PHARMA INDUSTRY IN TRANSITION

Open standards smooth bumpy road to pharmaceutical supply chain

The pharmaceutical industry is currently going through what is seen to be the biggest change in its history. The growth in world population, the universal desire for higher living standards, the expiry of patents and the subdued forecasts for the economy are forcing the industry to take action. This is underscored by the trend towards personalized medicine, with ever smaller batch sizes and more diverse packaging materials, as well as the whole issue of counterfeiting. As if these challenges were not enough in themselves in a tightly regulated environment, senior management now have to rethink everything in terms of digital transformation. That's because major corporations such as Google and Amazon are permanently changing business models in the healthcare and pharmaceutical industries.

The mechanical and plant engineering sector is becoming acutely aware of the dynamic in the pharmaceutical industry. Whereas customers had previously tended to place orders for single machines in order to enhance an existing production line, entire system solutions are now in demand. Mechanical engineers are expected to come up with innovative designs that not only meet the changing requirements of the pharmaceutical industry but also, in spite of high regulatory standards, take into account criteria such as connectivity. The processes across the entire value chain will need to be made much more flexible while maintaining drug safety. This will have a big impact on communication within the process.

As in most other industries, communication in the pharmaceutical industry is characterized by the hierarchical system of the automation pyramid. The purpose of this structure is to reduce complexity across the entire drug production process. It is achieved by organizing the company into hierarchical levels. Each of these levels is supported by various systems such as ERP, MES, LIMS, SCADA and SPS. All automation levels require communication and a variety of data transmission systems. The upper levels have complex IT systems connected to extensive user networks and processing large amounts of data, the numbers of participants in the lower levels are fewer and the network is smaller. At the lower levels, however, the demand for speed increases for the real-time processing of infinitesimal amounts of data.

Distributed control level and MES, important building blocks for digitization

The central element within the automation

pyramid is the Distributed Control System (DCS), which can be regarded as an interface between human and machine. The DCS provides the system operators with all the relevant information regarding the system states and alarms and data from the pharmaceutical production process is recorded here. Subordinate to the DCS level is the control level at which the logic of the automation stations is implemented. All results from the control level together with information from the field level are transferred to the DCS level and visualized there.

Featured elements at the field level are multiple sensors which transfer measured values to the controller. This in turn performs a logic operation and triggers actuators that intervene appropriately in the process.

One system in particular that depends directly on good communication with DCS level is the Manufacturing Execution System (MES). Many pharmaceutical companies have recently begun to upgrade their MES in order to make processes more efficient. Manufacturing Execution Systems receive information from DCS level, acquire operating data, process it and control the manufacturing in real time. The MES therefore takes on a central role, and not only in quality assurance. Manufacturing Execution Systems have a key role to play in keeping track of products and/or intermediate products throughout their lifecycle. With digitization, MES data will make the drug manufacturing supply chain even more transparent, contribute to the reduction of production costs, enhance quality assurance and ultimately help to deliver drugs even faster to individual target markets.

Future vision: Smart pharmaceutical production

The most important prerequisite for achieving this objective (and currently also the biggest obstacle) is standardized interfaces. Only a standardization of interfaces and transmission protocols can guarantee error-free communication across the entire value chain in a digitized future. The highly-charged nature of the matter is further underscored by the fact that, in the future, applications at the Supervisory Control and Data Acquisition level (SCADA), production level (MES) and plant management level (ERP) will present themselves in the form of Cloud-based Software-as-a-Service solutions.

