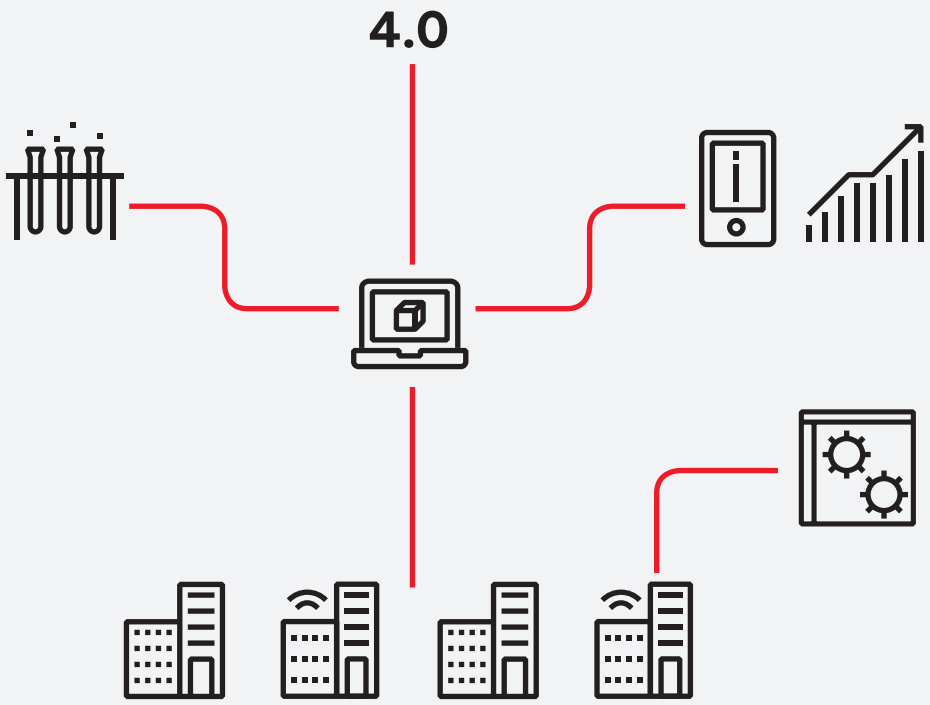
WHITE PAPER

Digital collaboration in the pharmaceutical and biotech industries



Message-based communication simplifies data integration between shop floor and production management systems

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About this white paper

For a pharmaceutical plant to operate in the digital world, integration of the distributed control system (DCS) and the manufacturing execution system (MES) is essential.

Critical to this integration is the replacement of traditional tag-oriented peer-to-peer communication with a new message-based communication format that simplifies validation and engineering effort.

The message-based method is applied to installed equipment by modelling the application. The model enables the smart equipment integration and message-based communication to be simulated and tested before being implemented.

This white paper describes how the integration of the MES and DCS, together with the message-based communication, is set to meet the challenges faced by the pharmaceutical sector. It shows how the newly created solution saves up to 75 percent engineering effort while increasing data integrity and productivity.

Footnote: In 2015, ABB – the market leader in DCS – started a cooperation with Werum IT Solutions – the market leader for MES for life sciences. The collaboration aims to create an integrated automation solution for the pharmaceutical and biotechnology industries.

Werum's PAS-X MES and ABB AbilityTM System 800xA Batch Management form an integrated solution which is mainly targeted at – but not limited to – API production and biotechnology upstream and downstream processes in a GMP (good manufacturing practice) production environment.

Together, the companies developed a lightweight message-based communication, which eliminates the challenges faced when integrating an MES with the process/ distributed control system (DCS). The solution is called Shop Floor Integration for Life Sciences by ABB, or Message Based Shop Floor Integration by Werum.

Shop Floor Integration 1.0 specifically refers to ABB's DCS and is targeted towards bulk or primary production. The next step towards integration – Shop Floor Integration 2.0 – targets secondary production where a MES is currently installed. It can be applied to any third party automated equipment. It can translate any signal based automation into message-based and vice versa, providing the ideal way to digitalize installed equipment.

Challenges facing the pharmaceutical and biotech industries

Today's life science companies need to be more agile and scalable than ever. Companies need to manufacture greater product varieties, with shorter production runs, partly driven by the demand for personalized medicines. The end-products need to be brought to the market quicker. The challenge is to create efficient workflows that fulfill FDA 21 CFR part 11 by following GAMP5 guidelines outlined by the International Society for Pharmaceutical Engineering (ISPE). These guidelines are for engineering and validation to ensure data integrity and conformal production.

Many pharmaceutical companies are challenged by the need for digitalization in a validated production environment. Even more so, the installed equipment may not be ready to deal with the modern digital world and will need to be upgraded accordingly.

While vertical integration of the different levels is key in a modern production environment, it is even more critical in the pharmaceutical industry. Here data integrity is an imperative for product quality and mandatory to assure compliance with regulation bodies like FDA and EMA.

While integrating Level 3 to Level 4 (ERP) (see page 6 for an explanation about the different Levels) is quite common and well standardized, it is less so between Levels 0-2 and 3.

Achieving integration based on the standard OPC DA – i.e. "soft wiring" – requires much engineering and validation. Moreover, should a recipe change, it impacts the master batch record (MBR) for the MES and/or the batch management in the DCS. Thus, integration cannot always deliver the highest productivity or quickest time to market as the engineering effort needed to keep the MES and DCS batch level updated remains high.

Pharmaceutical companies need to rise to the challenges of today's validated production environment. They need to recognize that Industry 4.0 and the benefits that digitalization brings to all devices, machines and systems throughout a facility is the key to unlocking the future.

Realistically this can only be achieved by integrating automation and the quality management system/ electronic batch recording. The uncompromised data integrity comes with improved operational expenditures (OPEX) and easier implementation of efficient CAPA management through much higher transparency of the production process.

Principles of plug and produce integration

What is plug & produce?
Incorporating new machinery into the production network used to be highly complex, time consuming and unproductive with endless I/O lists, configurations and qualifications necessary for pharmaceutical compliance. Today everything is simpler with the introduction of the plug & produce concept.

