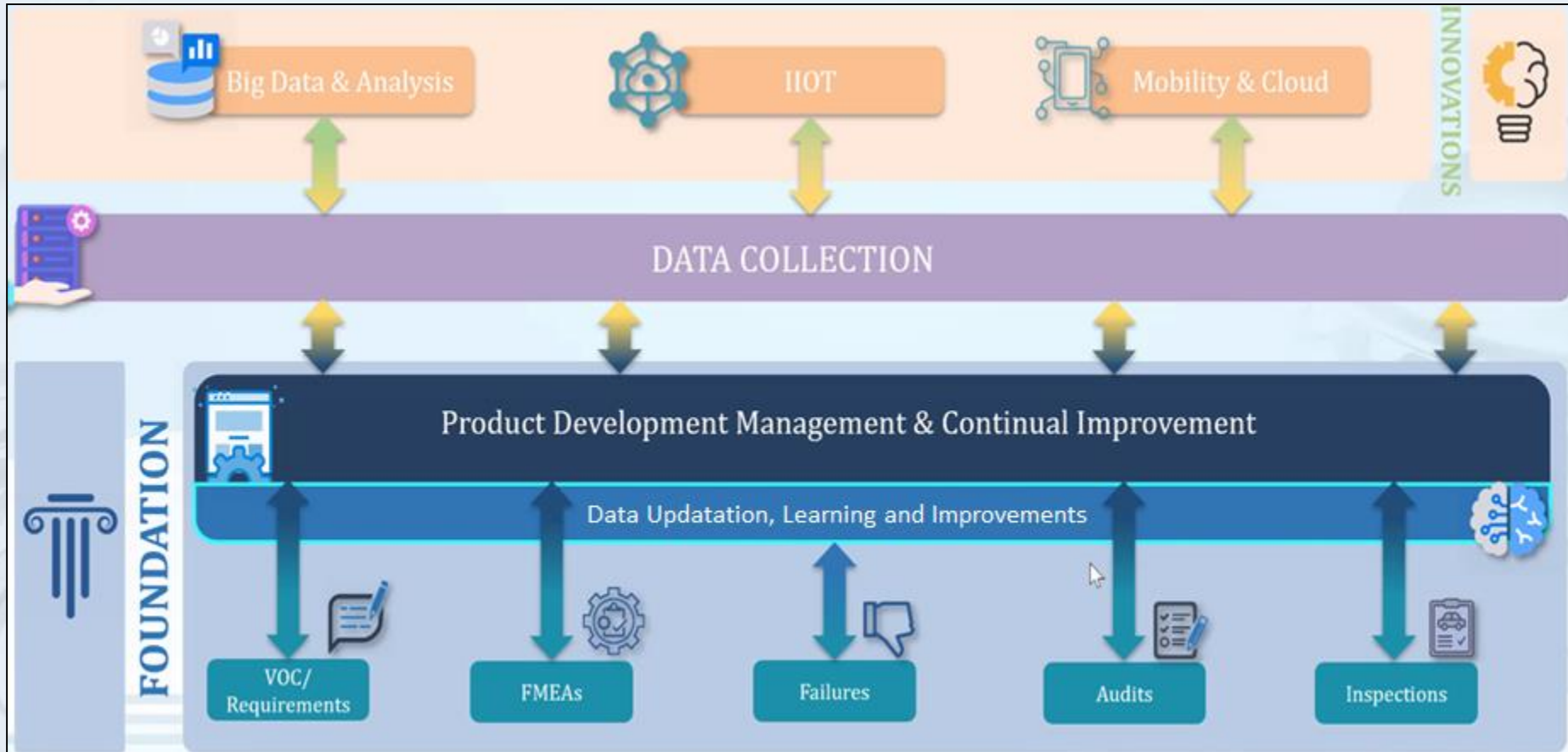
The integration with operational technologies and legacy systems - The difficulty of rolling out IIoT solutions in the existing manufacturing ecosystems and that to without data losses and security as they were based on different technologies and networks.



IIoT Sensor



Overall Summary



Thank You!

Questions?



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