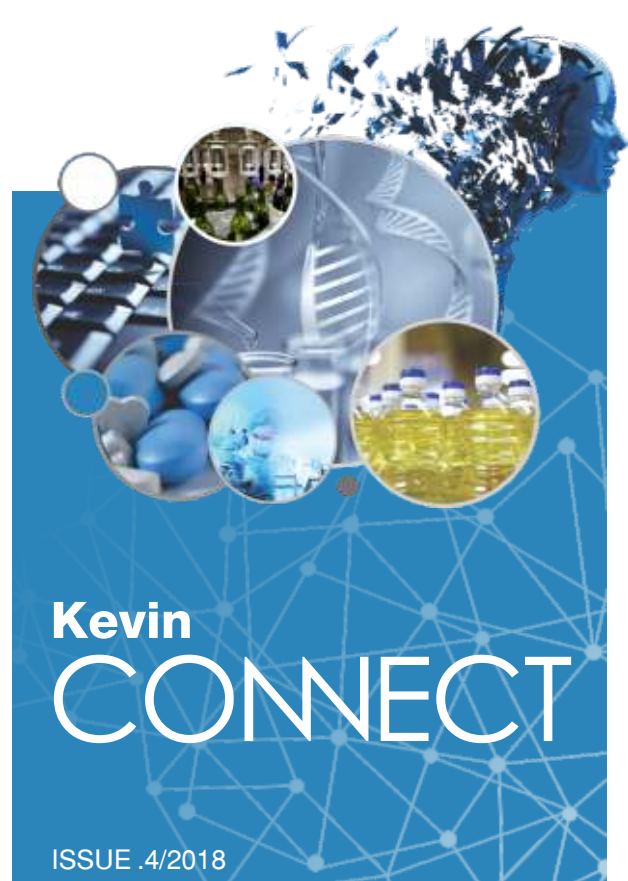




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Kevin CONNECT

ISSUE .4/2018

CONNECT INSIDE

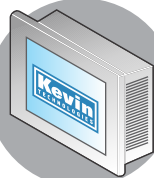
- 1 Advantages of Implementing MES & Modules of MES
- 2 Insights on challenges and Approach for Implementation of L2 Integration Solutions
- 3 Importance of Connectivity of Process Equipment to Central SCADA & typical architecture
- 4 Validation Approach to MES

ERP



MES

PLC & SCADA



MACHINES

DIFFERENT PRACTICAL
APPROACHES TO

**MANUFACTURING
EXECUTION
SYSTEMS**



Dear Customers / Friends,

Kevin has an impressive legacy of partnership with its customers in successfully applying technology-based solutions and supporting their competitiveness. We are proud of our reputation as a reliable & trustworthy solutions provider for factory automation as well as Regulatory Compliance Services.

Our corporate culture is one of dedication, respect, and continuous improvement. We measure our success by our customers' successes. In a time marked by rapidly changing customer expectations, I am enthusiastic about the opportunities available for us to address the emerging requirements of our customers.

It is always a challenge to maintain manufacturing and inspection systems in validated state in continuously demanding standard to achieve high levels and regulatory requirements. Apart from guideline requirements this industry also demand for maintain high quality and elevated level integrity to ensure compliance. Need a close monitoring with predefine intervals to schedule validation requirements. Especially for inspection systems in packing area which use computerized system also required documented evidences for validation to meet compliances such as GAMP.

Yours Sincerely,



Ketan Khambhatta,
Managing Director



Driving Performance with Technology

Providing world-class technologies and solutions

Founded in 2000, Kevin Technologies is a leader in Automation for Life Sciences, Starch & Edible Oil, Consumer Packaged Goods & MES (Manufacturing Execution Systems) solutions. We are also one of the largest companies, in the area of Regulatory Compliance & Validation for FDA approved facilities across pan India.

We specialize in conceptualization & development as well as engineering of automation and supervisory control systems. Kevin helps clients meet their business objectives by providing effective project management capabilities and expertise in state-of-the-art technologies including Regulatory Compliance & Validation Services.