The term plug & produce is used to describe the next level of connecting software and hardware throughout a pharma facility. In the context of the pharmaceutical industry, the International Society for Pharmaceutical Engineering (ISPE) is encouraging this term to describe and achieve a standardization in the production environment.

The aim is to provide a fast and easy integration of machines and automation systems into a pharmaceutical production environment. This is a prerequisite for those companies striving towards implementing Industry 4.0 solutions.

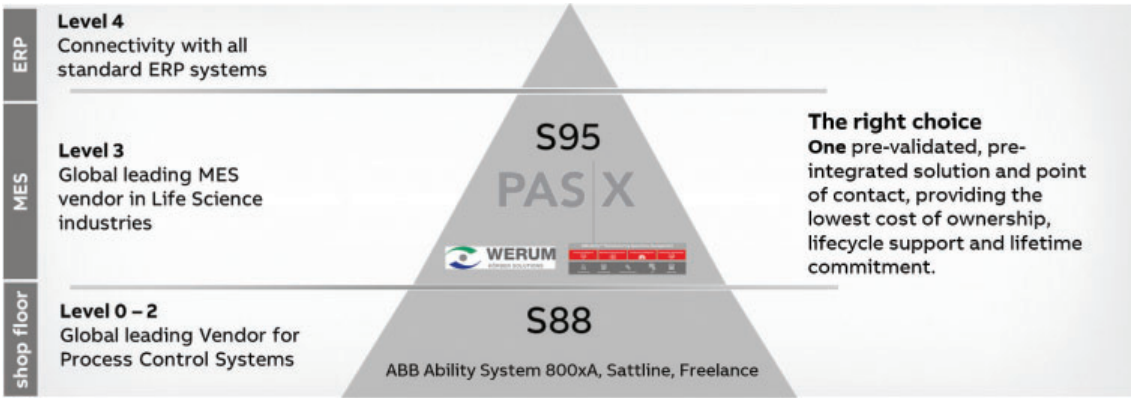
What is the role of ISA95/S88?
At the heart of the plug & produce concept is the ISA95 model. The model consists of the three levels, shown in Figure 1.

Level 0-2 (shop floor) is where the distributed control system (DCS) is positioned and is often isolated within the operational technology (OT) department. Level 3, meanwhile, is the layer for the manufacturing execution system (MES) and is often isolated within the information technology (IT) department. Level 4 provides the connectivity to enterprise resource planning (ERP) functionality.

A digital factory of the future, will see a convergence of the IT and OT systems and departments. As such, there is much discussion on how best to ensure this integration is seamless.

The aim of plug & produce is to simplify how different parts and levels of a production communicate with each other within the ISA95/S88 layer. This is achieved by providing cost effective, standardized, cyber secure and robust solutions throughout the complete life cycle of a facility's operations.

The key is for all levels to communicate digitally. In a good manufacturing practice (GMP) environment this is even an imperative, as data integrity is key for quality production.



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01 Automation is subdivided into five levels (ISA95) aimed at different areas of the company

What are the benefits of plug and produce integration?

By integrating the MES (Level 3) and the DCS-batch (Level 0-2), engineers, shop floor workers and plant management gain from increased flexibility and higher productivity. The integrated solution achieves:

- Standardized and transparent process flow from ERP production order to batch control recipes
- Simplified communication structures between automation and quality management system
- Significantly reduced engineering effort creating recipes and master batch records (MBRs) with up-load, download and synch functionality between DCS and MES
- Higher flexibility to apply changes to the process
- Ability to connect any equipment to the message bus even based on classic OPC
- Combined/integrated concept for data handling (master data, users, data collection)

For pharmaceutical companies this translates to:

- Significantly reducing the time to market for setting up new production plants and processes
- Improved agility and speed for new product introduction
- Significantly reducing the operation cost by avoiding manual interactions and by automating operations
- Considerably reducing efforts and cost involved in regulatory compliance and validation
- Using a modern message-based architecture that is designed to be highly secure and reliable

Principles of integration

The principle behind plug & produce is to successfully connect the MES system to shop floor systems such as batch, DCS and SCADA in a common way. Analogous to a printer integration, connecting the MES to DCS should be as easy as plugging in a USB into the computer whereby the driver installs automatically. While this scenario may be some way off, the effort of integration shall be system agnostic and based on cyber secure communication methods.

Integration in the past
Previously, integration used OPC DA for tag-based communications, relaying data back and forth between the shop floor and the MES (see Figure 2).

Engineering of tag-based communications involves defining all the OPC tags at both the Level 0-2 (DCS) and Level 3 (MES). Then all the interface handshakes must be defined in the MES, along with the state and logic.

Similarly, with the DCS, all the handshakes, towards the MES, along with the state and logic need to be defined. And finally, the steps required for the interaction need to be defined, both in the MES/MBR (master batch record) and within the batch recipe in the DCS.

The challenge with tag-based communication is that it entails much engineering work, which can be difficult to build and validate. Moreover, any time a change of the recipe is requested, it must then go through the similar definition and adaptation routines as described, impacting the MBR for the MES and/or the batch management in the DCS.

Integration using tag-based communication, therefore, does not deliver the highest possible productivity nor address the quick to market demands. It can also be cumbersome and time consuming and thus inflexible to easily cope with production changes.

Because of this, the pharmaceutical industry has been reluctant to prioritize MES and DCS integration, resulting in poor implementation across the industry. Those that have attempted the integration have documented it using SOPs on paper i.e. via manual operations, double signature, etc. For most cases the state of the art is “paper on glass”, which just replaces paper, but does not eliminate the risk of human errors.

