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Novartis' Road to the Manufacturing Workcenter of the Future

By Valentijn de Leeuw

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Novartis, OSIsoft, Automation Strategy, Standardization, Simplification, Machine Interfacing, Application Interfacing, Data Gateway

Overview

Global pharmaceutical company Novartis has grown over the years due to acquisitions. Today, the company aims to increase transparency and simplify its governance structures and employee empowerment. To this end, Novartis recently implemented a common shared services organization. As we learned during Antonio Buendia's presentation at the OSIsoft EMEA Users Conference in Lisbon, Sept 22, 2014, this philosophy also impacts manufacturing.

At global pharmaceutical company Novartis, innovation and standardization go hand in hand. In pharmaceutical manufacturing, the automation strategy supports the division's goal to "produce quality medicine on time, every time." This strategy involves simplification and standardization to provide the "right information to the right users at the right time." This also enables process and product analysis and improvement, as well quality consistency across sites.

Mr. Buendia is the head of manufacturing process controls, automation and electrical of Novartis Pharma, the innovation-driven pharmaceutical business of Novartis. His visionary plenary presentation explained the division's automation strategy for manufacturing and the progress achieved so far.

The strategy includes rigorous standardization and paperless workflow, supporting the operational goals. Mr. Buendia explained the three main steps in the execution of his strategy: providing the right data to the right people at the right moment; providing manufacturing control using these data; and enabling the user to analyze, take corrective action, improve, and take preventive action. Novartis' "Workcenter of the Future" environment enables this strategy.

Novartis applies a similar approach to engineering software, using a rigorous integrated, paperless engineering and qualification process. ARC recently published a white paper that discussed this approach and Novar-

tis' CEO Mr. Jimenez's role in promoting innovative modular process design.

This Insight, based on ARC's observations, does not necessarily reflect Novartis' exact position.

Novartis Pharma

Novartis focuses on three groups of activities: producing innovation-driven pharmaceuticals, eye care, and generics. The company is reducing its stake in over-the-counter products by creating a joint venture with GSK and divesting its activities in animal health and vaccines. The company had almost US $58 billion in turnover in fiscal year 2013. The technical operations of the Pharma division has over 11,000 associates and produces around 2,400 tons of drugs per year, which are transformed into 30 billion patient doses. According to the company, its priorities are growth, innovation, productivity, and people.

Technical Operations and Automation Strategies

Mr. Buendia explained that the automation strategy directly serves the strategy of technical operations: making quality medicine, on time, every time.

The three parts of Novartis Pharma's automation strategy build on one another:
1. Provide the right information for the right user at the right time.
2. Provide data analysis and process control.
3. Provide product and process analysis for product optimization

The first requirement to accomplish this, according to Buendia, is to provide the right information for the right user at the right time. With this information, the process can be analyzed and controlled to achieve business goals for quality and productivity. An integrated environment enables further goals, such as flexibility. This involves several areas:

- To achieve quality goals, the user needs to know if the process is well controlled, the sources of variability, and how he or she can improve both.

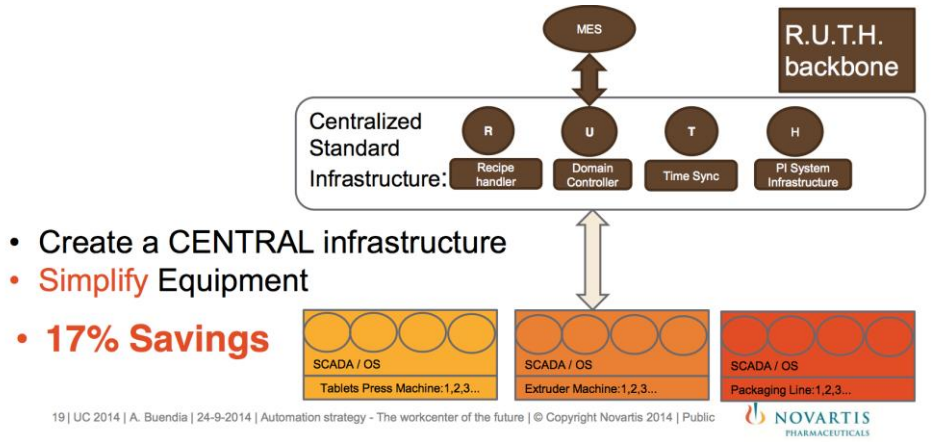
- Analyzing and controlling productivity requires knowing the overall equipment efficiency (OEE) and yield, the reasons for machine stops, and visual dashboards to be able to act upon prioritized issues.

