

Automation India

Issue 9 – April 2007 A newsletter of the Automation Industry Association of India



Dear Friends,

Manufacturing industries in India — be they process manufacturing or discrete manufacturing have, over the last 2-3 years, achieved a higher growth trajectory than ever before in our history. Demand is burgeoning — be it cement and steel — the basic building blocks of an economy, or be it consumer durables, automobiles, electronics or white goods. Driven by growing disposable incomes, domestic demand alone accounts for much of the growth. Given that global economies too are going through an unprecedented growth

cycle, clearly India has a huge opportunity to participate in global demand fulfillment, particularly of "engineered manufactured" goods — not to talk of product design and engineering services — PES.

Whilst China leads in terms of mass manufactured goods, India has a great window of opportunity in the "engineered-manufactured" space. In close competition for this space are the emerging economies of eastern Europe. If one analyses for manufactured goods, Automation and productive use of assets would be high on the list of key enablers that could have a positive impact on our global competitiveness.

Global competitive pressures mandate that manufacturers seek higher economic returns from production assets. At the same time, integrating these assets has become quite a challenge, where disparate systems of various generations — supplied by multiple vendors — are now the norm. Automation and plant information system integration would necessarily play a key role in achieving both objectives — asset management and information integration.

Then there is infrastructure. Power generation and distribution, transportation infrastructure — airports, metro rail, highways; upstream oil and gas exploration and development and transportation of hydrocarbons — pipelines, in particular, are vital infrastructure elements that will fuel competitiveness. What is interesting for both Automation providers and infrastructure developers is that Automation is key to maximizing the returns from infrastructure assets too. SCADA for electrical transmission & distribution networks for pipeline grids and water management systems; integrated airport automation, automated ticketing, traffic management for rail and road networks as well as efficient use of power generation assets are just some of the areas that automation is crucial to.

Automation Tech 2007 and the CEO Roundtable featuring eminent industry leaders, will highlight many of the areas of Manufacturing and Infrastructure that impact Global competitiveness of Indian Industry. AIA believes this event will be the forerunner to many such events that will focus attention on this crucial aspect of national endeavour.

Automation is clearly then a key next enabler to global competitiveness in manufacturing and infrastructure. IT is good, but can contribute little without the right Automation at the plant or field level. AIA newsletters will continue to present themes that will drive interest in our community to educate, collaborate, innovate and upgrade.

Best wishes,

JP SINGH Hon. President, AIA



Automation — The Next Enabler to Global Competitiveness in Manufacturing & Infrastructure 12th April, 2007, Mumbai

Role of Automation in globally connected businesses A RAJA BAHADUR

Imperatives for Indian Industry Dr K KASTURIRANGAN

Global trends in Process Automation — the way forward for Indian Manufacturing HARSH CHITALE

Leadership through real-time integration in Oil, Gas & Refining BR MEHTA

Delivering tangible customer value in Power Distribution through Automation Dr K RAJAMANI

Automation trends in Global Supply Chain Management KOH JUAY MENG

A case study of Manufacturing Automation in Automotive Industry LP PEREIRA

Quality & Consistency through Automation in Metal Finishing Lines ANUJ MIGLANI

Compliance to global regulatory demands in Pharmaceutical Industry through Automation SURINDER GULATI

CEO ROUND TABLE

Panelists ANIL SARDANA GERHARD KLEMENT K VENKATARAMANAN KULDIP KAURA UDAY BHANSALI RAVI UPPAL JP SINGH

Asset Performance and Reliability

he path to asset performance and reliability excellence can be viewed as a journey through multiple platforms of maturity and growth.

Each platform can contribute significant performance and reliability benefits although the commitment in terms of time and resources increases accordingly. The extent to which organizations pursue the path to asset performance and reliability excellence depends on their perception of the cost versus the benefits they believe are possible and practical within the context of their business environment.

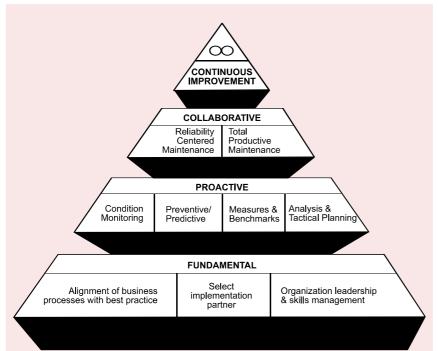
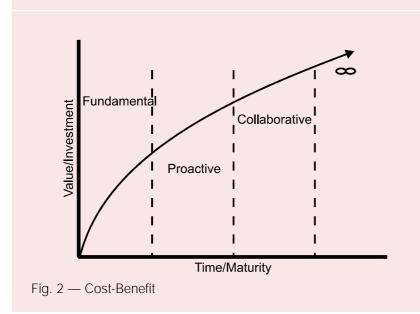


Fig. 1 — Path to asset performance and reliability



A broad cross-section of organizations are asking for:

- Rapid implementation
- Low risk
- Low cost to implement
- Minimum demand on internal resources

A good methodology assures a low-risk initial implementation without compromising the ongoing evolution and continued growth of the applications in use.