Our Mission

To provide technical excellence through innovation teamwork and commitment.

Our Ultimate Vision

To be the number one company in the area of expertise that we operate in, especially Factory Automation & Regulatory Compliance Services.

ADVANTAGES OF IMPLEMENTING MES & MODULES OF MES

- MES functions as a key component of The Connected Enterprise, delivering transformational value in operational intelligence
- It is estimated that by 2020 more than 20 billion industrial smart devices will be on the plant floor.
- Such growth of smart devices is already creating new opportunities for companies to encourage workflow adherence, and to expand their ability to pull, analyze, contextualize and share data.
- Today operational intelligence has become a reality. It gives real-time information, analyzes problems and identifies solutions. With operational intelligence, from the plant floor to management level, everyone will be given the visibility that they need to make decisions faster and manage the business better.
- MES solutions provides manufacturers the information designed to help improve performance management.
- There are different MES solutions that are available for companies to implement. Since no system can be defined as “out-of-the-box” manufacturers might find it challenging when choosing a system that works best for the company and its operations.

ADVANTAGES OF MES

Achieve Operational Excellence:

Helps to Optimize throughput and improve asset efficiency by leveraging fixed and variable manufacturing assets such as materials, machinery efficiency, manpower, and energy spend. Increase yield while reducing losses and improving first-pass quality, without affecting on-time delivery.

Improve supply chain effectiveness:

operators can quickly and easily recognize deviations from performance targets - enabling manufacturers to reduce their impact. Maintain accurate inventory levels by controlling the scheduling and execution of plant assets and tracking material production and consumption.

Comply with regulations and trading partner reporting requirements:

traceability with better reporting and documentation

Meet Sustainability Goals:

Gain a greater understanding of the effect of production on utilities and help manufacturers to gain control of resources, drive equipment improvements, and maximize company's achievement of sustainability goals.

