ARC BRIEF

OCTOBER 2007

Packaging Execution Systems Benefit Lean Manufacturing Initiatives

THOUGHT LEADERS FOR MANUFACTURING & SUPPLY CHAIN

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By ARC Advisory Group

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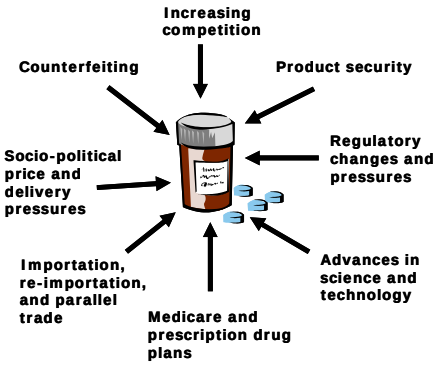
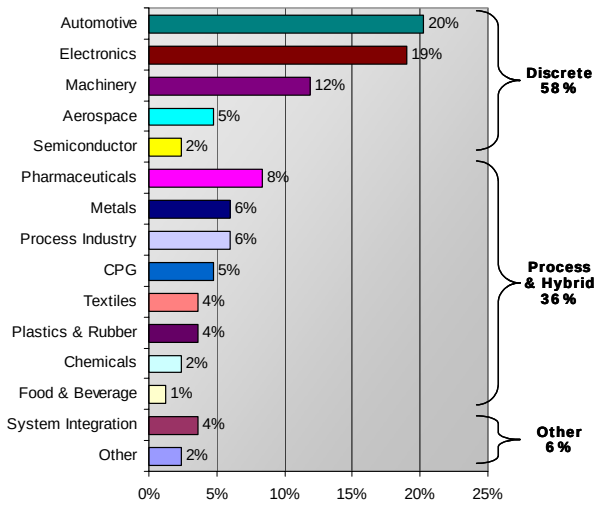
Pharmaceutical Industry Adopts Lean Principles

It is a fact; the pharmaceutical industry business model has been dramatically altered. The industry no longer relies exclusively upon blockbuster drugs to drive growth. There is an increasing reliance on small market drugs and a greater use of demographically focused packaging in order to cater to the child safe and senior friendly segments. The industry is in rapid transition from a supply-driven market to a demand and service-driven market where manufacturing efficiency and responsiveness plays a critical role in future success. While the new biological drugs are the future in driving revenue and margin growth in the business, the pharmaceutical industry needs to operate the traditional chemical drug business at peak efficiency. To remain successful, pharmaceutical companies must transform their chemical drug discovery business to a high quality, manufacturing, and global drug supply chain operation. There is a need to transform the current and future manufacturing to better compete with both generic and branded Rx competitors in their franchises. This will enable pharmaceutical companies to achieve their business objectives via entry into the generic drug manufacturing business and move branded non-Rx drugs to OTC.



Pharmaceutical Manufacturers Must Operate the Chemical Drug Business at Peak Efficiency



Industries Adoption of Lean Principles
Source: ARC Survey of Manufacturers

There is no longer any room for inefficiency or waste in any aspect of the pharmaceutical value chain. The very same principles credited for driving out inefficiencies in manufacturing in the automotive industry and the consumer package goods (CPG) industry are applicable to operations in the pharmaceutical industry. The adoption of Lean Principles has spread beyond the discrete industries and is rapidly permeating the pharmaceutical industry. Specifically, a large emphasis is being placed on the efficiency of packaging operations in the pharmaceutical industry. However, Pharmaceutical, Food & Beverage, and Automo-

tive are all experiencing increased regulatory requirements and as such, these industries are interested in controlling the cost while increasing their rate of compliance.

Packaging Line Operations Take Center Stage

The pharmaceutical industry is facing the same challenges in packaging line operational efficiency as the Consumer Packaged Goods manufacturers. The increasing importance of product security is driving pharmaceutical manufacturers to take ownership of packaging operations by moving packaging operations in house rather than relying upon contract packagers. However, many pharmaceutical producers have not created the information infrastructure to optimize operational efficiency of their packaging lines. The greater imperative in the business is to provide assurance that the product is "authentic", which is driving mass serialization as an integral part of the packaging operation. Overall, there is a growing concern about the business risk impact of counterfeiting, which is as much a "responsibility" issue as it is a financial issue. More secure labeling such as Radio Frequency Identification (RFID) or with 2D bar code technologies for serialization of the product are being incorporated at the packaging line.