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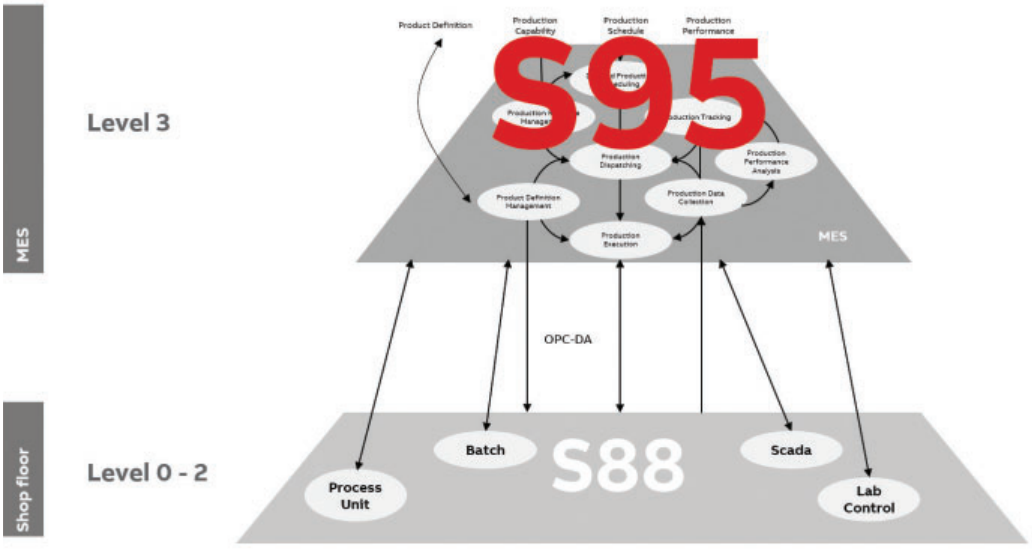
02 Point to point communication via OPC DA or proprietary communication



A typical OPC tag interface includes the following steps:

- OPC tags
- MES interface handshake
- MES interface state and logic
- DCS/ Batch interface handshake
- DCS/ Batch interface state and logic
- MES/ MBR interaction steps
- DCS/ Batch interaction steps

Integration in the future

The newly introduced integration concept is a plug & produce message-based communication between the shop floor and MES systems, see Figure 3. This is a qualified method of interchanging data between the different system levels. This concept is being driven towards a standard by the ISPE in a special interest group (SIG): a forum in which ABB and Werum are actively planning to establish a message-based interface as an open industry standard.

An implementation towards this concept is available today from ABB and Werum.

With the message-based communication interface, the synchronization messages are firstly defined and then the interaction steps are further detailed inside the MES/MBR and in the DCS batch system.

From an engineering standpoint it is much easier to validate, with up to 75 percent engineering savings on the MES side, while savings on the DCS-side depends on the complexity of the process and the interactions between the systems. However, much time can be saved as it is easier to integrate the messaging. Engineering of MBR and recipes can run much more independent with a qualified method of ex-changing data and synchronizing recipe execution and electronic batch recording (EBR).

Typical message-based interface includes the one time effort of:

- Defining the messages
- Defining MES/ MBR interaction steps
- Defining DCS/ Batch interaction steps

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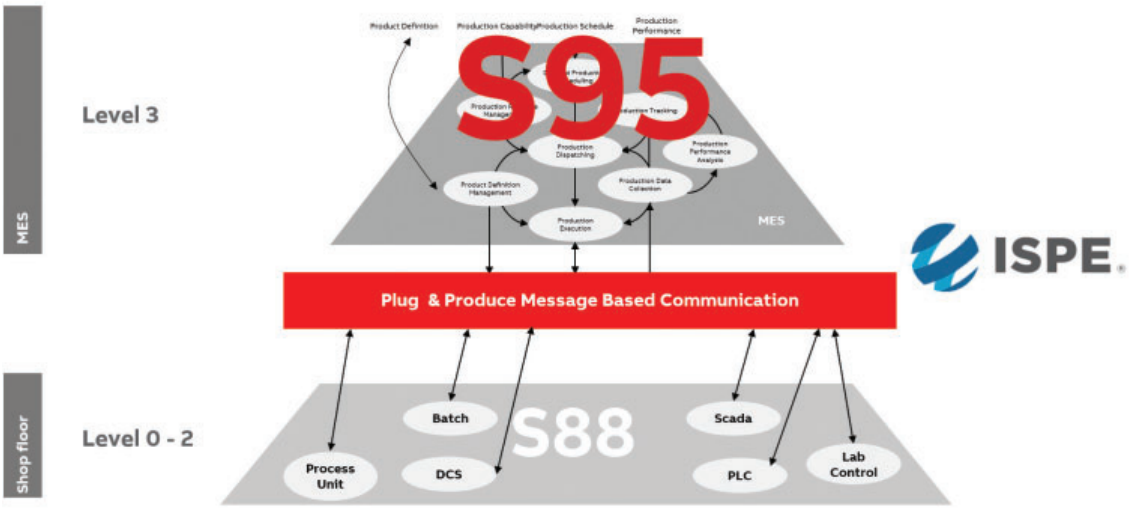
03 Messages replace tag-based communication



Message driven systems and equipment integration

Figure 4 shows the physical structure for the message driven system.

At the top is the enterprise resource planning (ERP) level. This level communicates to the MES which then uses the plug & produce message-based communication to talk to the interface.

The interface shown here is the ABB Ability™ Manufacturing Operations Management (MOM), also referred to as Shop Floor Integration. The MOM acts like a gearbox between System 800xA Batch Management and devices (shown bottom right) and the gearbox between installed machines (shown bottom left).

The MOM interface can then communicate with the batch system (shown bottom right) or it will interface with machinery (shown bottom left) if it does not have the plug & produce message-based communication installed.

Very few machines today have the message-based interface. Manual machinery (shown far left) are not connected to anything. They are controlled manually or through standard operating procedures (SOPs) from the MES system.

Advantages of the message-based approach includes the ability to buffer, route or transform messages when relaying from sender to receiver. Most importantly, however, is its robustness for changes in the connected components, mergers of systems or additions of services. Most implementations also add administrative capabilities as monitoring or tuning performance.

In the pharmaceutical factory, using messages opens the ability to establish a qualified integration rather than having to validate each individual connection as is required in a tag-based connection.

Message flow

Looking at how messages flow back and forth, the important aspect with two systems, such as EBR on the MES side and batch execution on the DCS side, is to ensure that they are in synchronization. The illustration shows the recipe and batch. The EBR will kick off the batch and the batch will synchronize to the EBR using synchronization data exchange through the execution of the batch. At the same time, it will execute the EBR/ MBR with the manual steps needed.