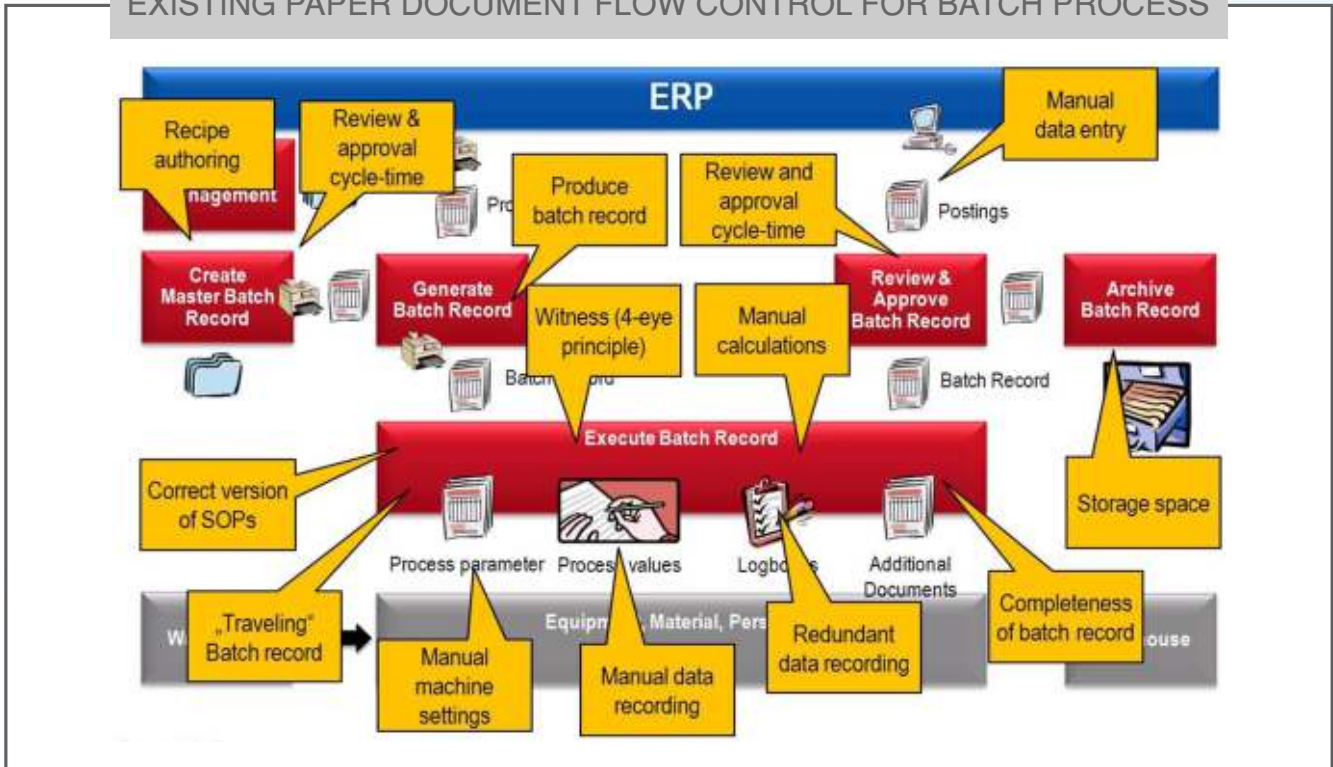
MES Life Cycle Best Practice

When choosing an MES, companies should think about long-term system maintenance and prepare for solution upgrades. Customized systems may need extensive engineering to upgrade or replace altogether. A clearly defined URS is crucial to successful MES usage because it can provide a better understanding of MES possibilities. Thus, this will help a company leverage as much as they can from their investment.

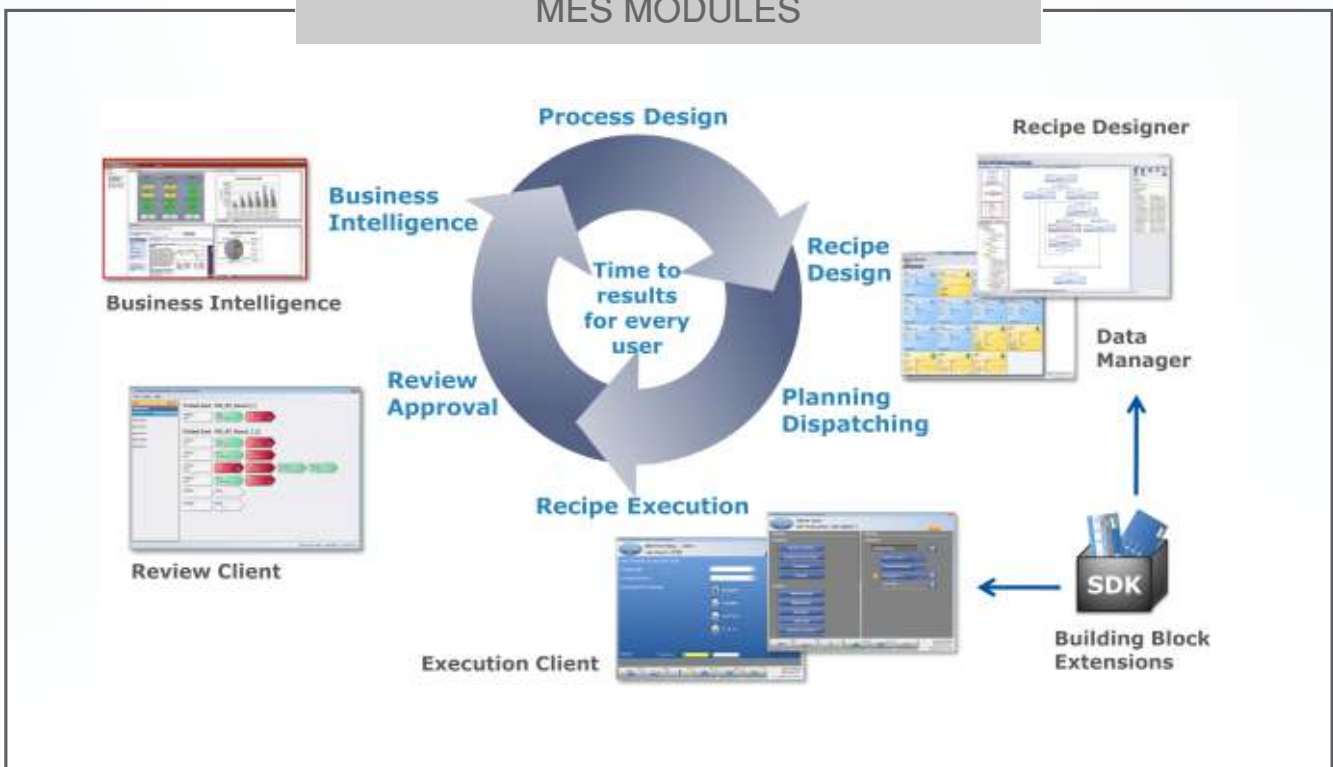
Along with a well-defined URS, unmet goals, unreliability, or understanding process to handle documents not part of MES, can define the needs for upgrades or overall replacement of the MES. Each company will have its own set of implementation and upgrade criteria, but it is important to remember that outdated systems may not adhere to production compliance or data quality. For this and many reasons, it is important to have a plan in place in the event of an MES upgrade or replacement to quickly and compliantly resume production.