Product Authentication Mandated in California by 2009

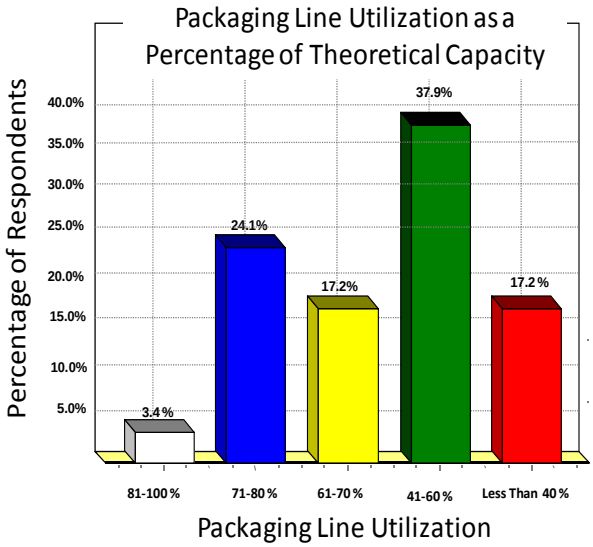
Beginning on Jan. 1, 2009, California will require that all drugs distributed within the state be accompanied by an electronic "pedigree" that documents the movement through the supply chain. Although it's not required to use RFID, e-pedigrees can also be created using bar codes. The California law will require pharmaceutical manufacturers to originate item-level pedigrees for drugs distributed within the state's borders. The legislation also requires companies within the pharmaceutical supply chain to update those pedigrees upon each change of ownership.

Retail and country specific customized drug packaging for over the counter drugs is forcing pharmaceutical manufacturers to place a considerable amount of emphasis on the agility and flexibility of the packaging line. Shorter production runs along with wide variations in labeling, cartons, and special insertions such as promotional materials are moving the industry toward packaging lines that are capable of late stage packaging. Child safe and elderly friendly packaging along with packaging security and pedigree are now an integral part of packaging line capabilities. In the past, electronic data records for packaged goods included only information about the people and equipment used in drug production along with capabilities histories. This is in contrast to ingredient assays, which have always needed detailed electronic record keeping. Systems that track ingredients from product manufacturing through final packaging out to the retailer or consumer are being

Packaging Line Operations Define Manufacturers Capabilities

integrated. Efforts are underway to ensure both the security of the drug supply and the organization's ROI on the individual product line. Most importantly, electronic tracking and tracing systems, in conjunction with product serialization, must be extended out to the packaging line to ensure product authenticity and timely and accurate delivery, as well as satisfy regulatory requirements. Combining information management, quality management, and tracking systems to follow product manufacturing through the packaging line and beyond ensures the capture of the genealogy of the final shipment.

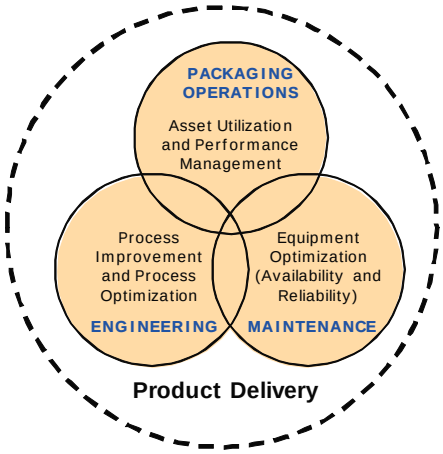
The **packaging line operations** are defining the ability of the organization to configure product delivery at the final stage in the manufacturing process and provide retailers with a rapid response to inventory fulfillment. Essentially, packaging operations are demand driven and now a critical path in the supply chain. Often there are only one or two plants dedicated to the manufacturing and packaging of a critically lifesaving drug. The production capacity of these plants is limited by the end of line packaging operations. Due to the need to reconfigure lines for shorter production runs, packaging requirements for specific retailers and regional regulations are reducing the utilization of packaging machinery. Throughout the industry, manufacturers are faced with shorter production runs that have increased the number of line changeovers and setups. The result is that packaging line utilization is rapidly deteriorating.