The methodology would include predefined business processes founded in Best Practice, a preformatted core database configured to support those processes, implementation tools and templates, structured workshops and a data conversion tool. End-user training is also provided using standard training and reference materials.

Taking Control

With the fundamental elements in place, the organization is empowered to truly influence asset performance and reliability. The proactive level includes:

Condition monitoring which

involves tapping directly into control data sources to capture statistics to manage preventive maintenance and to enable instant reaction to failures when they occur, or preferably, before they occur.

Preventive maintenance which covers the range of periodic tasks (from inspections and adjustments to component replacement) that are performed on assets on an elapsed time, or preferably, a usage basis in order to keep assets functioning.

Predictive maintenance which

goes a step further by using nondestructive testing methods to uncover hidden or pending failures in their primary mode.

Measurements, or KPIs (**Key performance indicators**), are used to convey strategic direction, to allow the organization to select and evaluate tactics needed to pursue the direction and to monitor operational performance related to those tactics.

Benchmarks provide a specific comparison of relevant KPIs against known standards of performance or the performance of complementary processes or companies that are considered as good examples of achievement.

Fundamental to taking control is the collection of accurate maintenance and materials management activity data and the transformation of that data into information through relevant compilation and presentation. With insight, direction and involvement, this information provides the knowledge to guide tactical planning and decision-making processes.

Unleashing Creativity

Two key elements are defined at the collaborative level:

- TPM (Total Productive Maintenance)
- RCM (Reliability-Centered Maintenance)

Total Productive Maintenance

TPM has been defined as changing the corporate culture to form a partnership with engineering, maintenance and production focused on improving equipment effectiveness, and product quality and reducing waste, while continually refining teamwork among labor, management and individual workgroups.¹

TPM begins with a sound maintenance program that includes effective preventive maintenance programs, planned and scheduled maintenance, training programs, EAM system, and moves beyond into a more quality-focused employee empowerment approach.

As with the proactive level, the collection of accurate maintenance and materials management activity data and the transformation of that data into information through relevant compilation and presentation is critical for an effective TPM program. With insight, direction and involvement, this information provides the knowledge to guide the TPM teams in their tactical planning and decision making processes.

The creation of a central collection point for all asset information (cost, performance and history) provides unparalleled access to this data allowing you to maximize the return on your critical assets.

Reliability-Centered Maintenance

RCM is defined as "A process used to determine what must be done to ensure that any physical asset continues to do what its users want it to do in its present operating context."²

The classic RCM methodology as presented by Nolan & Heap recognizes three pillars:

1. Failure modes and effects analysis (FMEA) is a

structured analysis based on experience and "what if."

- Functions: What are the functions and associated performance standards of the asset in its present operating context?
- Failures: In what ways does it fail to perform its functions?
- Failure modes: What causes each functional failure?
- Effects: What happens when each failure occurs?
- Consequences: In what way does each failure matter?
- 2. Decision algorithm determines the maintenance action plan and its execution in terms of:
 - Proactive tasks: What can be done to predict or prevent each failure?
 - Default tasks: What should be done if a suitable proactive task cannot be found?
- 3. Age exploration The continuous analysis, revision and upgrade process.

There are numerous variations and derivatives of the classic RCM process in use today; most of which are aimed at facilitating the failure modes and affects analysis and developing the appropriate plan of action. These methodologies are often supported by tools such as:

- RCM Analysis Software
- RCM Forms Generators
- RCM Spreadsheets

Reliability is the responsibility of "all" employees, not just maintenance. Unreliability or failure, thus downtime, is the consequence of poor processes, not events. There is a process behind each of the six points listed above, for example. This means that there must be considerable effort devoted to eliminating defects that cause failure. This, in large part, is RCM.

Reliability Centered Operations (RCO) expands the idea of RCM as purely a maintenance tactic, to include all areas of an organization. Operational inputs, as they pertain to determining maintenance strategies, are used when looking at equipment reliability, which extend from a tactic to a state of mind or culture within an organization. Reliability should be a measure for both maintenance and operations.