ADVANTAGES OF IMPLEMENTING MES & MODULES OF MES

EXISTING PAPER DOCUMENT FLOW CONTROL FOR BATCH PROCESS



MES MODULES



INSIGHTS ON CHALLENGES AND APPROACH FOR IMPLEMENTATION OF L2 INTEGRATION SOLUTIONS

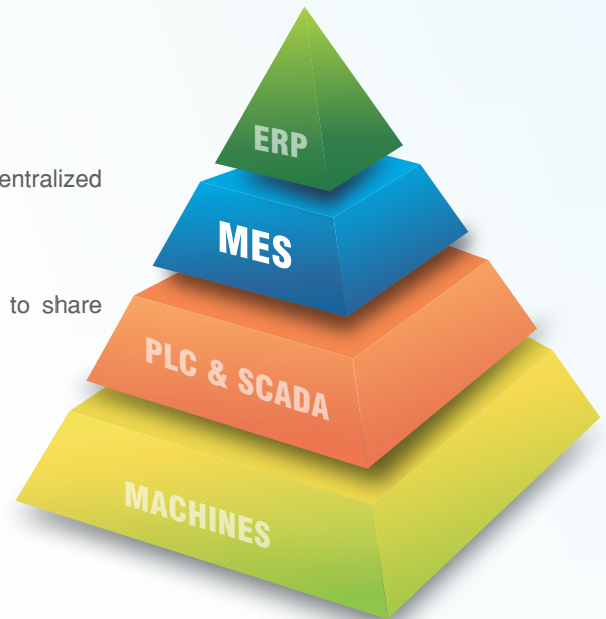
STRATEGIC STEP – INTEGRATING MANUFACTURING ASSETS

Requirements

- Standardization of Batch Reports.
- Easy Retrieval of historical data.
- Connectivity to MES for integration of production data to ERP.
- Easy availability of manufacturing data for MIS.
- Integrity of Batch Data for Compliance Requirements.

Challenges

- Connectivity of various machines having different PLC & HMI to a centralized location or machines without PLC.
- Process Knowledge of various machines and different PLC platforms.
- Availability of program backups, password, apprehension of OEM's to share information.
- Ensure availability of data at centralized SCADA at all time.



INTEGRATE YOUR MANUFACTURING, QUALITY & COMPLIANCE

Integration Challenges

- Machine Availability for Modification & Software Revalidation.
- Modify SOP for operation of the system.
- Installation of LAN network for connectivity of PLC systems.
- Change mindset of operating persons.
- Revalidation of the PLC system.
- Maintaining SCADA system in a validated state.
- Involve all depts. – production, QA, IT to agree to implement and maintain the system.
- Vendor selection with required knowledge of different PLC, Pharma machinery and validation.

