



Plant i.T.

Process Control Systems. MES inside.

Works with

EcoEtruxure™

The IT industry solution for the Life Science Industry

proleit.com

ProLei.T.

by **Schneider** Electric

Integrated IT solution for the Life Science Industry

You have to set market trends to win customers. Increasing Life Science Industry requirements in terms of regulatory demands, product variety, quality assurance, plant utilization, traceability and sustainability necessitate new approaches. Demand is toward automated communication from goods intake through production to dispatch, from the plant production control level to the business system and back. Integrated solutions are required to meet the demands of unified production.

The requirement for a flexible manufacturing facility to produce multiple product lines from the same configurable unit operations with minimal re-validation can now be met thanks to an integrated IT system that controls and monitors all manual steps, all subordinate semi or fully automated processes and is connected to the ERP system. Due to increasing competition in the Life Science Industry and increasing regulation across the supply chain, all production processes must offer the highest level of security and flexibility – from the raw material stage through the production processes to formulation & finishing, as well as packing for final distribution.

Integrated solutions with Plant iT

Plant iT is a modular IT system with integrated MES functionalities for all process areas in the Life Science Industry. These industry-specific features combined with cutting-edge information technology enable data transparency from the operational to the planning level and at all stages of value creation. Manufacturing Execution Systems (MES) provide production managers with new opportunities to overview the entire production chain from raw material delivery to the packaged product. **This enhanced transparency optimizes processes, improves product quality and yield, reduces production cycle times, optimizes raw material, minimizes waste and increases the availability of machines and systems whilst saving energy.**

Plant iT and integrated Life Science production

We have been collaborating with the Life Science Industry for many years, developing systems that meet current needs and delivering automation and information solutions in conjunction with industry SIs and OEMs. Plant iT can cover the entire production process with its modular architecture, which is built upon one concept: **one database, one configuration environment and one operator environment.** In partnership with customers, machine suppliers and the Technical University of Munich (TUM) and the Friedrich-Alexander University Erlangen-Nuremberg, we have defined and implemented standard interfaces for processes and data quality by machine type based on the Weihenstephan Standards (WS Pack). This enables real-time quality control across multiple unit operations, from managing recipe controlled formulation to warehouse management tasks. ProLeiT's innovative methodology and adoption of new technology ensure customer-specific requirements concerning the distribution and recording of process and QA-relevant data are met. Through this approach for the Life Science Industry, we are able to achieve integrated real-time Overall Equipment Effectiveness (OEE) analyses. Batch orchestration enables coordination of the higher order process control, connecting internal and external data systems, mapping the information flow for individual process steps and interconnecting processes, establishing a single view of all production event data and providing a fully compliant complete electronic batch record.

The requirements of industrial Life Science production

IT controlled integration of all the processes

When taking a closer look at industrial Life Science manufacturers, you will often see production areas consisting of systems and machines from various manufacturers with little or no intercommunication. This heterogeneous system and machine scenario is divided into numerous process areas and very rarely fully automated or connected to a higher-order IT system. Although many system and machine manufacturers offer information solutions in the form of SCADA systems, these solutions are often limited to their own systems and thus to a specific process area, and are not intended for a production line or the entire production facility. This often results in the development of so-called “islands” which have, for instance, their own recipe management whose adjustment in case of original recipe modification can only take place manually and, in the worst-case scenario, can only be carried out by a programmer. Furthermore, actual data, for example temperatures, are not permanently recorded by these local automation systems. Skids/units, mixers and bio-reactors are a good example of this. The necessity of higher-order process management becomes apparent

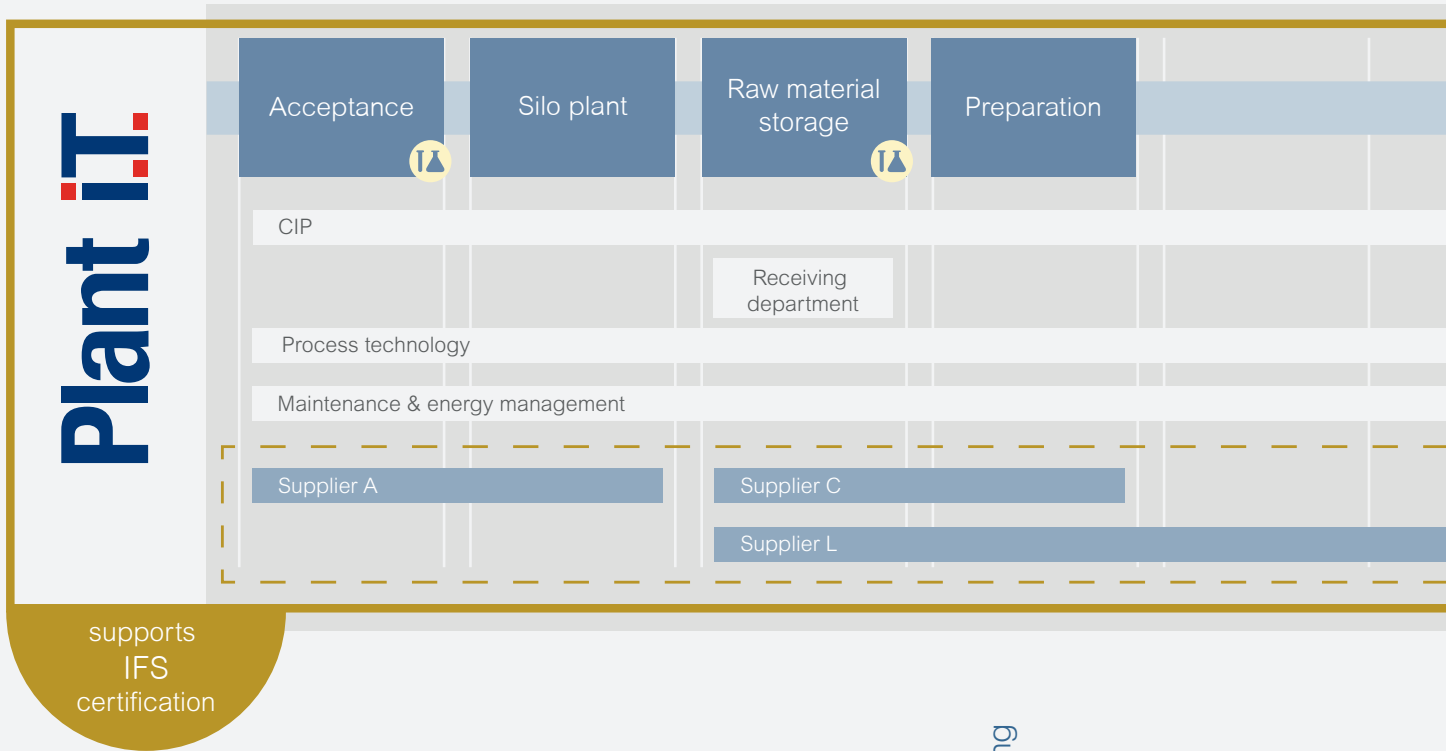
when further considering existing dispatching, storage and logistics systems. The flow of information becomes an even more critical factor for production areas which map a workflow with pen and paper as so-called routing or accompanying sheets. In this case, the manual recording of production data is a typical source of errors for electronic material tracking and operator guidance.