To run world-class uptime (85 to 95% as a rough measure), equipment must be reliable which encompasses more than the maintenance team. Reliability is the responsibility of "all" employees, not just maintenance personnel. The maintenance strategy needs to keep one eye on reliability and the other on maintainability. The operational strategy should be designed so that operational parameters are driven and determined by the need to maintain inherent reliability.

To push machinery operationally past that point will cause reliability degradation. As a result, machinery operates in a state of inefficiency. This is only acceptable if it is deliberately determined to operate in this mode to achieve a specific goal, and then usually only for a specific time frame. When examining the life cycle of a particular machine, keeping RCO in mind, the following should be considered:

- 1. Plant must be designed for reliability and uptime
- Equipment/spares must be purchased with the purpose of reliability, not just cost
- 3. Equipment/spares must be stored to retain its reliability
- 4. Equipment must be operated reliably using process limits
- 5. Equipment must be correctly installed to lead to a long life
- 6. Correctly installing equipment leads to a long life

All plant personnel are responsible for following processes; doing all the small things prevents the "big one." It is important to measure the organization holistically to ensure accountability. Process integration within all areas of a plant and committed team work with clear, strong leadership facilitate reliability and uptime using RCO. RCO facilitates reliability as Asset Performance Management facilitates utilization and availability. Reliability, along with Maintainability, are the two main facets of availability employing RCO which helps facilitate APM.

The Goal

Continuous improvement creates an ongoing environment of reanalysis and renewal. It involves shifting paradigms and opening possibilities that evolve over time as business needs dictate.

¹ A definition, courtesy of R.W. Williamson, 4th Annual Total Productive Maintenance Conference and Exposition, 1993.

² "Reliability-Centered Maintenance" by F. Stanley Nolan and Howard F. Heap, 1978

Souvik Chatterjee

Integrated Safety Solutions with Motion Control Products

unctional safety is a major issue when it comes to the safety-related requirements of machines and plants. The safetyrelevant parts of the protection and control devices must function correctly and, when a fault condition develops, must ensure that the plant or system either remains in a safe state or is brought into a safe state. As a result of the high-speed drives that are generally used if there is a system malfunction on a machine this can result in potentially hazardous motion. The integrated safety technology used in motion control systems essentially provides protection against this hazardous motion. The highly effective safety functions are used to monitor velocity or speed, zero speed and also position. These monitoring functions are required if personnel can access hazardous zones of machines and plants - e.g. when setting-up. However, also when testing and in production, in addition to providing effective personnel protection, they also offer a high degree of protection for tools, materials and machines.

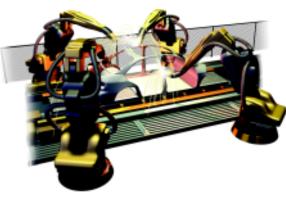
Safety solutions available today can detect critical situations and initiate appropriate measures in just a fraction of second — at the speed of light. These can integrate into standard control architectures, curtailing downtime by allowing operators to diagnose machine stoppages more intelligently especially nuisance trips - and quickly get production up and running again.

Overview

These solutions are built around a harmonized series of products that all fit together. These products can be used in the automation and drive environment to implement innovative solutions to provide the required level of safety for plants and systems. It is important to note that integrated safety solution is an integral part of our standard automation environment.

The individual components can safely communicate via standard buses. Therefore offering innovative safety technology, which when it comes to flexibility, diagnostics and standardization, is certainly on a par with standard automation. The range products include for example, safety-relevant low-voltage controls and sensors, fail-safe PLC controllers, fail-safe CNC controls and variable-speed drives with integrated safety functions.

Standard PROFIBUS and AS-Interface buses can be used for both normal and safety-relevant communications along one and the same bus cable. This results in significantly lower installation and engineering costs. The PROFIsafe profile for PROFIBUS DP and ASIsafe with the safety monitor for AS-Interface form the basis. The functional safety of the components fully comply with the safety relevant requirements of the appropriate Regulations and Standards and are certified by acknowledged bodies.



Benefits

• Highly cost effective

Integrated and seamless from the sensor through the evaluation unit down to the actuator

• High cost-effectiveness

Reduced hardware and installation time and costs

• Plants and systems can be simply coupled

Using safety-relevant communications via standard field buses

• Effective, fast diagnostics To

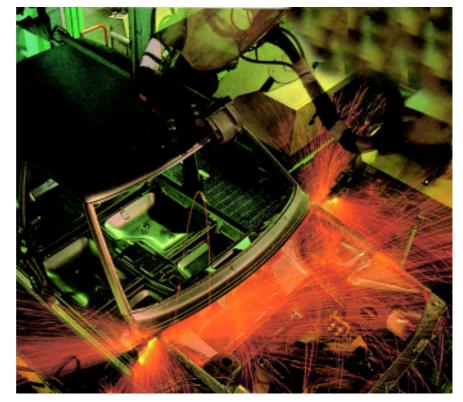
secure a high degree of availability for machines and plants

• Safe programmable logic (SPL)

Safety enabled sensors and actuators can be directly connected to the safety relevant I/O of the control system when using safe programmable logic. External evaluation units are not required and signals are safely evaluated in the software. The associated logic operations are redundantly implemented in the NC and in the integrated PLC.