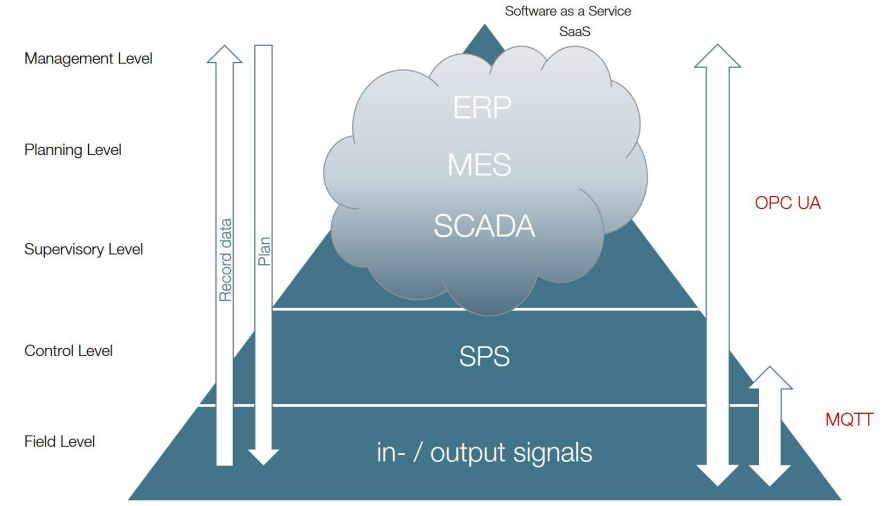
How can the pharmaceutical industry, with its monolithic IT infrastructures and pyramid architecture, progress its digital transformation? How can the operational level with LIMS (Laboratory Information Management System) and SiLA (Standardization in Lab Automation), the tactical level with MES (Manufacturing Execution Service) and the strategic level ERP (Enterprise Resource Planning) be networked with each other and, exploiting the Internet of Things (IoT), become the Smart Pharmaceutical Factory?

There is no single answer to this question. Nobody likes to interfere with validated processes, especially in the pharmaceutical industry. For this sector to open itself up to the digital transformation at the rate of change necessary, it will in the long term need to bring on board machinery and equipment manufacturers who are likewise endeavoring to cut the plethora of different bus systems, interfaces and sensor systems down to a bare minimum. If the pharmaceutical industry manages to do this, it will find that the machine-builders make optimal partners who, together with service providers from IT and process engineering, can drive forward the digitization of the pharmaceutical supply chain instead of wasting valuable time on the solution of interface problems.

OPC UA can accelerate system integration

One solution for the future is Open Platform Communications Unified Architecture (OPC UA). It is a collection of standards for communication and data exchange in the field of industrial automation. This also means that, in future, OPC UA will be able to affect the transfer of data from machine to machine, taking into account measured values, sensor data, controlled variables and control statements. OPC UA is the key to standardizing industrial connectivity while ensuring interoperability between products from multiple vendors. How can pharmaceutical companies, machine builders, and their suppliers operate until such time as OPC UA is established, do they use a variety of different systems instead? What can all industry players do to develop digitization and automation across the board, including the classic use of robots in

Automation Pyramid



pharmacological research, the production of basic substances in combinatorial chemistry, secondary packaging and logistics?

Long-term technical strategy focusing on pharmaceutical needs

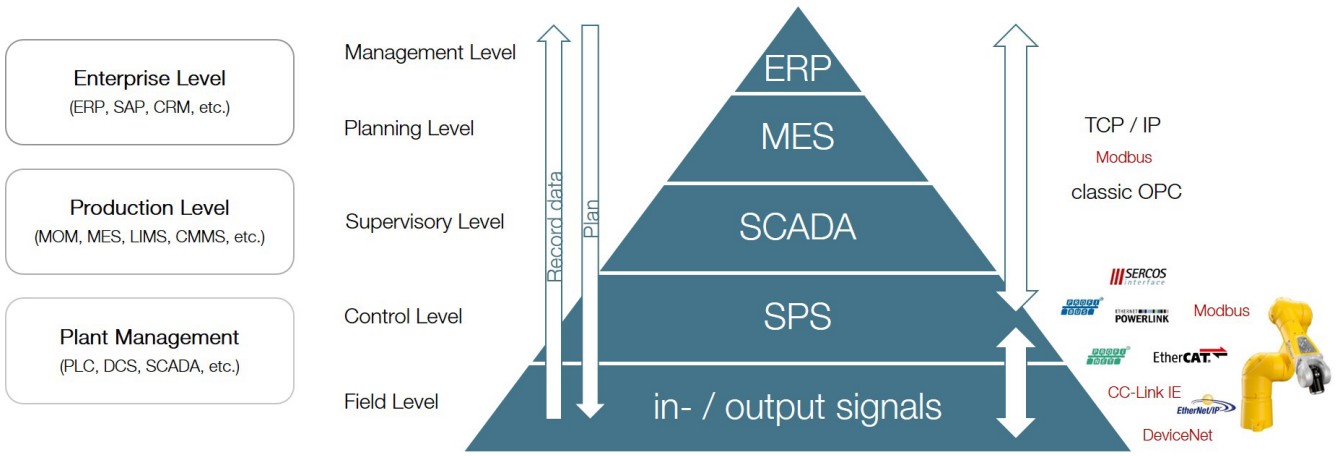
With its long-term technical strategy, Stäubli Robotics demonstrates that, even at the lowest level of the automation pyramid, it is possible to eliminate problem interfaces at the field and control level. This works in the case of Stäubli because the manufacturer does not use its own communication protocols for robotics and control. Instead, Stäubli robots support all protocols that have been defined as an international standard. The robot specialist offers its customers all options for digital transformation and guarantees maximum flexibility in process integration and operation, regardless of which bus generation, protocol or interface a customer wants to operate with.