Figure 5 shows a simplified swim lane diagram with few interactions. In reality there could be easily a multitude of exchanges required during one production, which can now be handled through simple and pre-designed operations in the recipe and the corresponding parts in the master batch record (MBR).

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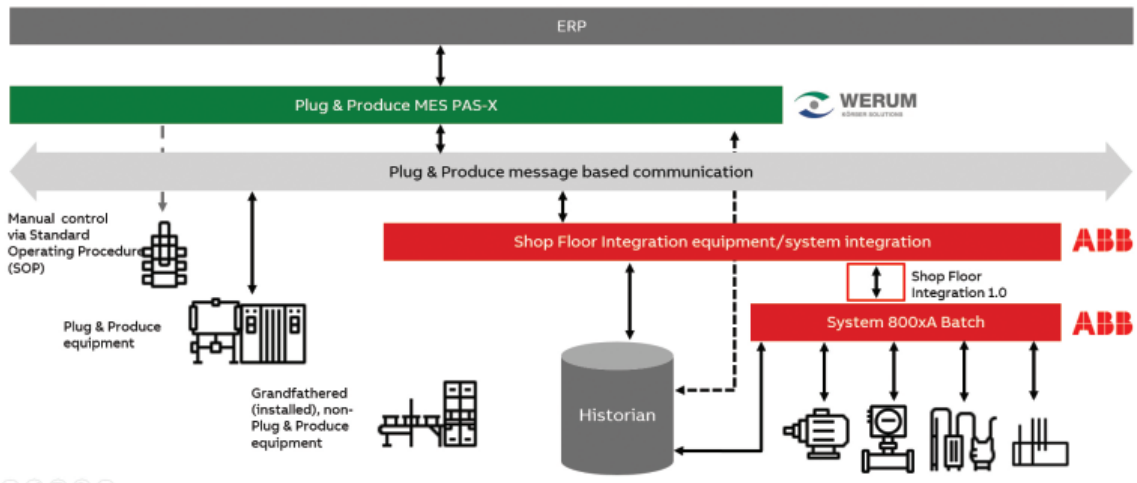
04 Physical architecture of a message-based communication



Data exchange is like sending letters to the different systems – lightweight but very reliable. Figure 5 shows the three different types of messages and symbolizes the validated transportation via message-based communication (the envelopes).

1. Start recipe execution and passing parameters to the DCS
2. Document the execution of the recipe
3. Synchronize the execution of batch production with the EBR.

Benefit of the standardization

The most evident benefit is having a qualified solution, which is change resilient and system agnostic. MBR and recipe design can happen independently and do not need to be done sequentially, where one is waiting for the other. Swim lanes are the master for the process design and both of the systems (DCS or MES) are taken off the critical path, which shortens the time critical PQ phase.

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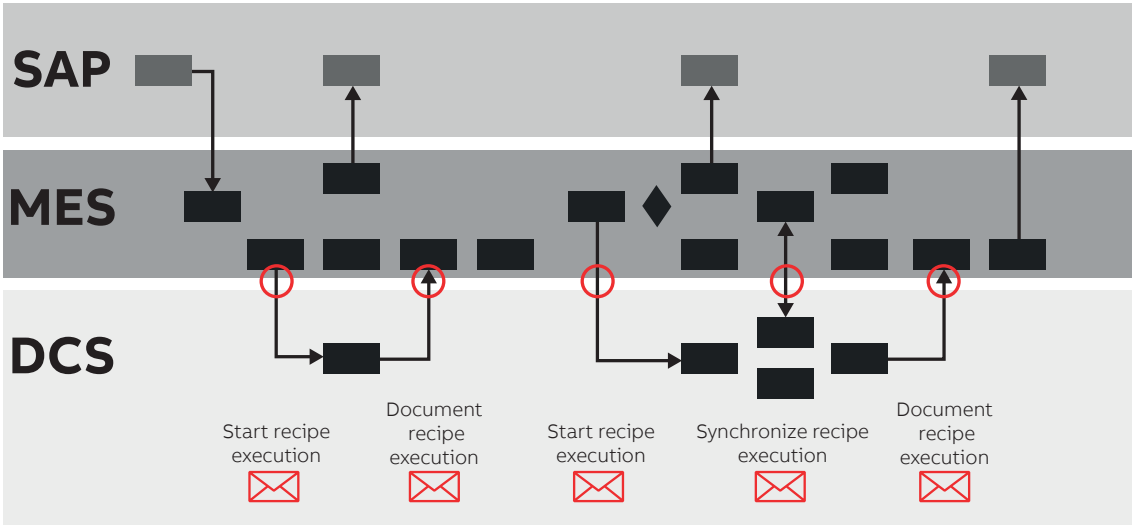
05 The figure shows a simplified swim lane of a simple production scenario. During a real production, each recipe can easily have 20 to 100 interactions between the different systems



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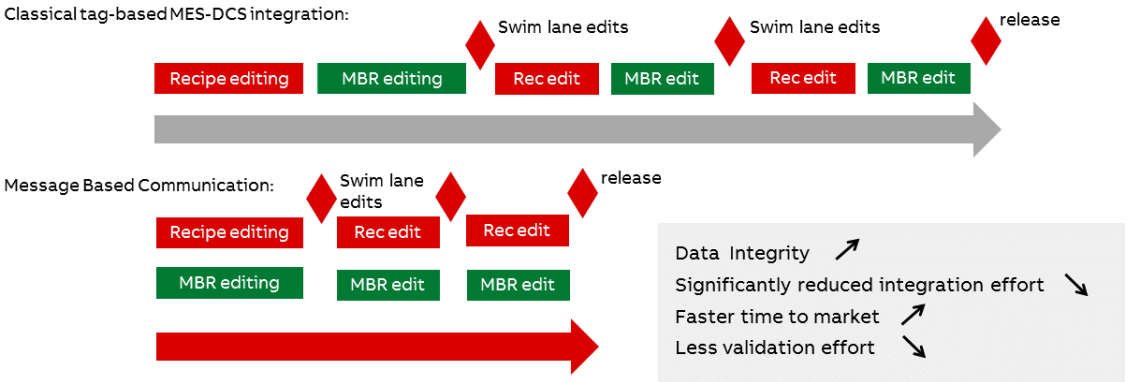
06 Benefits of the message based MES-DCS integration