Safe brake management

The safe brake management function comprises a safe braking signal and a cyclic braking test. The safely controlled and tested brake in conjunction with the safelymonitored drive results in a redundant holding system to prevent vertical axes falling. The reliability of a mechanical brake is an essential component when it comes to providing protection against vertical axes falling. The brakes that are generally used today are not safety-relevant components. A safe brake function is obtained by integrating the standard brake (a component that has been well-proven in the field) into the safety integrated concept. The brake is safely and electrically controlled in accordance with Category 3 (EN 954-1). It is controlled through two channels, P/ M-switching (Plus/Minus). The safe brake test cyclically checks whether the expected holding torque is generated. Faults and errors in the control and in the mechanical braking system can be identified



using these extended test procedures.

Safety-related communications via a standard bus

The safety-relevant sensors and actuators can be directly connected via the fail-safe PROFIsafe I/O. This distributed I/O is connected through the standard PROFIBUS field bus with the PROFIsafe profile.

Integrated acceptance test

When a machine is commissioned all of the safety-relevant functions of the electric drives must be tested in the form of an acceptance test. The test results must then be appropriately documented. This procedure applies to all electric drives no matter whether the safety functions are integrated in the controls and drives or whether external monitoring devices and equipment are used. This integrated acceptance test provides the OEM with a tool that he can use to semiautomatically carry-out this test with operator prompting. In addition to saving valuable time, this tool stands out as a result of its prompted test procedure and the fact that trace functions can be automatically configured. The automatically generated acceptance report proves the guality of the functional safety of the machine — both for the OEM as

well as for the company that actually operates the machine.

Safe, practical, cost effective Motion control systems with integrated safety

A new generation of Motion control system offers the optimum solution for the widest range of machines for specific industry sectors. These systems help manufacturer to increase their productivity and at the same time their quality. It is integrated in the electronics and software of the control systems and drives and offers completely new possibilities as it is integrated and is part of a seamless total system. Just like in an automobile where electronics and software provide effective safety functions - e.g. airbags, ABS and electronic stabilization systems — Safety Integrated helps to reliably and quickly protect machine tools and production machines from hazards. With Safety Integrated, machines and systems can be operated inline with standard procedures but at the same time are equipped with highly effective safety functions.

> Pradeep Karnik Pravin Panchagnula

Indian Manufacturing Must Leverage Automation

acro global forces such as globalization, emergence of knowledge economy, the narrowing divide between developed and developing economies, and demographic changes are ushering manufacturing transformation. While this transformation is taking place, consumers are increasingly demanding value for their money and instant gratification. While the influence of these forces may vary from industry to industry and company to company, at the macro level almost all companies are subject to time-to-market and cost pressures and other associated challenges. Although the overall growth of the world economy continues to spur manufacturing, only companies which continually discover ways to reduce costs and tightly couple all activities along the value chain have a chance to succeed in the fiercely competitive world. Manufacturers are squarely addressing these challenges by thinking out-of-the-box to optimize manufacturing processes and identify afresh controllable cost centers. Global companies extensively leverage automation to ensure productivity, improve plant availability, product Design consistency and quality, and such others, and they look upon automation as a business enabler and not as a technology enabler. It is necessary for Indian manufacturing companies also to leverage automation for achieving overall business goals, and they cannot ignore the imperatives of leveraging enabling technologies.

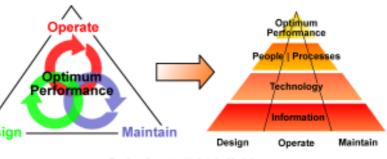
Manufacturing Transformation

From a historical perspective, manufacturing, which essentially is a series of operations that transform inputs, such as raw materials/components by deploying human and financial resources through processes, sprung up close to demand or raw material centers, dictated largely by the value-addition criterion. As the global economy expanded resulting in demand spurt, manufacturing responded by transforming itself. Whether it is process, hybrid, or discrete, manufacturing transformation is a continuous saga of change. Manufacturing companies are moving away from vertically integrated structure to horizontally linked network models. Spanning countries and continents, companies are becoming an extensive network of enterprises, with networks extending beyond manufacturing supply chain to include design and engineering. Companies are seeking design, operate, and maintain (DOM) interoperability. The DOM interoperability ensures continuous iterations to reduce costs by continuous review and evaluation

mechanisms relating to products or processes, operational and maintenance strategies.