Plant iT offers the perfect solution

Irrespective of existing systems and requirements, Plant iT can process information from all process and packaging areas and assumes integrated process management thanks to defined interfaces. A feasible solution for “islands” could be to interlink the controls in order to, for example, specify order parameters as well as record, analyze and send actual values to an ERP system in a condensed form. Plant iT ensures compliance to quality parameters, the calculation of material consumption according to the order list and complete traceability of the entire production process in line with statutory regulations. Plant iT supports IFS certification as well as FDA/GMP compliance.

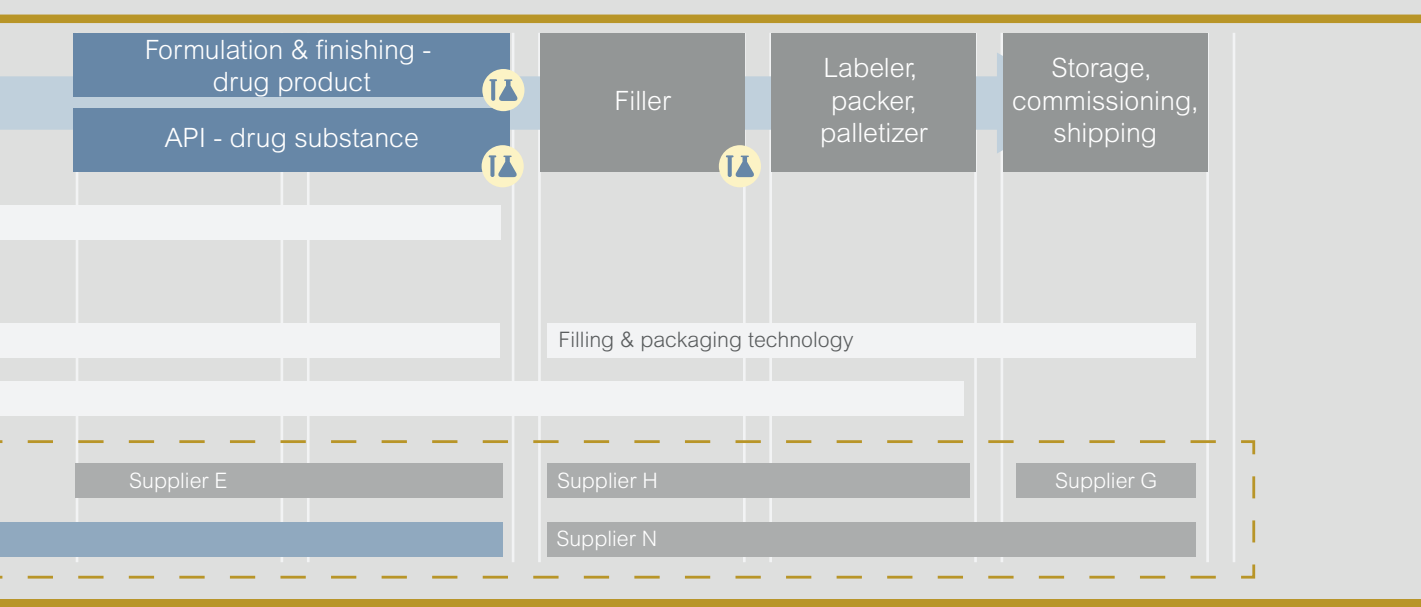


Process chain in industrial Life Science production



supports
IFS
certification





Automatic recipe optimization

Web reporting

Packaging plant connection

Bills of material

OEE performance data

Plant iT

Cleaning schedules

Material batch parameters

Batch management

Serialization

Remaining quantity processing

Dynamic residual batches

Audit Trail

Integrated tracking and tracing

Detecting optimization potentials

Cleaning matrix

Line management

Paperless production