The production conditions in the pharmaceutical industry are as varied as Stäubli's portfolio. What they all have in common is the high level of regulation and the stringent quality standards that are in place to ensure operator and patient safety in equal measure. Pharmaceutical manufacturers are seeking more automation for a variety of reasons, for example to facilitate cleanroom production entirely without human intervention, to respond to competitive pressure with even higher production speeds and to offer the markets even more flexible batch sizes.

The figures show that the German robotics and automation industry generated domestic and foreign sales of around €14.5 billion in 2017. Robotics alone accounted for a respectable €3.8 billion of this total, this is more than a quarter and the biggest customers were China and Japan. German robotics suppliers regard both countries as a perfect example for innovation because China is not behind Europe in terms of digitization, not least since it adopted the Made in China 2025 strategy. This is not all: the People's Republic has recently taken over the number two spot in the list of the largest pharmaceutical markets in the world, second only to the USA. According to forecasts, sales will rise to one trillion US dollars by 2020.

Robotics: Compatibility in all directions

The only mechanical engineers and suppliers who will actually be in a position to shape the global pharmaceutical market of the future will be those who are open to new technologies, who promote standardization by means of OPC UA or similar, and who design their robot controls flexibly to take account of the structures that have grown over time. Stäubli has adapted to the current dynamics and challenges of the future in its next-generation modular robot series such as the TS2-40, TS2-100, TX2-40 and TX2-90XL. From high-performance industrial robots, this can also be used for collaborative applications (optionally with sensor skin) to mobile robotics (HelMo) and mobile platforms (Stäubli WFT). This multinational company provides standardized communication protocols all the way through to real-time Ethernet and its compatibility with a wide range of connected systems such as MES or ERP. Regardless of the current interface landscape, companies benefit from the use of Stäubli robots and their powerful multitasking capabilities. This shows, for example, in permanent communication with peripheral manufacturing technologies or ERP and MES systems, with response times of a millisecond. The resulting high-performance communication offers greater flexibility within drug production for rapid adaptation to changing production parameters while guaranteeing secure traceability within the supply chain.



Production cockpit: Visualization of robotics

The majority of global robot manufacturers offer variations on different fieldbuses and Ethernet. A combination of all established interfaces and OPC UA, however, is rare. The open control architecture of Stäubli robots is already enabling the implementation of predictive maintenance concepts in the pharmaceutical industry today. For example, axes and their loading can be visualized and adjusted on the robot. Production lows and peaks are adjusted equally for balance and performance, which has a positive effect on the lifetime and TCO (Total Cost of Ownership). In the future, engineers will be able to use a so-called Production Cockpit to visualize in detail the parameters of robot use across multiple levels, enabling situational decision making and intervention in the ongoing production process.

Drug manufacturers who aim to automate towards the Smart Factory can simulate their turnkey robotic system at the planning phase by means of a 3D simulation. This allows theoretical calculations such as at cycle times to be made as early as the design phase. The comparison between theory and practice by means of simulation thereby ensures maximum benefit from an investment at the planning stage.

A further important step towards the Smart Factory is Optimize Lab from Stäubli, a software package which, as the name implies, allows robot loading during operation to be measured, analyzed and ultimately optimized for the total cost of ownership.

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