Integration Best Practices

- Involve all Departments – Manufacturing, Engineering, QA, IT to agree to implement and maintain the system.
- Top Down Approach always helps. Buy in from Management as well as Stake Holders.
- Define a Team Leader & a Team that can drive this across the plant/s.
- Identify the need & the Gaps-Take help of suitable experts in this field.
- Vendor Selection for Execution-Vendor to have a good track record of Automation / Integration / Various Devices & Networks/Software & the Regulatory Landscape. Prior experience is a key to ensure that the Vendor is an asset.
- Bring on board all Equipment & Systems Suppliers to support your plans.
- Identify Software & Hardware platforms that are current, stable & with a long history of successes in the area.

IMPORTANCE OF CONNECTIVITY OF PROCESS EQUIPMENT TO CENTRAL SCADA & TYPICAL ARCHITECTURE

KEY BENEFITS

Archive

- Centrally Manage Versions of Electronic Files & Folders.
- Provide Scheduled Back up & Compare Operating Asset Configurations.

Archive

- Track User Actions – Who did What, When, Where ?
- Searching & Reporting on Log Files (Scheduled or Ad Hoc)

Security

- Prevent unauthorized access to make changes.
- Restrict Viewing of artifacts.

Extensibility

- Ability to extend & add support for 3rd party devices.
- Easy to scale asset management to meet your needs.

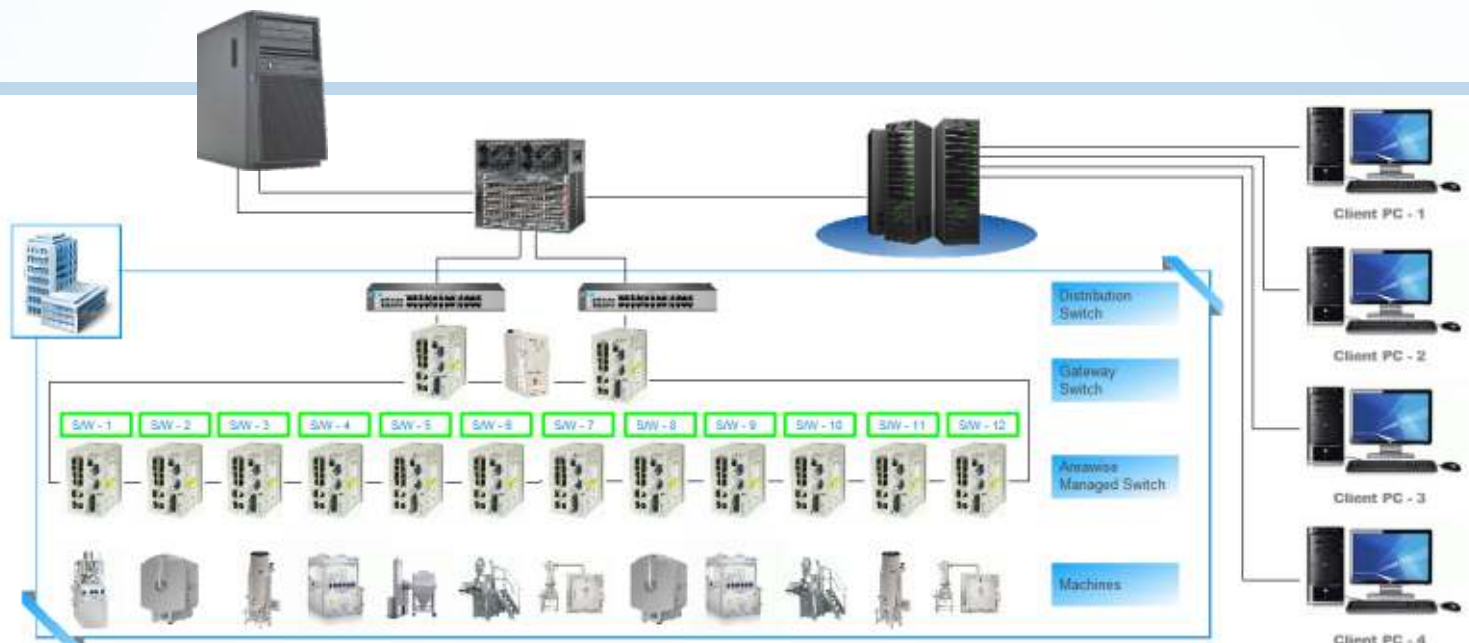
Process Device Configuration & Calibration

- Support for Process Device Configuration.
- Paperless Management of Instrument Calibration Data.



