Kevin TECHNOLOGIES

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DATA ANALYTICS of

Manufacturing Assets

Kevin CONNECT

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CONNECT INSIDE

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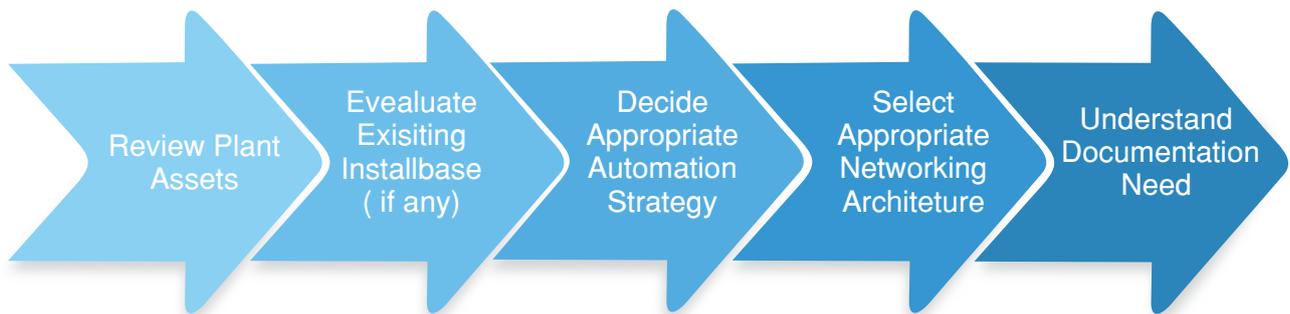
Our Ultimate Vision
To be the number one company in the area of expertise that we operate in, especially Factory Automation & Regulatory Compliance Services.

Introduction

Manufacturing assets are basic building block of capturing information from plant floor, a useful information can be extracted and used to manage business process more effectively. With help of a well design network architecture and precise machine up-gradation provide to integrate cutting edge technological solution to achieve information from machines. Nowadays extracted information is feed in to data analytics software to capture various data useful to optimize manufacturing process.

An existing plant have different types of manufacturing assets for example, some generate non-electronic data and on other side some generate electronic data. We need to sort them according to various categories. An elaborated URS and detailed plant study by skilled automation solution provider can help to segregate installed base into various categories which will help to make project management smooth.

Review Plant Assets → Evealuate Exisiting Installbase (if any) → Decide Appropriate Automation Strategy → Select Appropriate Networking Architeture → Understand Documentation Need

In a running plant, to perform modifications to capture data may have following challenges :

- ❑ Various install-base for different Automation platforms
- ❑ Fulfil proper documentation criteria
- ❑ Coop up with production schedule and Up-gradation simultaneously
- ❑ Unavailability of some critical information like past modification details ,program backup etc.
- ❑ Some machines are Legacy systems and a big challenge in terms of alteration

During plant production is on , deploying automation to achieve high level of data availability is a major task. This up-gradation is not only to ensure manufacturing data, but also to achieve data integrity, along with production schedule. These interconnected processes required proper project management and firm scheduling.

MOBILITY

PRODUCTIVITY

21 CFR Part 11

OEE

PROCESS AUTOMATION

UMS

BMS

VISUALIZATION

SECURITY

Various Automation Strategies

Decide Appropriate Automation Strategy and Networking architeture

In recent years, open communication protocols help to take manufacturing data from various production assets through automation implements and gives flexibility, scalability and equipped with matching up with communication medium available in near future. Ethernet/IP is one of the open protocols which are compatible with plant IT network with a high level of data security.

There are majorly three different automation strategies available:

1. Integrate

2. Upgrade

3. Retrofit

Integrate

Usually the machines that fall in this category, already come with open Ethernet connectivity. Just need to "integrate" these into central SCADA system.The machines have capability to communicate and give raw data with the open protocol, which can be easily accepted by standard data capturing software like SCADA or historian. This SCADA system will ensure batch reporting, audit trails, trending and activity log viewer for set point changes.

Upgrade

Machines with PLC and HMI which do not have open communication protocol, falls in this category. These machines need to be studied, in depth and each machine should be evaluated separately. Each machine should be replaced or upgraded with suitable communication hardware to make it compatible. As manufacturing plants have variety of PLCs, the automation solution design should be compatible to all platforms. Also the solution provider should have ample knowledge or hands-on experience of such types of system.

Retrofit

These old/legacy machines are without PLC or with dedicated controller, which do not have standard communication protocol. These machines are mostly manual machines, but data which is available in these machines are important. The automation solution provider must has process knowledge or experience in similar machines. After refurbishing, these machine also have functions like unique user ID and password, audit trails, batch printout etc. Manual blenders are a classic example of such type of a system.

Maximum Flexibility & Seamless Integration are important aspects, specially for Legacy Systems.

Mr. Bhavesh Shah
- GM - Business Development

Understand Documentation Requirements

Pharmaceutical industry is driven by various guidelines for validation and documentation. Up-gradation process should have proper documented evidence to provide during various audits. As per the latest guideline of GAMP 5, Risk assessment documents are also required. Each category requires separate set of documents. Few of them are listed below:

- ❑ User Requirement Specification(URS)
- ❑ Functional Design Specification(FDS)
- ❑ Functional Risk Assessment (FRA)
- ❑ Installation Qualification(IQ)
- ❑ Operation Qualification (OQ)
- ❑ Validation Summary Report (VSR)

Other Important Factors :

Selecting an appropriate automation solution provider for up-gradation or retrofitting is very important in such projects. Few capabilities of a solution provider are mentioned below, which may speed-up the process:

- ❑ Ample knowledge of processes as well as control strategies
- ❑ Capable to work on various automation platforms
- ❑ Capable to design solutions for different categories
- ❑ Deep understanding of industrial networking
- ❑ To do/support on regulatory compliance requirement and documentation activity

We at Kevin Technologies provide below mention Solutions at various stage of integrating manufacturing asset :

- Automation Solutions:
  - ❑ OEE Solutions
  - ❑ Up-gradation of machines to collect raw data
  - ❑ Integration of Process Equipment
  - ❑ Retrofitting of existing systems
  - ❑ Integration of utilities
  - ❑ Device Level Redundancy Networking
  - ❑ Audit Trail / Named User ID functionalities for 21 CFR part 11
  - ❑ Compliance of HMI's
- Regulatory Compliance Solutions
- 21 CFR part 11/EU Annex 11 Assessment
- Comprehensive GAP Assessment