Integrated solution concept

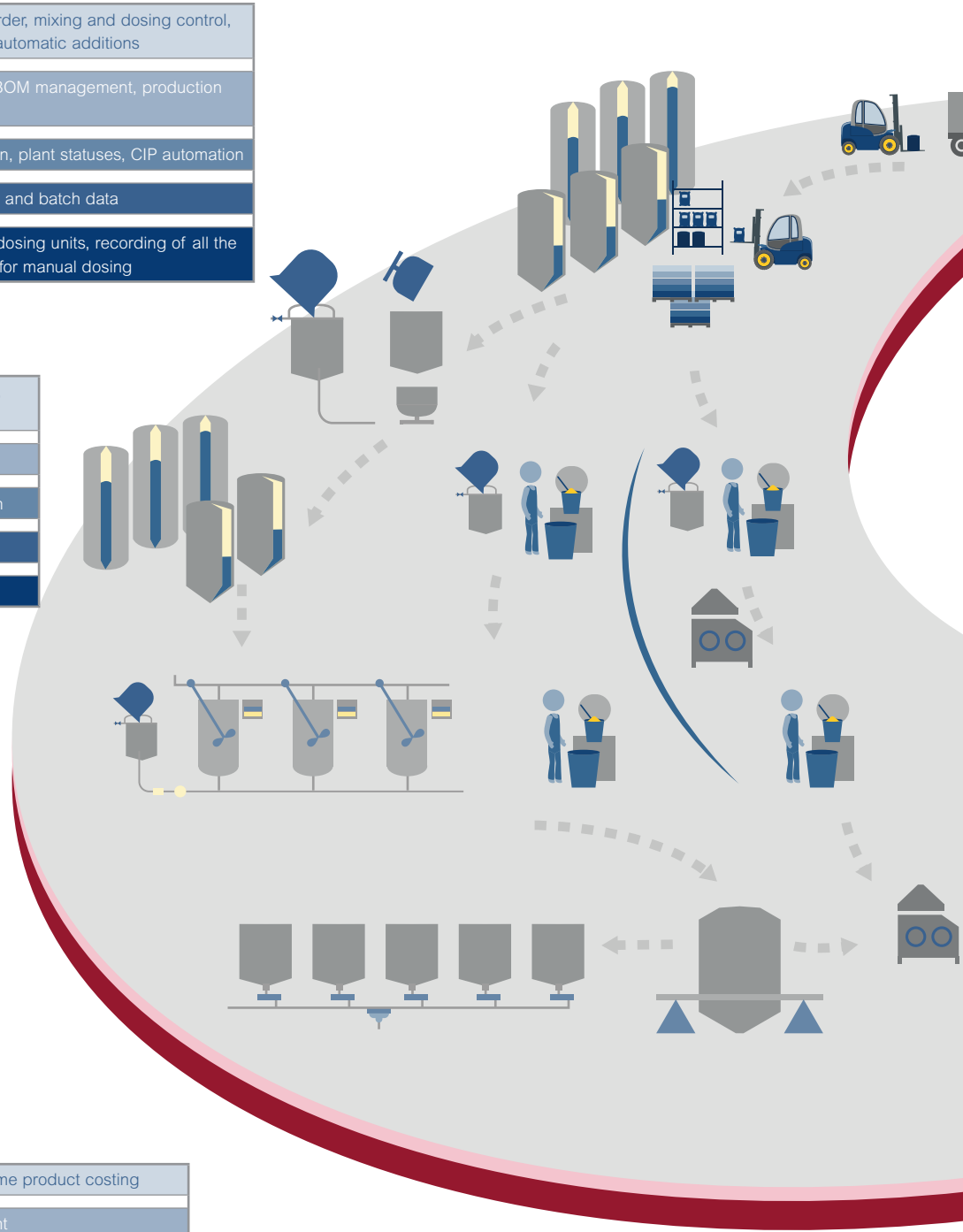
Preliminary solutions	Production order, mixing and dosing control, manual and automatic additions
	Recipe and BOM management, production parameters
	Line allocation, plant statuses, CIP automation
	Consumption and batch data
	Tracking via dosing units, recording of all the components for manual dosing

Mixing/ preparation tank	Production order, mixing and dosing control, manual and automatic additions
	Quality inspection
	Line and machine allocation, CIP automation
	Product quantity, temperatures
	Tracking via raw material batches

ERP	Order dispatching
	Execution management
MES	Specification management
	Resource management
	Data recording & analysis
	Tracking & tracing
PCS	Process control

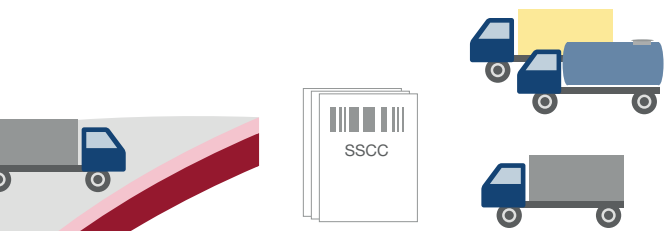
Grinding & dispensing	ERP integration for real-time product costing
	Specification management
	Model predictive control
	Energy reporting & management
	Multivariable control and coordination
	Complex control (i. e. Auto-Tune)

Complete & nuance	Production order for filling/inline mixers
	Machine and quality parameters (temperatures)
	Line and machine allocation
	Temperatures, pressures, quantities, etc.
	Tracking via mixing/preparation tank