- In an integrated infrastructure, data flows from the ERP to the shop floor and vice versa, enabling a number of applications related to production and quality control. In Novartis, these include data historian, Continued Process Verification (CPV), MES, alarms, environmental monitoring, maintenance and calibration.

- Flexibility for Novartis' production implies the capability to transfer products (and production) across sites, create visibility on this complex supply chain, and provide information transfer from R&D to production and from production to commercial activities.

Simplification and Cost Reduction by Rigorous Standardization

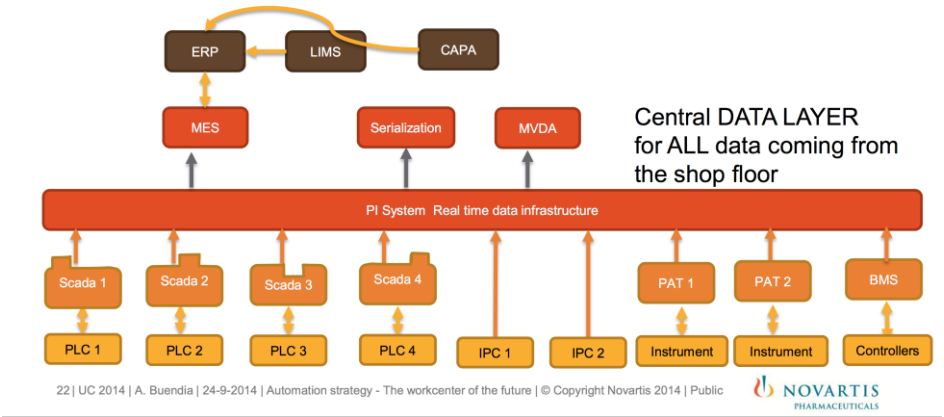
Novartis has established an equipment standardization program to reduce procurement costs and both engineering and qualification effort. The company realized that identical machines can be set up and automated in various ways and that operation and maintenance procedures can differ, just as KPI definitions and their visualization can differ. As a result, the current standardization approach includes all those elements, with the goal to "Design one and build many."



Novartis' Standard, Centralized RUTH Backbone

Other elements of "Novartization" relate to choices about recipe management, user management, time synchronization, and historization that Buendia refers to using the acronym RUTH (see diagram). Engineering and implementing RUTH and connecting it to the SCADA of each machine used to cost the company at least US $50,000. Now the company implements a centralized standard infrastructure (the RUTH backbone). This includes the PI System to fulfill the historian function. This simplifies the equipment and significantly reduces engineering and implementation time and effort. It also reduces equipment purchasing costs by 17 percent, according to Buendia.

Finally, connecting level 3 applications, such as the historian, MES, serialization and multivariate data analysis (MVDA), tends to create a multitude of interfaces with different SCADA systems, machine HMIs, or Process Analytical Technology (PAT)-type systems. Here, Buendia and his team use the PI System as a "data gateway," similar to connecting ERP and MES applications to a bus, with a single connector for each application type. Each level 3 application type has a single interface with the PI System that provides the data required for its functions. This interface can be instantiated as many times as needed to connect the same type of application to the PI System. Machines are connected uniformly via the RUTH backbone to the PI System, not only to read information but also to write non-real-time control information, such as parameters for machine initialization.



Simplified Interfacing between Layers 2 and 3 Using Centralized "Data Gateway"

These three aspects provide cost and time benefits and provide the full organization and all applications with data needed for analysis and process control. At the conference, the term "operational intelligence" was regularly used to describe this type of application that provides real-time visibility and analytics into operations information for manufacturing management. At a different level, this corresponds to what business intelligence provides for business management. Standardized equipment and operating procedures enable the flexibility needed for product transfers. As data structures and transfers are harmonized, this also enables technology transfer from R&D to manufacturing, and reporting about products for commercial purposes in a standard way.