An ARC Survey of Packaging Operations "Identified Under Utilization of Packaging"

The survivors in the business will be characterized as low cost producers capable of operating at high efficiency with zero-defects in a world of customized packages. The security bar will be raised even further. The security of the supply chain along with zero-defects will be imperative in the pharmaceutical business. These are fundamental to protecting the customer, the business, and maintaining a high brand value. Flexibility in packaging operations and packaging lines are essential to ensure profitability and market expansion goals are achieved. This is in tandem with raising the security of shipments where counterfeiting prevention will be

achieved through the combination of secure package design and mass serialization of product at the item, case, and pallet level.



Leaders in the pharmaceutical industry will recognize that systems put in place to manage these new information management and design change requirements in packaging operations can be leveraged as a competitive advantage and form a catalyst for business growth and market penetration. Organizations that have visibility throughout the entire product value chain, more specifically, information acquired from packaging and manufacturing operations is invaluable in both the conceptual and product design phases in order to shorten product and production process lifecycles. Ensuring that information is retained in a manner that is common in terms of data formats, time base, and context throughout the enterprise is an absolute necessity. Currently, there is a void in the management of packaging operations that requires a production management system that is capable of meeting the challenges of the pharmaceutical industry today.

Packaging Execution Systems: The Cornerstone of Lean Packaging Operations

Fundamentally, applying Lean Principles to a packaging operation requires production visibility. Production visibility in terms of unbiased and accurate information from packaging operations is essential for management to achieve productivity improvement targets and continuously improve on asset efficiency. In particular, for a Lean strategy to have an impact requires a holistic approach involving people, processes, and technology. Converting information into knowledge to provide a consistent measure of asset utilization and performance across multiple facilities as well as obtaining an accurate baseline to better focus on improvements. Information consistency is a requirement in order to prioritize improvements and capital investments. On the factory floor, this information also provides line operators and team leaders with actionable data in real-time to help

A new generation of production managements systems is emerging exclusively for packaging operations, Packaging Execution Systems.

them make better decisions. The bottom line expectations from the implementation of Lean Principles in packaging line operations are higher productivity, profitability, and faster time to market. To achieve this, Packaging Execution Systems are now an absolute necessity to operate production at optimal efficiency in the pharmaceutical business today.

Filling the Gaps in Traditional Production Management Systems

Organizations employing lean principles and compliance to the FDA Process Analytical Technology (PAT) initiative are driving manufacturers to build an information rich production management infrastructure. Production management information is an invaluable tool to optimize the skills of the labor force and realize the full productive potential of packaging lines. Specifically, the FDA PAT initiative is synergistic with a lean initiative in that it is creating a culture of continuous improvement and innovation throughout every facet of the pharmaceutical business. To be clear, the goal of this initiative is not to replace skilled operators. The goal is to produce highly proficient operators independent of the individual equipment and variability of the daily production requirements. Otherwise, the impact of human errors is costly in terms of waste and equipment failure.

To optimize the efficiency of packaging operations requires an operations management infrastructure that integrates with the enterprise systems. Traditionally, a Manufacturing Execution System (MES) would be considered for most production operations; however, gaps exist between packaging requirements and traditional MES solutions. These solutions are generally suited to the specific needs of the upstream manufacturing in the Process Industries such as Oil & Gas, Brewing, Chemical, and CPG. Off the shelf MES solutions lack application expertise in the pharmaceutical industry packaging lines where the real challenge has been to manage production information at the item-level. In addition to being challenged with item-level tracking, most MES implementations are unfamiliar with the equipment employed in pharmaceutical packaging lines. While a MES provides an infrastructure for the electronic transfer of production orders and recipe management, there is virtually no emphasis on inspection, labeling, coding, item-level electronic record keeping, and line performance evaluation capabilities. Similar to MES on the packaging side, but more suited to the specific needs of packaging operations are Packaging Execution Systems (PES).

The performance of the packaging line is critical to the pharmaceutical value chain. As such, the vast amounts of data available from systems on the packaging line needs to be used to enhance these capabilities. PES and MES complement each other to deliver a comprehensive operations management system that is an effective knowledge tool surpassing the basic functions of collecting and storing data; the ability to recognize and understand the implication of patterns and relationships between pieces of data and information is inherent in these combined solutions. The intention is to enable management and production personnel to

make the best use of available knowledge to generate positive results that improve the performance of the entire value chain. Overall, management decisions that have a coherent view of the manufacturing performance are much more capable of achieving the goals of the business.