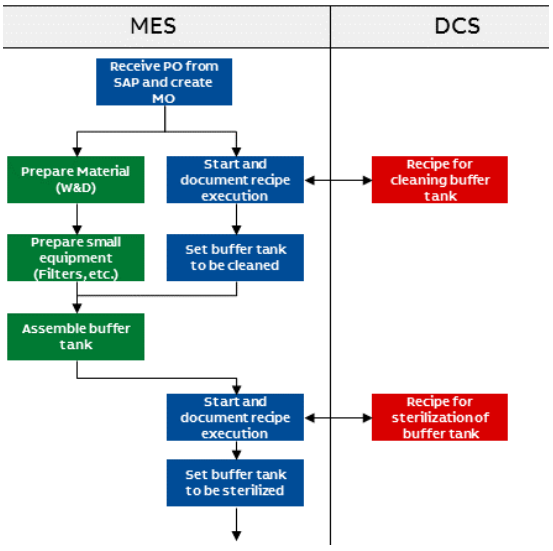
EBR and batch execution – operation philosophy

— 07 MES taking the lead, manual heavy production
— 08 DCS taking the lead, MES for EBR

When you have two individual systems, but connected tightly, then you will have some operations on the MES side and some operations on the DCS side – so you have to decide if your MES will be the main integration point where you do all the operation, or should it be the DCS, or should it be a mixture between the two.

Consider the first example, that is MES driven, see Figure 6. A typical scenario may feature a lot of manual interaction with many manual steps. Most operations on the shop floor will be done in the MES system. Then you might have some automated process such as cleaning-in-process (CIP) so you might not have any user interaction. Here the DCS system is seen as blocks that the MES system kicks off and supervises automatically but there is no user interaction. This is a typical operation philosophy with many manual operations.

Alternatively, you might have a few manual operations but many automated operations. In this case the MES is receiving information from the ERP system and will kick off the batch. The DCS takes over the control and determines how the MES is executed.



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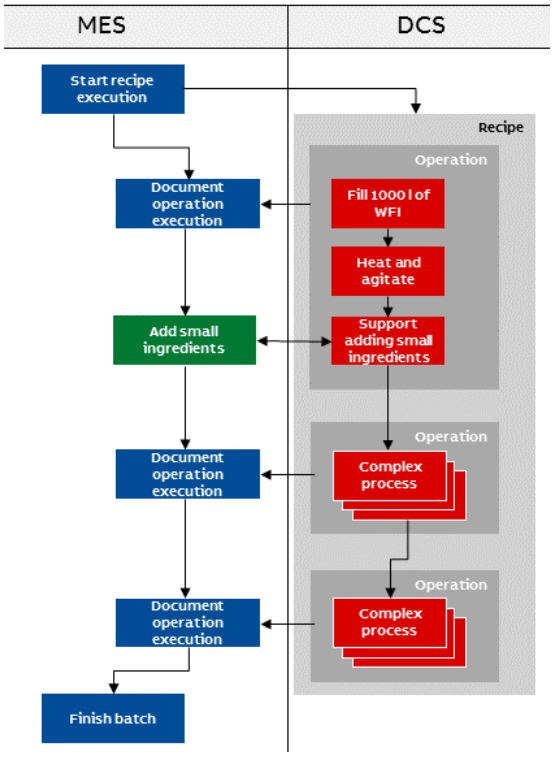
In this case, production is simply started and the DCS takes over the responsibility of pushing through the production.

Most likely there will be a mix of these two, such that part of the production will be driven from the MES, and then it will hand over the execution to the DCS or vice versa.

Both systems can appear on the operator's screens. So, System 800xA alarming will still be on the top even while operating the MES. The MES operator screens can be accessed by right-clicking the related process graphics element which then appear in a managed window within the DCS console.

Different operating philosophies depend on the preference from the customer and the number of manual and automatic work.



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Plug and produce implementation
Shop Floor Integration for Life Sciences

How plug and produce is implemented
Figure 9 shows the view from both the client and server side. On the server side is the ABB Ability™ Manufacturing Operations Management (MOM) which is the back bone for the secure data server. This server enables secure communication towards the client side with access to a variety of functions, shown below in red. From a configuration point of view, a new panel or App is added to the client side to configure the interface.

In Figure 10, the MOM server integrates towards the System 800xA Batch Management (shown left) and the smart equipment implementation (shown right).

To carry out messaging, back and forth, and in a secure way, OPC UA is used. The MOM server features both OPC UA server and client, and the client is used to send messages to the MES. The OPC server is used to receive messages from the MES.

This communication is secure using certification from Werum and ABB. It is an encrypted line so from a cyber security point of view it is a safe way of sending messages back and forth.

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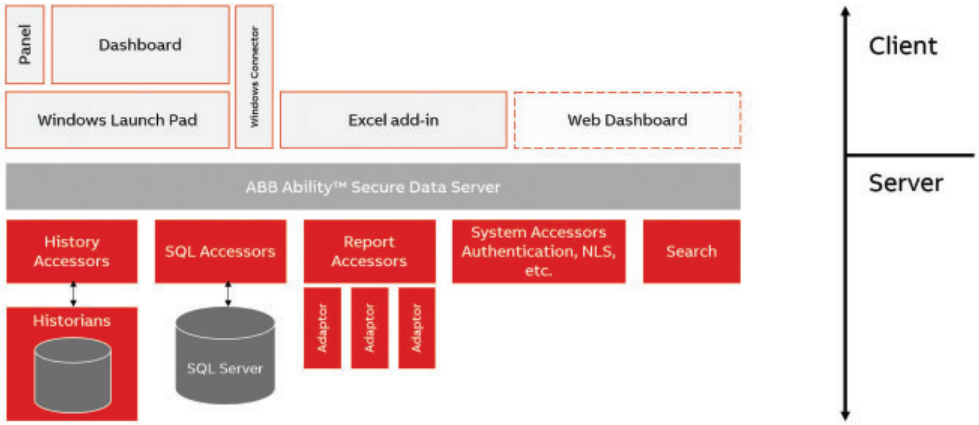
09 System architecture