Design-Operate-Maintain Model

In the present day world, business is done at the speed of thought, and therefore it is necessary for manufacturing companies to be agile both in spotting opportunities and in competitively responding to them. While opportunities are global, in many manufacturing segments, the world is awash with excess capacity, and in that scenario, what is important for manufacturing companies is in achieving 'availabilityto-promise'.



Design-Operate-Maintain Model

Role of Automation

The success of a manufacturing company will be determined by their ability to become globally competitive and successfully integrate with the emerging globally extended enterprises. Companies wanting to become agile, competitive, and globally networked must extensively deploy automation. While the automation at the plant-level deals with real-time decisions that impact shop-floor operations, automation at the enterprise-level relate to business decisions that are mostly transaction based. Since today's business is done at the speed of thought, the enterprise-level support decisions have a direct bearing on the production and scheduling decisions that cascade down to the shop floor operations.

Actionable Information and Real-time Performance Management

Therefore, manufacturing companies have to invest in automation to become more agile, gain visibility across the extended supply chain, and synchronize their production and business decisions. They require synchronized actionable information which comes by

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deploying collaborative production management systems including manufacturing execution systems (MES) that link plant floor systems to enterprise solutions. With actionable information at its command, the company can seek Operational Excellence (OpX) or Continuous Improvements (CI). OpX is an on-going journey, and companies have to constantly work at it, year after year. Real-time Performance Management (RPM) is the key to achieve continuous improvement or OpX. Real-time Performance Management (RPM) is taking decisions based on Actionable Information provided by Collaborative Production Management (CPM) Systems. Automation helps a manufacturing company to efficiently deploy its resources — men, material, and finances. Automation brings within the company's sphere of influence the factors that affect the deployment of these resources. For achieving this, synchronized actionable information is the key.

Indian Manufacturing Landscape

The booming Indian economy with a surging domestic demand and global growth opportunities are spurring India's manufacturing companies to expand. Let us take a look at some of the manufacturing verticals, where Indian companies are moving beyond targeting the domestic market. These companies are going beyond exploiting factorial advantages and are seeking sustainable competitiveness. And in these endeavors, automation has an important role to play.

Some companies in India, having made a successful transition from operating in a sellers market, have emerged as global-sized world class companies capable of competing in a free market. Examples, such as the recent take-over of Corus by Tata Steel and the bid by India's aluminum major Hindalco for Novelis, show how some of these companies are aggressively pursuing global growth opportunities through mergers and acquisitions. The pharmaceutical industry has witnessed many M & A deals. These trends clearly indicate that Indian manufacturing companies are plugging themselves into global networks. Their success will be largely determined by their ability to achieve convergence among people, processes, and technology; and this convergence is achieved through collaborative automation.

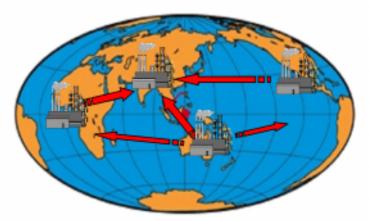
The automobile industry in India is going at full throttle. Spurred by domestic demand, India, the third largest manufacturer of compact passenger cars and the fifth largest commercial vehicle manufacturer in the world, is emerging as a major automotive market. The automotive industry in India, with its industry hardened homegrown vehicle manufacturers, the large number of quality conscious auto component suppliers, abundant supply of knowledge workers, and management talent, facilitates the growth of automotive companies. India is emerging as a global manufacturing hub for compact cars and auto components. The success of the automotive and auto component industry will largely depend on companies' ability to competitively design, engineer, make, and supply them on time. Automation plays a crucial role in the success of automotive industry living up to the promise.

Globally Extended Enterprises

The Indian steel industry, the ninth largest globally and producing around 38 million tons of steel per annum, is on the upswing. Additionally with rich bauxite ores, the country is also a leading producer of aluminum. Indian companies in the metals segment realize that the way forward for them would be to segregate value chain into primary metal and finished products. The demand for high-value added finished products is beginning to expand in Asia, while the production facilities for the same already exist in NA and Europe. Their strategy is to integrate their facilities in India with the already existing finished products production facilities in the mature markets where the demand still exists for finished products. While this strategy helps them to meet the growing demand for finished products in India and Asian countries by maximizing the return on existing assets by integrating them vertically, their ultimate success depends on integrated and synchronized automation across all geographically dispersed plants.