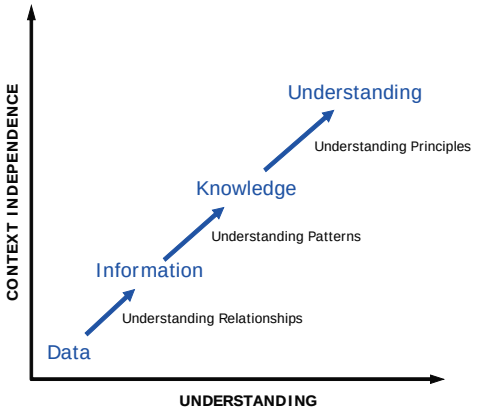
Building Production Line Infrastructure from the Bottom Up

MES solutions are beginning to address the requirements of pharmaceutical packaging lines in a hit-or-miss way, but there is fundamentally a lack of expertise in this niche to deliver a comprehensive, mature solution. In contrast, PES applications, up until now, have been standalone, isolated, point solutions. Today's PES solutions should be built from the bottom up; that is to say from the packaging line integration to enterprise integration.

Packaging Execution Systems

Key Components	Description
Plant Level Visibility	Centralized plant level and corporate-wide control, oversight, and data analysis of a company's packaging operation through ERP, MES and EPCIS integration. Includes: Configuration management, disaster recovery, domain security, lot/expiration management, historical data, encoding and recording of the Electronic Product Code (EPC) serial numbers to the RFID tags and 2D bar code codes
Line Level Management	Integration of machine vision inspection into a comprehensive production monitoring, control and reporting system. Includes: Data collection and configuration of packaging machines, labelers, vision systems, automated changeover, component reconciliation, and line level OEE analysis.
Machine Level Inspection	Fundamental component for implementing a defect free packaging line. Includes inspection and verification of: Blister-packaged product, bar code, lot and expiration date, print quality, general quality inspection such as gauging, object presence, shape, defect, count, and color.

Manufacturers can easily build a PES from the bottom up. The configuration and management of Inspection systems (Vision, Weight, Color, Level, Spectroscopy, etc), Secure Labeling, and Product Serialization data are all interrelated and a system that integrates this functionality has distinct advantages over standalone supervisory systems. A standalone supervisory system is not sufficient; these standalone types of systems create integration problems for the manufacturer that is moving toward zero-defects in production across the entire enterprise. Enterprise integration is essential as this allows management to perform



Packaging Executing Systems Achieve Greater Understanding of Operations

comparative analysis from line-to-line within a single plant as well as between packaging lines in plants throughout the world.

A core competence that drives zero-defects in packaging operations is vision inspection for both package quality as well as label inspection. Vision inspection is a core element that many solutions are required to rely upon third party systems integrators to get the same functionality of a PES if vision is to be connected to the packaging line. A PES is a complete solution that incorporates vision inspection as a core competence and builds upon this to offer a layered solution that facilitates: (1) Line Data Management, (2) Supervisory Line Control, (3) Analytics & Metrics, and (4) Enterprise Integration.

A bottom up approach ensures the ability to seamlessly control and measure the packaging line process. Every packaging line requires a supervisory layer to manage packaging operations. Core to this supervisory layer is the ability to automate changeover of the line, provide a repository for serialized data, and provide metrics for line performance management. Reducing changeover time is imperative and is one of the most significant value-adds that a PES solution can provide. However, the forward looking manufacturer will understand that this is only skimming the surface of improving your operational performance.

A bottom up approach ensures the ability to control and measure the packaging line process.

Using Lean Principles to optimize packaging operations requires consistent reliable metrics and analytical tools. Operations relying upon clipboards and manual record keeping cannot possibly provide the unbiased and real time metrics you need to manage the ongoing change required to get peak performance out of your operations. PES for the pharmaceutical industry provides an infrastructure that can be built upon like a strong foundation. PES developed from the bottom up is an enabler to creating a completely integrated digital enterprise solution that extends down to the packaging lines. This is the concept behind building an infrastructure on the packaging line that allows for both monitoring and controlling the packaging process. Effectively, you want to move toward completely digital packaging lines where line changeover, inspection, and data collection is all automated thereby eliminating manual intervention.