A TYPICAL SOLUTION

- Addition of required hardware for connectivity of each PLC on a network such as Ethernet.
- DLR Ring Architecture to ensure availability of data at all times.
- Suitable SCADA Software that can also be expandable to view from remote locations.
- Add on Historian and Software for Recipe transfer, Batch Report, audit trails.
- 21 CFR part 11 compliance of HMI's through use of Asset Management software.
- Integration of utilities in same DAS / SCADA.
- Software must comply to 21 CFR Part 11.



IMPORTANCE OF CONNECTIVITY OF PROCESS EQUIPMENT TO CENTRAL SCADA & TYPICAL ARCHITECTURE

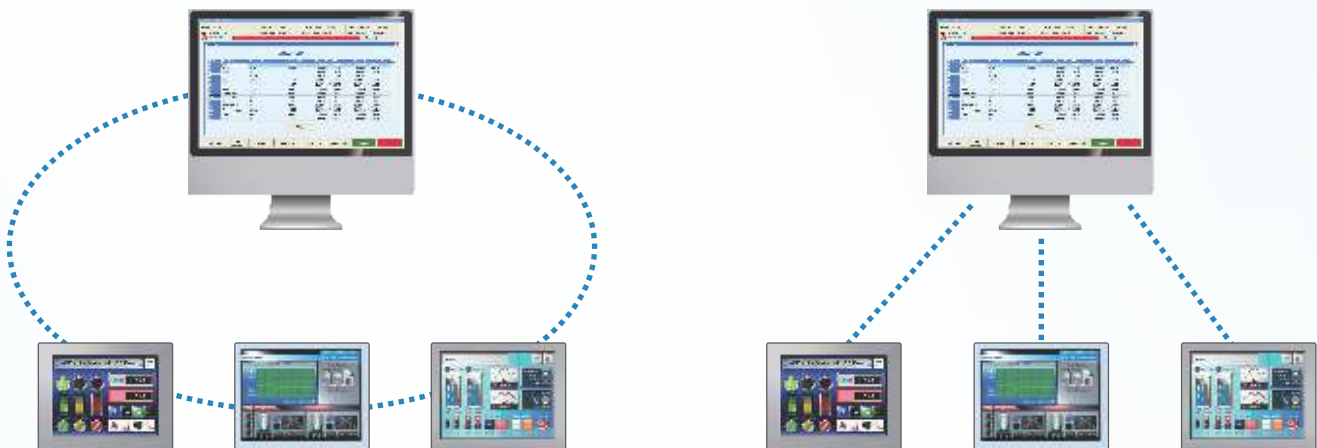
REDUNDANT RING VS STAR ARCHITECTURE

Device Level Ring (DLR)

- Data from all machines available at any given time at central SCADA.
- Addition to network is easy – no additional H/W at central level.
- Possible to give redundant station to buffer data in case of failure of central location hardware / software.
- Complex than Star topology – need more attention for maintenance.

Device Level Star (DLS)

- Data lost of equipment whose communication network has failed.
- Addition may required H/W at central level.
- Simple topology – Easy maintenance.