The Workcenter of the Future

Buendia builds on this standardization by further using information for process control and product optimization to create the next level of cost, quality, product and manufacturing performance improvement. The No-

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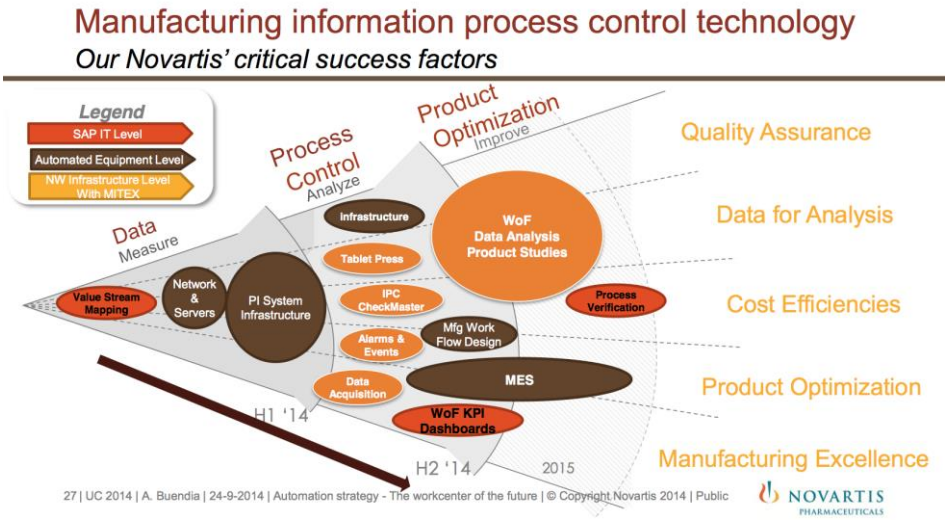
The Novartis "Workcenter of the Future" concept includes three goals: "lights out manufacturing," "paperless manufacturing," and "cockpits" for operators and process experts.

"Lights out manufacturing" is meant to create a manufacturing environment in which operators and experts have maximum information about the process, enabling them to make improvements. The process must be highly automated and require very little manual intervention, minimizing mistakes and contamination. The KPI for this objective is if operators can control and improve the process from the control room, enabling the lights to be switched off in the production area.

"Paperless manufacturing" means all information is automatically provided to the user when he or she needs it. Batch records are captured, stored, analyzed, visualized, reviewed, approved, and distributed in electronic form. Buendia mentioned that he is after intelligent and accurate data records, which excludes manual entries based on paper records or scanned information on paper.



Visual Roadmap for Manufacturing Information and Process Control

The "manufacturing cockpit" refers to an electronic dashboard, with allocated areas for quality, process productivity, environmental footprint, and alarms. This "cockpit" provides operators with access to all information and controls, enabling them to operate the machine and control the key setpoints.

According to Buendia, "It is great to monitor production performance from the headquarters, but the real point is to empower the operator to use data transformed into knowledge to improve performance and reduce issues

and deviations." Therefore, the Workcenter of the Future has a strong operational focus. The company has included the operators at every step along the program, using their input about which information to show, when to show it, and where to show it on their screens. The contextualized data enables operators to take appropriate action.

Buendia's experience is that presentations are not an effective way to gain buy-in from operators. Instead, he uses pilot projects to demonstrate the potential and the implications of his strategy. Today, he is convinced that the human aspects, the users' capability to digest the changes in thinking and acting, is the limiting factor; not the technical or implementation aspects. Nevertheless, the time scale of the pilot program for the first Workcenter of the Future looks ambitious given the objectives (see figure).

Novartis' roadmap contains further plans for MES, Data Analytics, and Process Studies within the Workcenter of the Future, as well as process verification. ARC will follow these implementations closely.

Recommendations

ARC believes that Novartis has raised the bar in setting and executing an automation strategy for industrial data. Each step delivers value, serves as foundation for the next step, and supports the global goals of operations. The rigorous and in-depth standardization also sets a good example. Furthermore, the use of a historian as a "data gateway" to simplify interfacing with level 2 and level 3 appears to be original, simple, and effective.

Novartis' approach has created significant cost savings related to equipment standardization. It seems likely that other important benefits will be associated with the approach to interface level 3 to the data gateway. ARC anticipates that the Workcenter of the Future approach will likely create quality and productivity gains.

ARC Advisory Group believes the program provides an excellent example for other manufacturers of performance materials, many who share similar goals for improving quality, consistency, and productivity across manufacturing sites, while reducing industrial automation and IT costs.

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