The Lean Enterprise Relies on Analytics and Metrics

Packaging Execution Systems are indispensable for optimally managing packaging production operations as they provide **Supervisory, Analytical, and Connectivity** functions from the individual machines and packing lines to enterprise systems. PES has taken these categories as an integrated production management framework, addressing the packaging production needs and establishing the basis for connectivity to the enterprise. The PES perspective is all inclusive such that it provides scalability from the individual packaging line level to a consolidated view of production information from all of the packaging lines in the factory. A consolidated packaging line view is a valuable management tool that enables fact based decision-making using unbiased production metrics and analytical analysis.

Tactical and Strategic Asset Management Metrics

Effective utilization of packaging line assets depends upon management of the production operations, maintenance, and repair. These operational elements have traditionally been areas that provided cost reduction opportunities for manufacturers. Preventative maintenance issues facing operations managers have not changed significantly; however, determining why assets fail, assessing operational costs, and making key tactical decisions quickly remain challenges. The challenge for an operations manager is to employ asset management metrics that drive plans and procedures that seek Optimum Output of quality product. Manufacturers in this quest have asked the question: "Which Key Performance Indicators (KPI) should be used - particularly in real-time?" What most companies don't recognize is that there are two types of metrics: (1) Strategic and (2) Tactical metrics. Strategic metrics drive long-term behavior and are useful at the management level to determine poor performing lines or plants. Tactical metrics are critical in that they empower personnel with knowledge to change behavior ensuring that an entire line or individual piece of equipment can improve performance. Tactical metrics are actionable metrics that provide the knowledge needed by production personnel to transition from a poor performer to a top performer. Using a consistent PES implementation throughout all global operations has a tremendous potential to create repeatability and consistency across all lines and plants.

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Strategic Asset Management Metrics

One commonly used asset management metric is Overall Equipment Effectiveness (OEE). The OEE metric identifies inefficiencies in manufacturing operations by providing a big picture relative metric that is normalized across production lines and facilities. Fundamentally, OEE enables operations managers to:

- Identify total uptime when a packaging line is producing.
- Assess the Availability, Performance, and Quality of production.
- Identify Best Practices by employing the procedures and processes of best performing lines and plants.

OEE and similar techniques are widely used in the CPG industries. Most notably Kraft, Procter & Gamble, and Unilever all use several variations of asset management metrics. Independent of which metric an organization chooses, the purpose is to provide a consistent measure of asset performance that provides a basis for fact based decisions regarding capital investments. OEE based asset management programs typify the strategic oriented nature of many of the other widely used asset management metrics. Manufacturers employing the OEE metric are able to gain insight as to where to target performance improvements going down to the granularity of an individual piece of capital equipment.

A comprehensive asset improvement program should ensure that the production lines are managed optimally by the operators on the production floor.

Line Analytics are Tactical Metrics that Provide a Basis for Progressive Improvements

OEE in conjunction with other packaging line metrics are the basis of a real-time decision support tool that augments the skills of the operator on the line, maintenance personnel, and production managers. Downtime reports, Pareto Charts, root cause analysis, production rates, setup time, hierarchical problem occurrences, utilization, and wastage are all valuable tactical metrics for the operator. A comprehensive asset improvement program should ensure that the production lines are managed optimally by the operators on the production floor. In this case, OEE as a metric cannot guarantee that the human behaviors on the production line result in corrective actions that optimize the performance of the assets. Today's packaging lines are very complex making it very challenging for an operator to determine the most appropriate corrective actions. To this end, information available at the

packaging line needs to include tactical metrics that drive corrective actions leading to measurable operational improvements.

Packaging Execution Systems in the Real World

Pharmaceutical manufacturers that are considering adopting Lean Principles to improve efficiency of packaging operations must give serious consideration to evolving their Packaging Execution System. By providing consistent, reliable metrics and detailed analytical tools and interfaces with central ERP systems, a PES serves as the core infrastructure to manage and optimize packaging operations.

There are a variety of tools on the market that, collectively, can be leveraged to achieve PES functionality – but not without extensive integration. In these cases, consultants can assemble disparate products and applications from multiple vendors and then write the code required to bridge the solutions and integrate them into a PES architecture. The more effective approach is to select a productized solution that addresses all the desired functionality, and which is supported by a single vendor that is well-versed in the intricacies and nuances of pharmaceutical-specific packaging.