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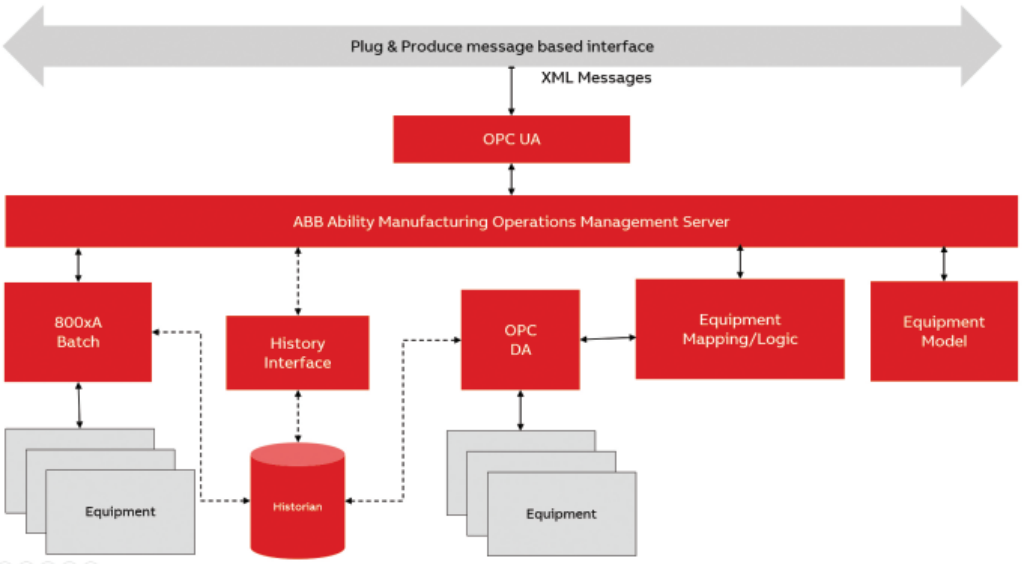
10 Shop Floor Integration



Plug and produce implementation
Shop Floor Integration for Life Sciences

How plug and produce works in practice
Connecting a new machine to the manufacturing IT system is possible because the machines on the shop floor and the MES software communicate directly via the new standardized message-based interface.

The MES automatically receives all relevant information and electronically executes and documents all production steps. The plug & produce standard interface ensures that the software and the machine speak the same language.

The plug & produce solution offers several advantages. The engineering and configuration workloads are significantly lower. Also, far less qualification efforts are needed to satisfy compliance requirements.

Installation is easy and therefore extremely reliable, greatly diminishing the likelihood of set up errors.

Finally, project run times are significantly reduced as the MBR design is simplified and can be conducted at an earlier stage.

Compared to tag-based communication, a company's workload for integrating a new machine into its production environment will be cut by some 75 percent.

Case study

Digital plant tackles changing customer demands while reinforces security of supply

Background
A new facility is the first site to use a message-based communications approach that connects a MES to a DCS.

Traditionally, the DCS is often isolated within the OT (operational technology) department. Meanwhile, the MES is often isolated within the IT (information technology) department.

A digital factory of the future sees a convergence of the IT and OT systems and departments, such that MES system is successfully connected to shop floor systems in a common way. In a GMP environment this is even an imperative, as data integrity is key for quality production.

Challenge
The facility wanted to avoid the need for the intensive engineering efforts previously required to integrate MES and automation systems. The facility wanted to move to an MES to meet customer expectations, dictated by industry standards, compliance and operational excellence. Furthermore, the company was seeking a tighter integration between the ERP and the DCS. It was not just a replacement for the paper to tablet solution - which carries no integration - instead it wanted a solution that would be fully integrated. Prior to the installation, the company did not have an MES. All MES functions were paper-based and all the control processes were carried out from the System 800xA, straight to the operator control stations.

Solution
The plant connects the Werum IT Solution's PAS-X MES to the ABB Ability™ System 800xA Batch Management. Together with ABB's expertise in batch production, ABB and Werum are the only companies capable of offering such a solution. Collectively, the entire solution is called "Shop Floor Integration for Life Sciences".

The Shop Floor Integration for Life Sciences solution sends and receives messages from the MES, straight down to the DCS batch system, see Figure 11. It shows the configuration featuring one PAS-X MES linked to one ABB Ability MOM server and up to five interfaces towards the System 800xA Batch Management. This provides a regular synchronization between the two systems. Such synchronization is critical as some of the batches run for between one to two weeks. It will transfer data from System 800xA to PAS-X MES such as quality data, setpoint, consumption or whatever is needed to report back into the production report.

System 800xA Batch Management is one of the most important applications for the biomedical industry, enabling the electronic recording of the entire production chain, from raw materials to packaging, ensuring that that client meets stringent requirements for traceability.

Case study - continued

Benefits
The Shop Floor Integration for Life Sciences solution prevents production bottlenecks and reduces cycle times so as to lower inventories, free up capacity and increase efficiency.

By fully integrating the MES and the DCS, engineers, shop floor workers and plant management gain from increased flexibility and higher productivity. The integrated solution achieves:

- Standardized and transparent process flow from ERP production order to batch control recipes
- Simplified communication structures between automation and quality management system
- Significantly reduced engineering effort creating recipes and master batch records (MBRs) with upload and synch functionality between DCS and MES
- Higher flexibility to apply changes to the process
- Ability to connect any equipment to the message bus even based on classic OPC
- Combined/integrated concept for data handling (master data, users, data collection)

For the facility this translates to:

- Significantly reducing the time to market for setting up the new agarose plant
- Improved agility and speed for new product introduction
- Lowering the operation cost by avoiding manual interactions and by automating operations
- Considerable reduction in efforts and cost involved in regulatory compliance and validation
- Using a modern message-based architecture that is designed to be highly secure and reliable