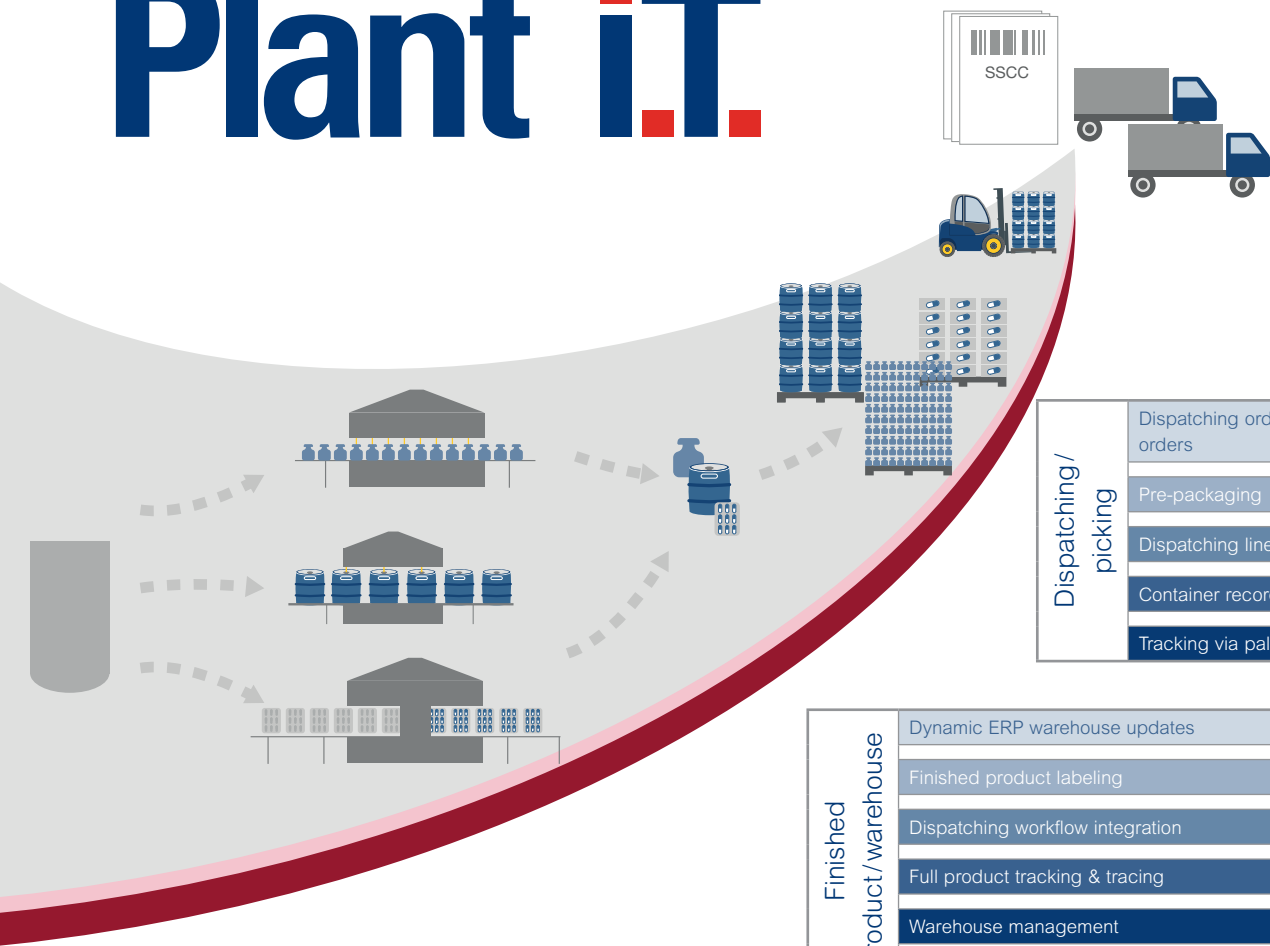


Raw materials warehouse	Stock intake and stock transfer orders, provision orders
	Raw materials management, quality inspection
	Silo management, storage location management
	Material bookings, warehouse capacity, warehouse utilization
	Tracking via raw material batches

Goods intake	Intake orders, lab sampling, silo allocation, declaration control
	Raw materials management, inspection instructions, material compatibility
	Vehicle monitoring, silo monitoring
	Feedback to purchasing dep., acquisition posting in materials management
	Tracking via raw material batch, possible re-declaration



Plant iT.



Dispatching/ picking	Dispatching order and coordination, loading orders
	Pre-packaging
	Dispatching line
	Container recording via SSCC
	Tracking via pallet tracking

Finished product/warehouse	Dynamic ERP warehouse updates
	Finished product labeling
	Dispatching workflow integration
	Full product tracking & tracing
	Warehouse management
	Tracking pallet/container via RFID/barcode

Packaging, cartoning & palletizing	Packaging orders and control, labeling orders
	Packaging parameters (packaging weight, quantity), palletizing parameters, labeling specifications
	Basket, roll cage and pallet management
	Number of pieces, OEE-relevant data, faults, etc.
	Tracking via container detection

Plant iT and MES

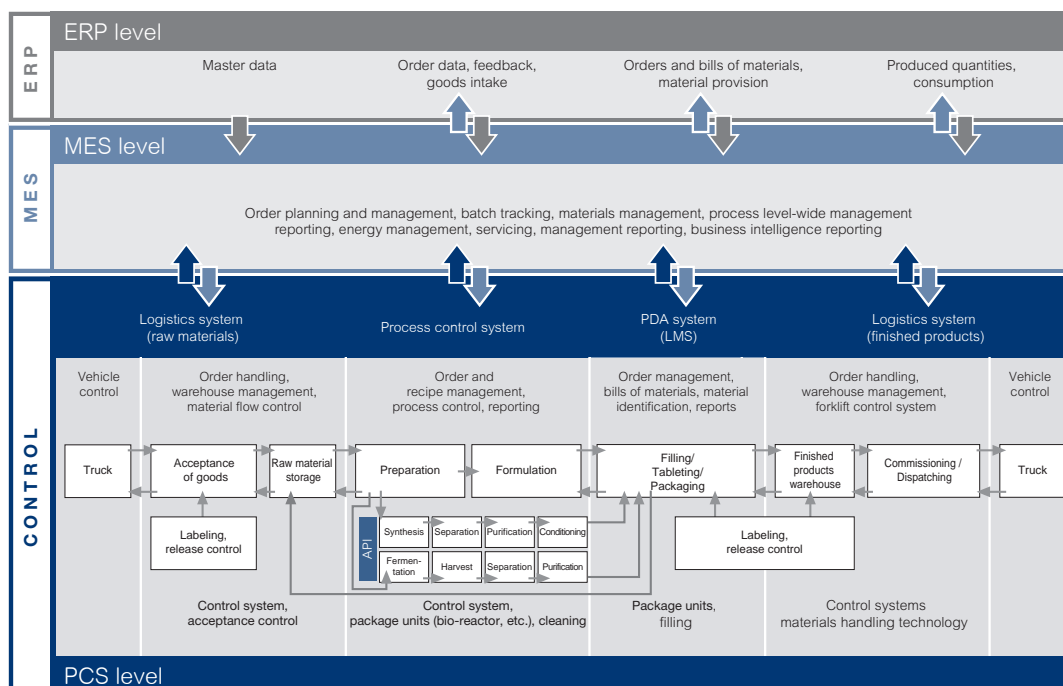
A vertical integration

MES and Process Control Systems are often seen at different levels or as two separate systems in one production plant. Plant iT unites these commonly separated systems. The provision of MES functions in the Plant iT system ensures a single environment for administration and reduces the need for multiple interfaces. This provides the perfect foundations for integrated information processing and increased efficiency for system operation, maintenance and repairs as well as future extensions.

ProLeiT's Plant iT platform offers a flexible environment, consisting of a base system and optional application modules for various areas of a production plant. The Plant iT material module is an excellent example of the modular design of the Plant iT system. Since the availability of materials is of key importance for Life Science plants, process-related materials management provides all the

data on a continuous basis. This ensures rapid decisions for any events that occur during production. An essential criterion for the quality of these decisions is the real-time availability of information regarding stock levels, local availability and quality status of the materials being processed. For wider supply chain traceability, Plant iT easily connects with the Schneider Electric EcoStruxure Traceability Advisor.