One vendor, Systech International, provides a productized PES offering. Systech can address independent facets of the pharmaceutical packaging line and also provides the full benefit of an integrated PES solution. Systech's extensible product line monitors and manages the packaging line to protect its integrity while optimizing its operation. Systech's software suite facilitates the collection and distribution of actionable information – enabling clarity across the plant and throughout the enterprise.

Systech's PES is built upon its suite of machine, line, and plant level products – Systech Sentri ™, Systech Advisor™, and Systech Guardian™. These products, combined with applications, create the infrastructure needed for vision inspection, line management, performance metrics, serialization solutions, and enterprise integration of packaging data. As a productized solution offering easy customization, the suite is repeatable across packaging lines and plants. This system's consistency not only streamlines deployments, but also reduces training requirements and associated costs.

This productized approach also provides scalability that enables manufacturers to deploy in progressive steps, depending on their requirements.

Leading Pharma Leverages Clarity to Counter Counterfeiting

In a sweeping effort to increase patient safety and combat the growing problem of counterfeit drug products, a major pharmaceutical manufacturer is adding 2D Data Matrix Bar-Code Serialization into its strategic product security initiatives. This initiative is allowing the company to more readily identify suspect product in the marketplace. Eventually, this system will extend the ability to authenticate products to both supply chain partners and consumers, further ensuring patient safety and brand integrity.

This pharmaceutical manufacturer must address these complicated safety challenges while dealing with the efficiency pressures associated with increased line changeover and line performance demands.

To accomplish this, the company has undertaken a multi-year commitment to establishing and growing a PES beginning with item-level serialization and will expand its operation with the addition of performance metrics. This manufacturer selected Systech's PES approach to serve as a flexible, extensible platform.

The implementation of this manufacturer's PES effort began with Systech Sentri for vision inspection and Systech Advisor for real-time production monitoring, control, data collection, line management, and serialization. Today, Serialized Product Tracking (SPT), a software application to Advisor, is enabling serialization of products at the item, case, and pallet level. SPT provides product authentication by using Electronic Product Codes (EPCs) on 2D bar codes and is integrated with existing packaging operations.

In the next phase, the manufacturer will extend their PES to include plant-level management of EPC serial numbers and OEE measurement using Systech Guardian. Guardian is a plant level product that connects to ERP and EPCIS systems providing a single point interface to the enterprise and ultimately, to the supply chain and customer. The expansion of their PES also gives the manufacturer the infrastructure to support the addition of RFID track and trace technology to its packaging operations.

The project currently includes 25 packaging lines across 12 worldwide sites. Measurable performance improvements have been achieved at the first

plant installation while simultaneously addressing regulatory challenges and without impeding new product releases.

The deployment provided the capability to manage production records and product serialization, which was an important consideration in the selection of Systech's PES solution. Systech has mastered these capabilities and is now capable of cost-effectively replicating this integrated PES solution across all manufacturing operations throughout the globe.

Analyst: Sal Spada

Acronym Reference: For a complete list of industry acronyms, refer to our web page at www.arcweb.com/Community/terms/terms.htm

API	Application Program Interface
APS	Advanced Planning & Scheduling
B2B	Business-to-Business
BPM	Business Process Management
CAGR	Compound Annual Growth Rate
CAS	Collaborative Automation System
CMM	Collaborative Manufacturing Management
CNC	Computer Numeric Control
CPG	Consumer Packaged Goods
CPAS	Collaborative Process Automation System
CPM	Collaborative Production Management
CRM	Customer Relationship Management
DCS	Distributed Control System
EAI	Enterprise Application Integration
EAM	Enterprise Asset Management
ERP	Enterprise Resource Planning
HMI	Human Machine Interface
IT	Information Technology
MIS	Management Information System
MRP	Materials Resource Planning
OpX	Operational Excellence
OEE	Operational Equipment Effectiveness
OLE	Object Linking & Embedding
OPC	OLE for Process Control
PAS	Process Automation System
PLC	Programmable Logic Controller
PLM	Product Lifecycle Management
RFID	Radio Frequency Identification
ROA	Return on Assets
RPM	Real-time Performance Management
SCM	Supply Chain Management
WMS	Warehouse Management System

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