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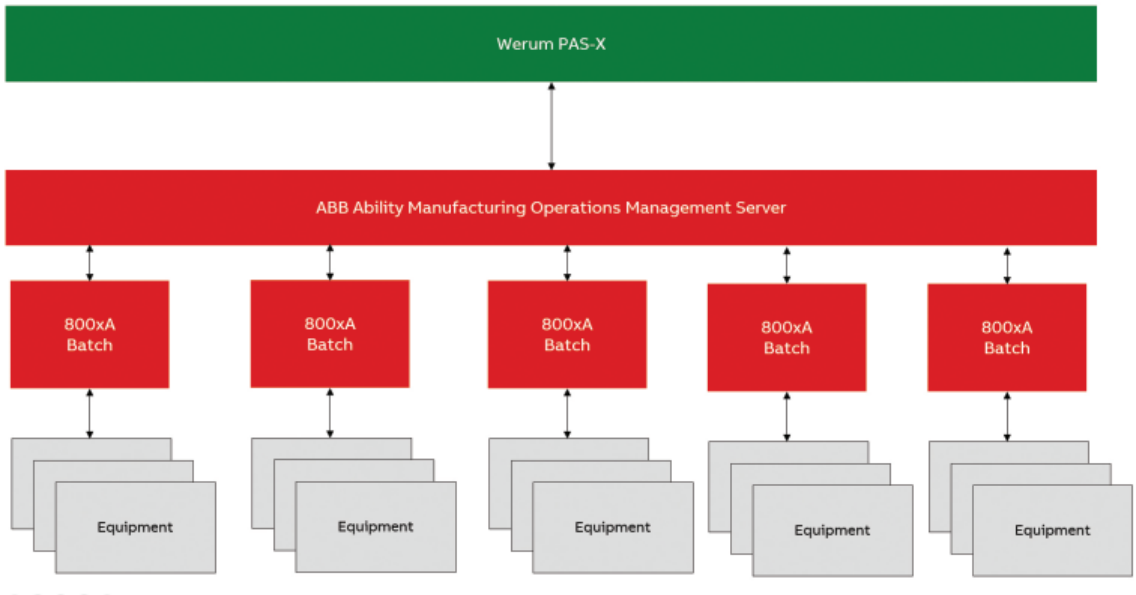
11 Set up at pilot plant



Smart equipment integration

ABB is now working towards expanding the functionality beyond communicating towards System 800xA Batch Management and opening communication with installed equipment which, at present, does not have the capabilities of using the benefit of the plug & produce message-based communication. Today that covers virtually every single piece of equipment, as very few have the message interface.

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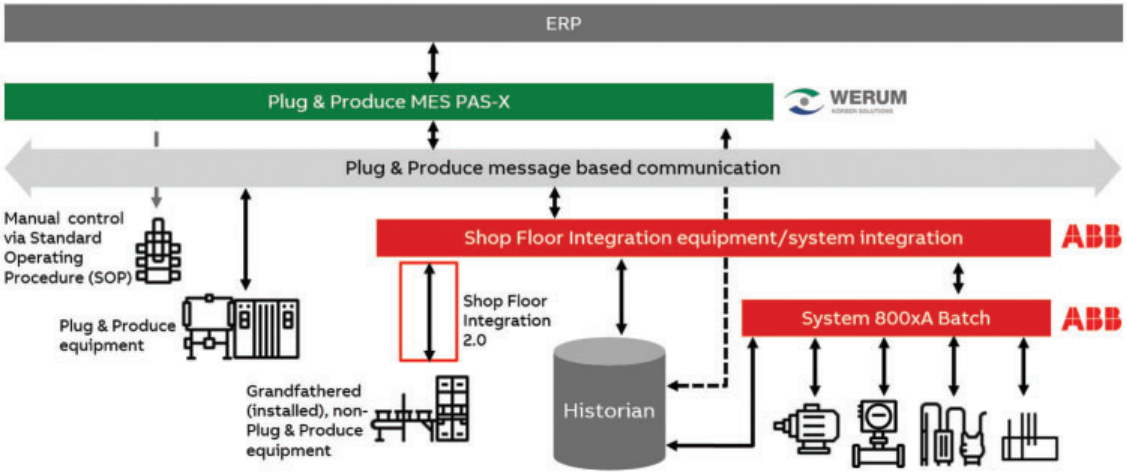
12 Smart Equipment Integration



Message-driven equipment interface

To achieve this goal, ABB is creating a digital twin: a model that fits the machinery equipment. There are several inputs from the machinery and some outputs to control the machinery. There will also be messages coming in and out, such as start and stop machine or setpoints to control the equipment in different ways.

Within the model will be all the mapping of the messages together with all the logic needed to control the equipment.

From the PAS-X MES or the MBR/EBR perspective this approach makes a huge saving as you no longer need to deal with the mapping or state logic in the PAS-X system as the digital twin takes care of that.

Configuration flow
The start is in the Shop Floor Integration modeler, wherein the messages are defined such as what are the parameters, back and forth directions and logic. Once everything is tested, the modeler contains a debugging facility thereby providing an ability to test out the model in the tool itself, without involving PAS-X MES. The input and output can be simulated in the modeler directly too, further increasing the testing options.

When the model is ready it can be approved before then moving to the configuration. At this stage the model can no longer be changed. The model can be exported to another machine along with the interface description and these are imported straight into PAS-X MES.

With the model ready, the configurator is used to substantiate it. So, for example, if you have multiple packaging machines then you do a model that will fit the machinery and then in the configurator you will configure it within the physical world because it could be attached. You will import tag lists that you get from the SCADA system controlling the machinery and then you will have some automation outputs and inputs for the model itself. You then instantiate the object instance and the instantiated object instance is the one that takes care of the true digital twin to the physical equipment. The object instances communicate with PAS-X MES using messages back and forth.