Plant iT therefore guarantees the required integration to ensure traceability, real-time adaptation of the bill of materials (BOM) and recipe optimization of critical process parameters (CPP) depending on the raw material critical quality attributes (CQA). Plant iT can map the entire received raw materials with the respective workflow and process parameters to summarize in an all-inclusive electronic batch record (EBR).



MES in the Life Science Industry

Plant iT's flexible modular configuration enables gradual implementation and system growth. Existing plant technology and processes can be easily integrated due to the agnostic open protocol connectivity.

The Plant iT platform provides considerable transparency to factory operations, ensuring migration times are kept to a minimum for any renovation project. An object orientated system infrastructure provides an agile approach to system development and minimizes validation and qualification efforts. ProLeiT has extensive project experience and numerous testimonials in the field of consulting and MES solution implementation in the Life Science Industry.

Manufacturing Execution Systems (MES) become the data hub between important areas of production. They answer, amongst other things, the following questions:

What is produced where and by whom? (Execution management)

How should production occur? (Specification management)

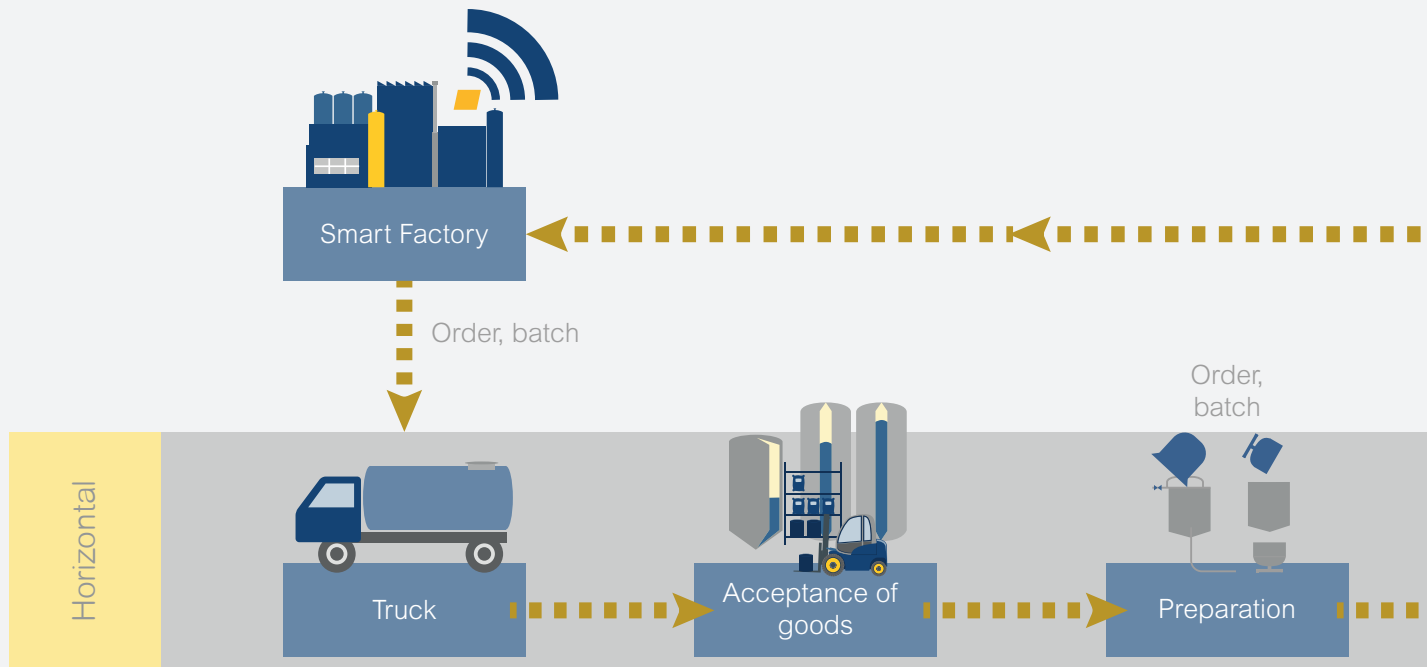
Who should produce what and where? (Resource management)

How did production occur? (Data recording, analysis)

When, where and by whom was something produced? (Tracking & tracing)



Industry 4.0 in the Life Science sector



Rapid development, including an ever faster and more networked world of production, offers not only new opportunities but also creates new challenges. In this context, the keywords Industry 4.0 or Industrial Internet of Things (IIoT) are often used. Industry 4.0 is usually only associated with conventional machine and plant engineering applications; in other words, production-related activities. That said, the smart factory provides many benefits for the process industry, including digital integration of all industrial facilities and processes. Furthermore, implementation is quite straightforward when using a Manufacturing Execution System (MES) as the central analysis and reporting unit.