The companies in the oil and gas segment have challenges which include sourcing crude, its transportation, refining it and distributing the refined products. They have to squeeze their margins by efficiently scheduling their crude supplies and by optimizing the refining processes among others. With some of the companies in the refining segment emerging as significant exporters of refined products, these companies have to adopt automation in a major way to manage their assets to maximize profits.

India's pharmaceutical industry, presently ranking fourth globally in terms of volume and thirteenth in terms of value, is growing. Domestic pharmaceutical companies, keeping abreast with global developments and adopting new technologies with relative ease, have created good manufacturing practice (GMP) compliant facilities to produce and formulate drugs.



Globally Extended Enterprises

Although some of them have taken strides along the drug discovery path, their main forte continues to be generic drug market. With generics pipeline worth around \$30-40 billion remaining full, India's pharmaceutical companies have ample growth opportunities. Wanting to seize growth opportunities, some of the pharmaceutical companies in India have taken the route of growing through mergers and acquisitions.

While Indian manufacturing have done well in adding production capacities and building economies of scale, it is time for them to evaluate how well they are leveraging automation technologies. While they are extending their reach beyond the Indian shores with export earnings growing robustly, it is time for them to evaluate how well they are leveraging automation technologies to achieve agility, supply chain efficiencies, and productivity improvements across globally extended and networked enterprises.

Recommendations

- Global companies extensively leverage automation and they look upon automation as a business enabler and not as a technology enabler. Indian manufacturing companies have to leverage automation for achieving overall business goals, and they cannot ignore the benefits of leveraging enabling technologies.
- The success of a manufacturing company will be determined by their ability to become globally competitive and successfully integrate with the emerging globally extended enterprises.
 Companies wanting to become agile, competitive, and globally networked must extensively deploy automation.
- Manufacturing companies have to invest in automation to become more agile, gain visibility across the extended supply chain, and synchronize their production and business decisions.

Rajabahadur V Arcot

Director of South and South East Asian Operations, ARC Advisory Group

Plant Connectivity Standards enable enterprises realise real-time benefits

Overview

Manufacturing organizations attempting to integrate the plant floor with ERP, supply chain, scheduling, quality and other systems in their enterprises today have difficult choices to make to base that integration on standards - specifically, what standard to choose. Fortunately or unfortunately there were not too many choices available, and each chose their path based on their own organizations strength and weakness. This paper provides an introduction to one of the standards- ISA 95, that has been in practice in the global manufacturing sector. It is applicable in continuous, batch or discrete processes and and provides a good platform for any user looking at a lean, adaptive or collaborative manufacturing environment.

ISA-95 is fast growing into becoming a common language and tool that can exchange application needs between the management and functional departments such as quality, maintenance, purchase, production, planning, IT and Automation. While each of the functional departments have their own nomenclature, ISA provides a common base line over which each of their terminologies can be translated and understood. The ISA 95 definitions and models enable organisations to structure their disparate application requirements into a common manufacturing application framework incorporating best practices. There are five parts of the ISA 95-Enterprise - Control system integration standard that enable seamless connectivity between organization layers.

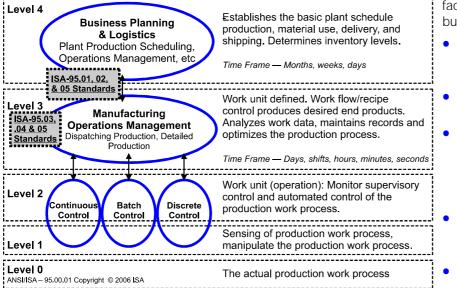
ISA Standards

ISA-95.01 Enterprise-Control System

Integration, Part 1: Models & Terminology consists of description of relevant functions in the enterprise and the control domain and which objects are normally exchanged between these domains.

ISA-95.02 Enterprise-Control System

Integration, Part 2: Object Model Attributes consists of attributes for every object that is defined in part 1. The objects and attributes of Part 2 can be used for the exchange of information between different systems, but these objects and attributes can also be used as the basis for relational databases.



faced with, in their day-to-day business operations.

- Non-contact distance measurement up to a range of 10 m.
- Managing multiple operations with plants across borders
- Managing multiple operations with plants spread Pan India based on available skills, or government incentives or proximity to client locations
- Developing and managing supply chain to match desired growth rate
- Growing migration of personnel to competitors or to other industries

ISA-95.03 Enterprise-Control System

Integration, Part 3: Models of Manufacturing Operations Management focuses on the functions and activities at level 3 (Production / MES layer). It provides guidelines for describing and comparing the production levels of different sites in a standardized way.

ISA-95.04 Object Models & Attributes, Part 4:

Object models and attributes for Manufacturing Operations Management. This technical specification defines object models that determine which information is exchanged between MES activities (which are defined in part 3 by ISA-95). The models and attributes from part 4 are the basis for the design and the implementation of interface standards and make sure of a flexible lapse of the cooperation and information-exchange between the different MES activities.