PLC + HMI & PLC + IPC Solution

PLC+HMI Based Solution

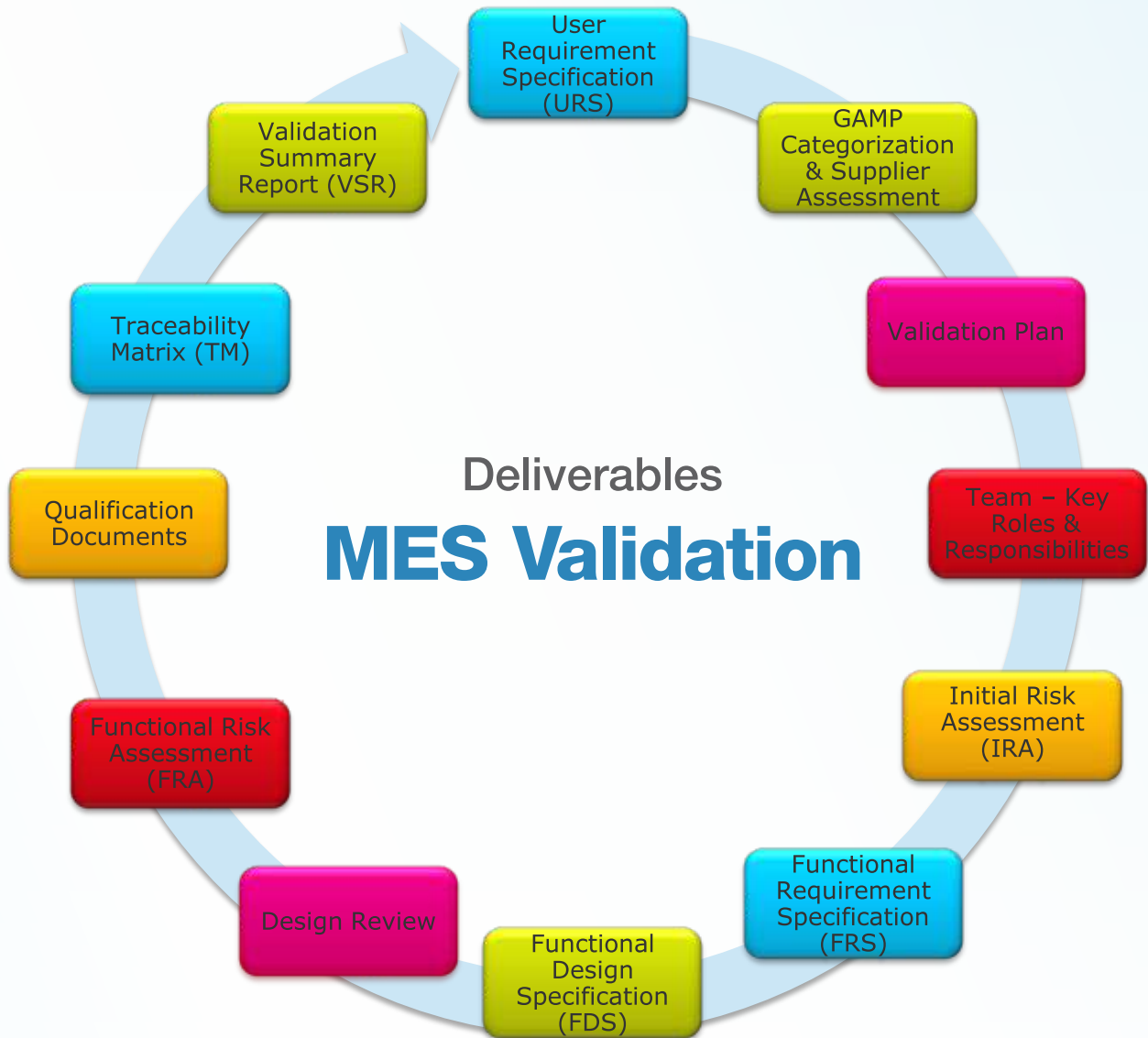
- Low cost of ownership over its lifecycle.
- Validation as per category 3.
- Easy to maintain.
- Need to upgrade PLC & HMI with Ethernet communication.
- Achieve compliance and data storage at central SCADA by connecting all equipments to SCADA.

PLC+IPC Solution

- High cost of ownership over its lifecycle.
- Validation as per category 4.
- Need more support for maintenance Need IT team.
- Maintenance of versions of OS, SCADA S/W & IPC.
- For backup again need to connect to server.
- Works with existing communication.



VALIDATION APPROACH TO MES



Reinforce your
Validation Link