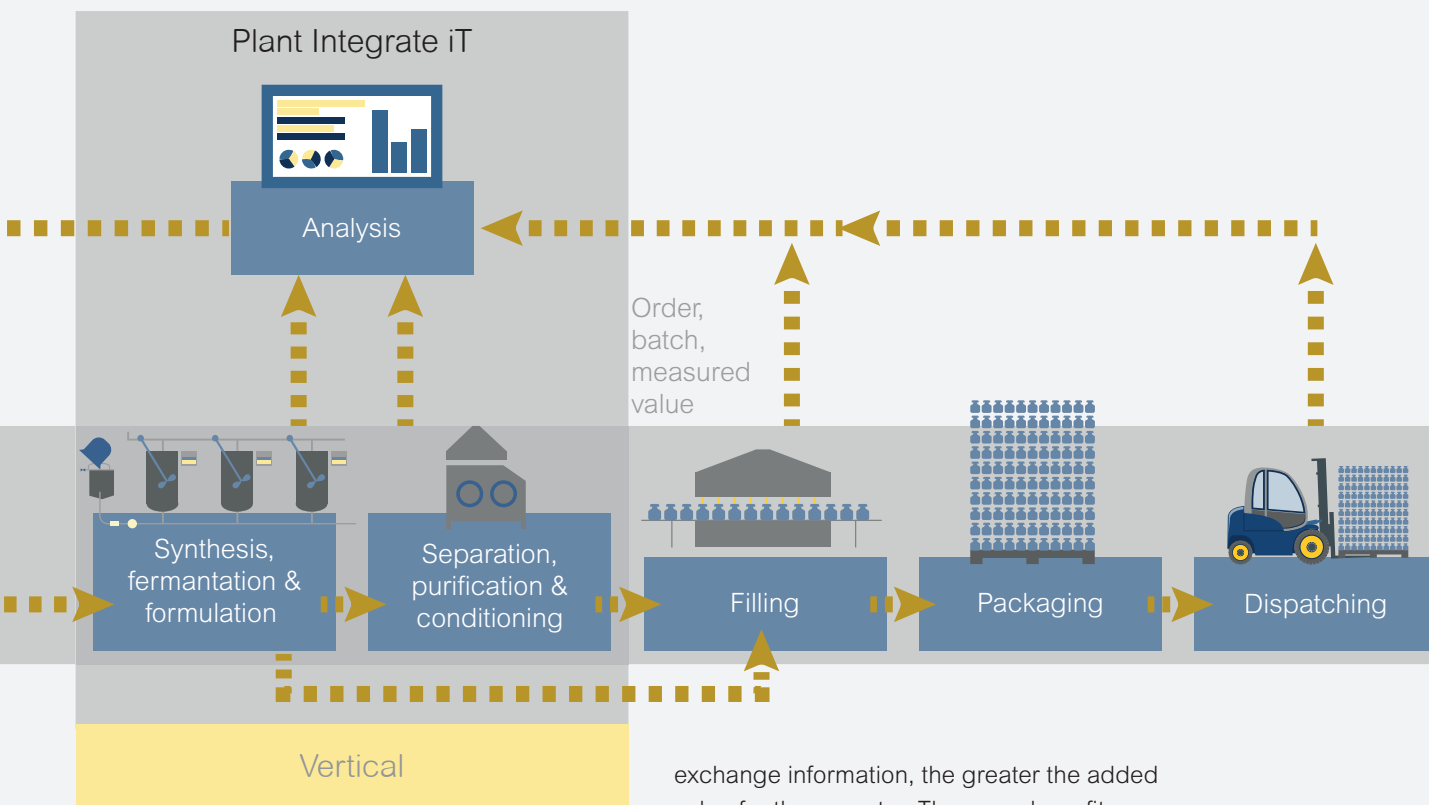
The smart factory

Transforming a traditional factory into an Industry 4.0 smart factory results in significant changes to the way it operates. Business processes respond dynamically to changes in the market, while production techniques adapt automatically to ensure an appropriate balance between cost, quality and environmental impact. Production technology will adapt to specific customer needs, identify and eliminate

bottlenecks and control plant throughput automatically. This goal – true to the vision of Industry 4.0 – is achieved by vertically coupling technical and commercial business processes and horizontally linking processes and systems along the value-added chain. Processes can therefore be controlled and improved across the entire plant. Production becomes completely transparent from start to finish, providing the ideal platform for sound commercial and technical decisions. The smart factory additionally enables companies to identify and satisfy individual customer needs, as even the smallest batch sizes can be produced economically.

New potentials for the Life Science Industry

These technical developments create new automation potentials for the Life Science Industry. Not only will the increased networking of the internal value creation process from development through procurement, production to sales and logistics lead to significant increases in productivity and efficiency; the new possibilities for fully automated monitoring and control of production plants also promise



significant optimization of production processes. Precise examples of existing Industry 4.0 approaches in the Life Science Industry include automated quality assurance, which is accomplished in many companies with the help of sophisticated sensor technology, paperless production as well as the possibility of tracing products throughout the complete value-added process in order to identify and eliminate sources of error.

Integration of heterogeneous systems via MES

This vision can be brought to life with a Manufacturing Execution System (MES) tailored to customer requirements. The MES solution from ProLeiT can be used independently of the process control system Plant iT. The MES integrates the heterogeneous information of the individual production plants and combines the production level with the commercial business processes. Needless to say, companies profit directly from a plant-wide and common database. The more systems that automatically

exchange information, the greater the added value for the operator. The many benefits include dynamic order management and the opportunity to develop and improve plant-wide recipes, as well as being able to trace production data.

Using KPIs wisely

Key figures are necessary to monitor success and investments. These KPIs should be identified and displayed in real time to ensure problems are not only identified promptly, but also in order to initiate appropriate countermeasures. Plant Integrate iT offers freely configurable dashboards to achieve this. Recorded and archived data can be filtered according to various criteria, including time period, order, customer, product, batch, location and energy consumption, as well as interlinked and presented in real time. In many cases, this reveals connections that would otherwise remain hidden. This enables those responsible to react more quickly and effectively to deviations and to counteract them accordingly.