ISA-95.05 B2M Transactions, Part 5: Business to manufacturing transactions. This technical specification defines operation between office and production automations systems, which can be used together with the object models of part 1 & 2. The operations connect and organise the production objects and activities that are defined through earlier parts of the standard. Such operations take place on all levels within a business, but the focus of this technical specification lies on the interface between enterprise and control systems.

Indian manufacturing industries perspective

While large manufactures have used aggressive capacity acquisition as a strategy and successfully transformed themselves into global players with footprints across geographies, the mid -sized firms have taken a niche position with end to end offerings from the design to delivery of products.

While it has been a growth story all the way, let us look at the challenges that management of these firms are

All these fundamentally point to a common factor, that geography no longer holds relevance in manufacturing sector operations and very akin to IT sector, the firms that are able to manage their anywhere- anytime delivery to meet client needs with lowest cost and highest quality would be the company of choice. As usage of anytime-anywhere, real-time information, like emails on mobile, chats within emails, can make individuals more connectable and productive, the same concept of anytime-anywhere, real-time plant information, can make organization segments more connectable and productive with real-time, decision enabling support systems.

Currently, the basic usage of ISA-95 standards has been to characterize the internal and external process flows within the production and enterprise areas. This mapping is physically very challenging as individual units within the organization do not conform to any generic functional model. Business processes vary extensively across manufacturing industries depending on whether they are discrete/batch or continuous. Variants within production rules like engineer-to order, make-to order, make-to-stock, mix-ratios are always a challenge for seamless integration. ISA 95 provides a good base to start analyzing company specific work flow process. The model provides tools and terminologies that enable production, business analyst, IT and Automation to jointly build an integrated system that captures effectively the work flow across the enterprise, and deal with distributed plant work data, with efficient data aggregation and distribution.

A phased approach to integrate Business with Shop floor data

1. Business needs assessment

- a. Identify the driving business need for Data integration. (Identify the expected tangible/ intangible benefits from the exercise)
- b. Identify the current organizational climate towards the change
- c. Determine the cost/benefit and ROI of achieving

integrated model for the enterprise

2. Requirements assessment

This step will have to be repeated in future as we are performing data integration

- a. Identify the focus area to achieve integration-Quality, production, planning
- b. Identify the segment/section to achieve data integration
 - Single plant/ Multi plant
 - Single Geographical location/ Multiple locations
 - Inclusion of Vendor/sub contractors data
 - Pilot project/ enterprise wide implementation
- c. Determine if you want to automate the data exchange process. If yes, identify the
 - Single plant/ Multi plant
 - Technology required
 - Data storage and band width load requirements
 - Skills required
- d. Identify any new technology/infrastructure/ automated information systems to be adopted
 - Skills required
 - Identify current technology/ software in place. Determine if they can be leveraged for the maximum advantage
 - Identify gap between current levels and required levels
 - Assess the skill sets of in house team and Determine training requirements
 - Determine cost/benefit analysis of the exercise

3. Feasibility/ Risk assessment

- Determine support from all levels- top management/ middle level management, supervisors and operators
- b. Identify level of training, knowledge and the cost benefit analysis of the training required
- c. Plan on the learning curve required to adopt the new systems
- d. Identify probable failure points and the reasons for their existence
 - Due to Work Culture
 - Due to Technology gap
 - Due to Financial implications
- e. Understand the return on investment
 - Assess financial benefits and ROI expected
 - Assess the provision for the exercise in line with the future business plans

4. Map a preliminary data interchange model

- a. Identify the activities in the focus area
- b. Identify the responsible position/ designation, their level for the activity
- c. Identify the information exchange required from and to the activity
- d. Identify the priority and the response time required for this information
- e. Identify the triggers for information exchange (whether it is a regular schedule or in response to an event)
- f. Identify the mode of information exchange (whether

it is paper or automatic), format for exchange, the operation to which the exchange is done

- Identify the structure and components for automation of the data integration as required
- h. Identify software and hardware used

5. Identify the gaps in the preliminary data interchange model

- a. Identify the bottlenecks created due to information exchange
- b. Identify additional information required
- c. Identify software and hardware requirements
- d. Identify information transformation required

6. Prepare the final data interchange model

- a. Identify and prioritize information exchange required
- b. Identify the software/systems/technology to be used
- c. Identify the logistics and mode of data exchange
- d. Finalize the specifications of the data interchange model