Overall Equipment Effectiveness

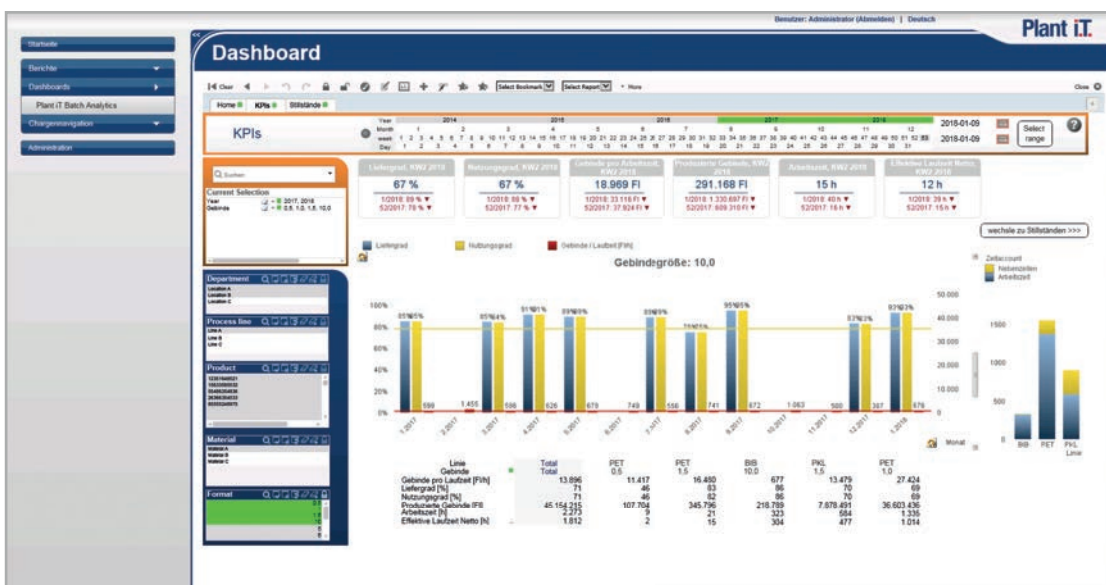
OEE – is the abbreviation for “Overall Equipment Effectiveness”, a method developed for the determination of key figures for monitoring and improving the efficiency of production plants. In many industries, the evaluation of process quality using the OEE method has already proven successful. There are also many advantages for Life Science Industries, but the most important thing is: transparency. Potentials for optimization can be systematically uncovered with the aid of OEE key figures. They indicate where productivity losses occur and analyze the availability, system performance and quality of the individual production lines. They therefore form the basis for all optimization measures.

Plant iT delivers OEE key figures and reports at the push of a button – per line and across production facilities. Since all production data are interlinked, it is also possible to provide OEE analyses and detailed representations of the plant efficiency of individual lines and machines. Depending on the respective customer requirements, the capacity utilization of the various lines can be compared as well

as compliance with key performance figures. Dashboards, tables or lists are available for the graphical presentation of data.

Life Science specific standard requirements have been integrated into Plant iT and can be presented in real-time as online reports. The following information is, amongst other things, evaluated:

- Golden batch analyses
 - e. g. process value comparison
- Consumption analyses
 - e. g. raw material/packaging materials per batch/order; waste/losses
 - Performance statistics
 - e. g. utilization times of all the machines
 - WIP cycle times
- Energy statistics
 - e. g. consumption per machine, line or produced container
- Fault analyses
 - e. g. causes of downtime and downtime per machine, line or product



Plant iT screenshot of an OEE display

Tracking & tracing

From the raw materials to the end consumer and back again

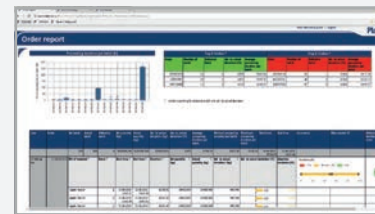
In the course of compliance with the international good manufacturing practices and industry standards FDA/EDURALEX/PICS, the issue of traceability of raw materials to the finished end product within a production process is vitally important. ProLeiT ensures complete traceability at all times through the consistent and complete recording of raw materials, process data, work in progress, operator interactions and finished products.

The desire for greater transparency on the part of consumers requires an enhanced transparent digital view enabling the effective review of batch records to reduce time to market but also the ability to recall products quickly. Clear identification and the complete traceability of goods throughout the entire production cycle offer a number of advantages. Since the chronological tracking of relevant process steps allows producers, logisticians and manufacturers to be assigned exactly to the respective product or production step. Errors can therefore be avoided preventively, or possible sources of errors can be more easily found retrospectively. Process-related

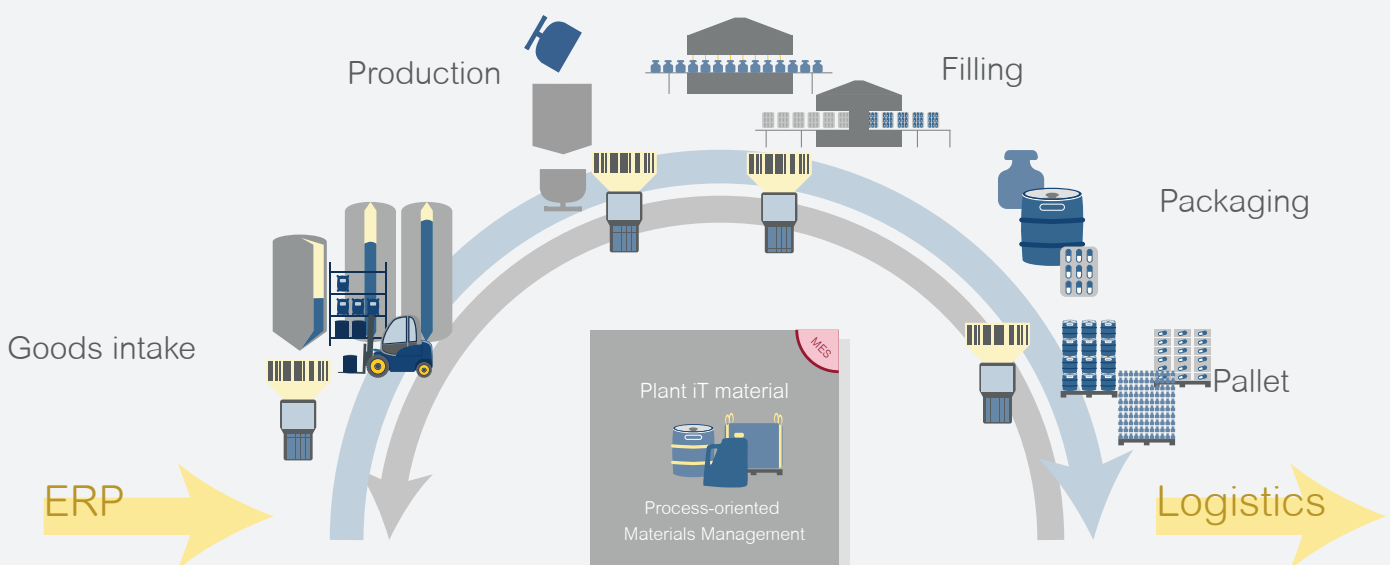
materials management, such as the Plant iT material module, offers a transaction-accurate online view of all material transactions. They are recorded on the basis of a process-compliant warehouse structure and provide precise inventory management that also enables investigation and evaluations in batch traceability. Starting at a freely selectable entry point, investigations can be carried out in both directions. An overview, divided into predecessors (upstream) and successors (downstream) with presentation of all the information, visualizes warehouse and material transactions and facilitates clear and easy navigation.



Batch tracking



Batch reporting



The industry-specific solution for the Life Science Industry

For all challenges in the Life Science Industry

- Order management
 - Process or production orders for the operations:
 - Goods receipt
 - Tank farm management
 - Asset and route management
 - Weighing and dosing/dispensing
 - Mixing/fermentation/bio-reactions
 - Formulation - bottling/tabletting
 - Packaging
 - Dispatching
- Recipe management
 - Acceptance of bills of materials as well as consumption and production feedback to ERP systems
 - Dynamic recipe changes (target quantity, water/concentrate quantity) of a current order
 - Manual component management and definition of addition times in the recipe (workflow management)
 - Recipe optimization and remaining quantity processing
- Process-oriented materials management
 - Mapping the material flow across all process steps
 - Inventory management for all materials
 - Material provisions
 - Recording and processing of rework
 - Batch and product tracking
 - Loss analysis
- Integrated utilities management
 - Utilities data acquisition per batch
 - Utilities statistics and consumption reporting
 - Integration into ERP to enable activity-based costing
 - Load management, intelligent scheduling and shedding
 - Integrated recipes, treating energy as an ingredient
- Integrated energy management
 - Energy data acquisition per batch and visualization
 - Energy statistics with detailed consumption reports
 - Feedback of energy consumption to the higher-order process cost controlling
- Load management with configurable parameters
 - Optimization of the operating mode of energy stores
 - Display of specific energy consumption
- Quality and production optimization/quality management
 - Cleaning and sterilization management and recording
 - Connection to laboratory systems
 - Workflow management of QA-relevant inspection processes
 - Operating/production data acquisition and batch recording (EBR)
 - OEE key figures
 - Process KPIs and loss analysis reporting
 - Integration of HACCP into process workflows
- Maintenance
 - Monitoring of runtimes and machine operating hours
 - Maintenance orders
 - Spare parts procurement, warehouse-dependent or order-oriented
 - Planning maintenance projects and tracking processes
 - Warehouse management of spare parts with minimum stock monitoring
- Process management
 - Plant-wide visualization and control
 - Integrated user management and process security
 - Integrated control for both batch and continuous process
 - Process historian/digital twin complete with Plant iT Visu-Recorder to drive continuous improvement
 - Class-based concept, simplifying the implementation of required process control strategies and minimizing validation effort
- Service and support
 - 24/7 support
 - System monitoring
 - Analysis and maintenance



Scalable



Demand driven



Industry-specific solution



Open, modular solution



High level of flexibility



Can be extended at any time



Tested technology



High level of standardization

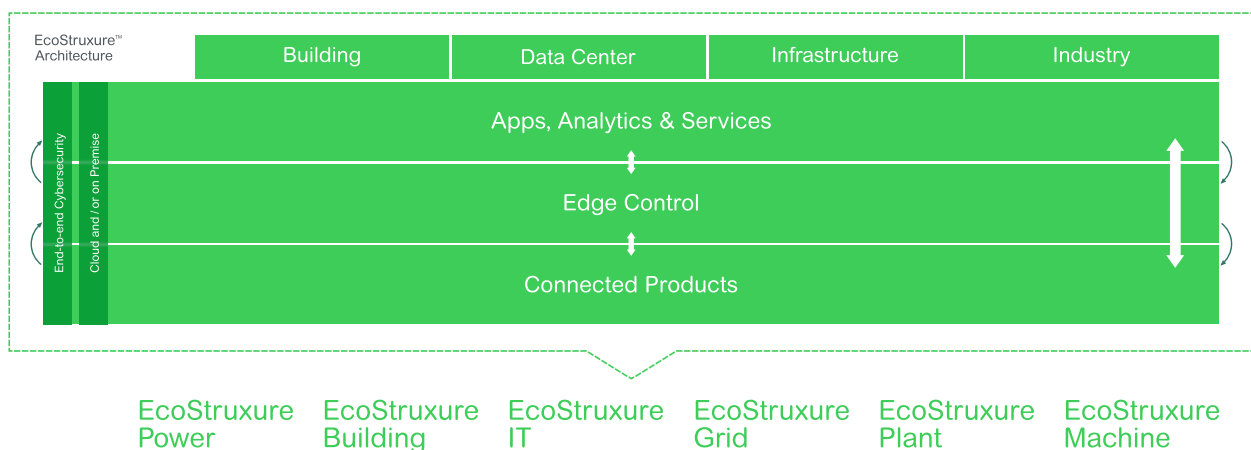
EcoStruxure™

Innovation At Every Level

Since the merger of ProLeiT and Schneider Electric in August 2020, Plant iT has been complementing the Schneider Electric EcoStruxure system architecture. Bringing together the expertise of Schneider Electric SE and ProLeiT offers tremendous value to the customers of both companies to increase their productivity and efficiency. The ProLeiT solutions specifically address the Life Science Industry and thus enable broad market penetration. Through its own EcoStruxure system architecture, which is further strengthened by the ProLeiT portfolio, Schneider Electric, a company active in over 100 countries worldwide, has long been successfully driving forward digital transformation in industrial automation.

EcoStruxure is Schneider Electric's open, interoperable, IoT-enabled system architecture and platform. EcoStruxure delivers enhanced value around safety, reliability, efficiency, sustainability, and connectivity for our customers. EcoStruxure leverages advancements in IoT, mobility, sensing, cloud, analytics, and cybersecurity to deliver Innovation at Every Level. This includes Connected Products, Edge Control, and Apps, Analytics & Services which are supported by Customer Lifecycle Software. EcoStruxure has been deployed in almost 500,000 sites with the support of 20,000+ developers, 650,000 service providers and partners, 3,000 utilities and connects over 2 million assets under management.

EcoStruxure™ Innovation At Every Level





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