7. Develop the manufacturing execution infrastructure (MEI) plan

- a. Communications criteria
- b. Control system for both software and manuals
- c. Complete details about the document management system, Including the documentation standards needed to fulfill the project goals
- d. Details about the management of the project, including chain of command, responsibilities, authority, and reporting

8. Draft an implementation plan and publish the same.

9. Create and execute a training plan including the end users and the super users

10. Prepare to execute a pilot project.

- a. Determine the phases, goals, and their objectives in the pilot project
- b. Design and deploy the pilot project
- c. Benchmark the deployment and produce a performance assessment
- d. Determine the ROI of each function in the Pilot project
- e. Analyze the pilot project and determine the changes required

11. Plan for enterprise wide implementation

Once the enterprise team has worked through several iterations of pilot projects, it can begin to design an enterprise wide support system

- a. Develop an enterprise wide implementation plan
- b. Identify teams and their responsibilities. Impart necessary training to them
- c. Draft a set of infrastructure requirements and support systems required throughout the enterprise
- d. Finalize the data exchange requirements between the Shop floor and enterprise based on the pilot project
- e. Publish the enterprise wide manual and implementation plan
- f. Deploy and benchmark the new systems

Uma Balakrishnan

Electronic record keeping systems help biopharmaceutical companies increase compliance and meet regulators obligations

Driven by changing market demand and to meet increasing compliance and regulatory obligations it is mandatory to have electronic record keeping systems in biopharmaceutical, food, beverages and personal care product industries.

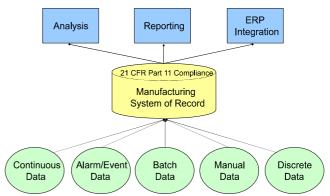
In an era of digital technology, when automation of processes increases productivity and reduces costs, the manufacturing industry still generates mountains of paperwork. These paper processes can result in liability concerns and difficulty in controlling and monitoring changes, updates, and approvals. Manually signing these documents is a long process that can take days to complete, thereby significantly hindering processes.

When it comes to managing this process data, the one thing everybody will agree is that there's endless number of data out there and the amount is getting larger and more unmanageable all the time. Most plants generate mountains of data, but without the right software capabilities to make the information content quickly available to the right people at time that is relevant to the manufacturing process, the data remains essentially untapped. How can manufacturers possibly handle the mountains of data that relate to both focal areas — quality with regulatory compliance (GMP) and operational/process stability?

Today companies are looking out for solutions that can automate data collection, paper-based procedures, meet increasing compliance and regulatory obligations and reporting needs-from FDA Regulation 21 CFR Part 11, or Compliant Batch End reports The shift from manual record-keeping to electronic records and measurements improves the accuracy and usability of collected data.

Digital recording solutions collect real time data from various sources, aggregates, and analyze current and historical process information at multiple manufacturing locations, in real-time. It generates production reports based on both real-time and historical data, from internal and external sources, such as relational and web service data. Report templates may be based on batch or time range. For batch process manufacturers, comprehensive systems are available to generate electronic batch reports that comply with regulatory requirements, incorporating all steps from data collection through report generation to sign-off. For continuous manufacturers, reports may be configured based on hierarchical time frames or interrelated time ranges. The system maintains all data at its original fidelity, offers a full audit trail of data and user security changes, and features stringent

versioning to remove errors, align reports with production, and support auditing. It also supports electronic signatures for efficient report approval. Authorized users can access reports online by means of secure Web services. Another feature is Dynamic Reporting which enable automatic report generation of details by using built-in trending, tabular data output and statistical features.



Manufacturing 'System of Record'

Easy access to the data also helps shorten process start-up, scale-up, troubleshooting and adverse trend reversal times; improve productivity, quality, and return on net assets; and finally, leverage existing technology investments, such as enterprise resource planning (ERP) systems, laboratory information management (LIMS) databases, data historians, and batch records.

It simplifies the batch-auditing process with the use of standardized manufacturing documentation. Using a powerful query engine, it identifies process exceptions in real time or anytime after the batch run is complete. Dynamic reporting capabilities enable automatic report generation of details by using built-in trending, tabular data output and statistical features.

These solutions are flexible and easy-to-configure, enabling authorized individuals within a company to visualize and share reporting data in a secure, customized environment.

These Record-keeping systems can help manufacturers collect, track, and update information that proves they are complying with the regulations. They help manufacturers quickly retrieve that information if they're audited and reduce the time it takes the FDA to review the records. In fact, integrating fully digital systems that comply with 21 CFR Part 11 into processes can add millions to the bottom line.

To avoid product recalls, fines, and FDA warnings, companies can now take one step forward by implementing such systems. The future is on-line, digital auditing from anywhere and at any time.

Rajesh R Shirodkar



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