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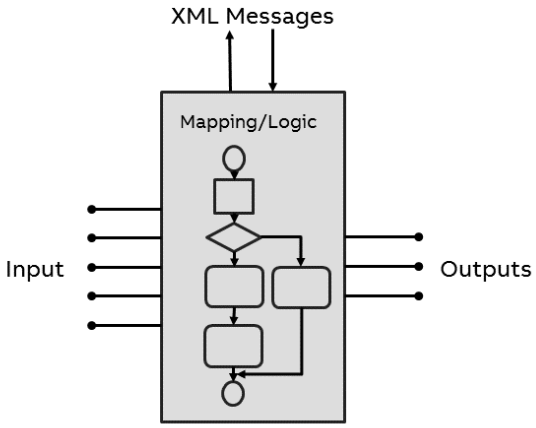
13 Model of the equipment to convert signals to messages



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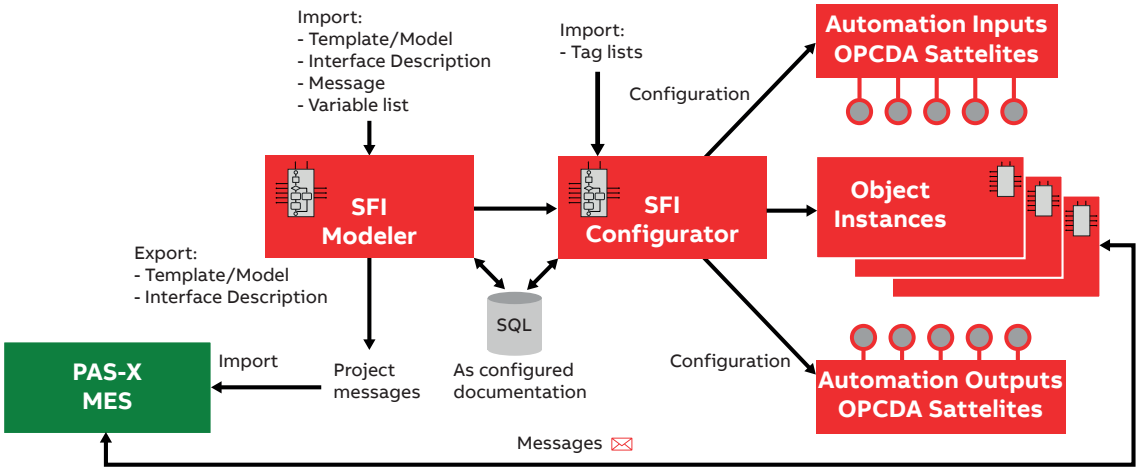
14 Process flow for smart equipment integration (SFI 2.0)



The future

What ABB has achieved so far is the integration of System 800xA Batch Management (Level 2) and MES/QA (Level 3) for API production and formulation.

Moreover, and even without introducing a DCS, the integration of equipment into the message concept is provided by the smart equipment integration.

Where ABB is heading is simplifying the engineering, increasing the usability and integrating the historian, providing the best user experience in an integrated environment for automation and MES.

Summary

Figure 15 shows how currently the quality of pharmaceutical processes is achieved. Many production facilities use paper validation, which requires a lot of paperwork and does not provide any digital transparency (e.g. for track & trace). Data is buried in reams of paper.

While paper on glass provides a digital storage, it still requires personnel to manually type in data, which was available in digital form before.

Tag-based communication takes the data without manual interaction, but is very hard to maintain. It also takes a lot of engineering to set it up and to keep up to date and validated when recipes change.

Message-based communication provides a validated method to relay the information and needs no adaption when recipes need to be altered or changed.

Plug & produce

- Simplified engineering (MBR engineering – recipe engineering) i.e. increasing usability
- Simplified shop floor operation with a joint user interface
- Additional benefits from MOM Apps/ Werum Apps
- Historian integration

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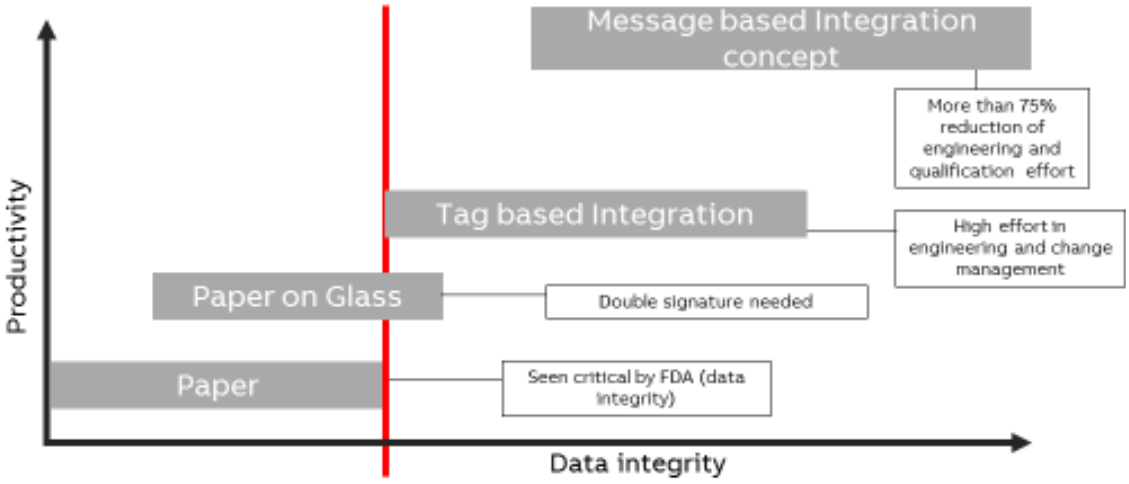
15 Message-based integration increases productivity



Appendices

About Werum IT Solutions
Werum IT Solutions is the world's leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions for the pharmaceutical and biopharmaceutical industries. Its PAS-X software is used by the majority of the world's top 30 pharmaceutical and biotech companies and also by many mid-sized manufacturers. Werum's manufacturing IT solutions help pharma companies to increase efficiency, improve productivity and meet regulatory requirements. Founded in 1969, Werum is headquartered in Lüneburg, Germany, and has many locations in Europe, America, and Asia. www.werum.com

Werum is part of Medipak Systems, the pharma systems business area of the international technology group Körber. The business area's companies, Dividella, Fargo Automation, Mediseal, Rondo, Seidenader Maschinenbau, Systec & Services and Werum IT Solutions, are global leading providers of high-quality solutions for the manufacturing and packaging process of pharmaceutical products. As a Medipak Systems company, Werum provides integrated IT solutions for all phases of pharmaceutical and biopharmaceutical production – including process development, commercial production, and packaging as well as track & trace serialization. Körber unites around 11,500 professionals in industry-leading companies worldwide, achieving annual earnings of 2.3 billion Euros. www.medipak-systems.com, www.koerber.de/en

About PAS-X MES
PAS-X is a complete MES solution comprising the PAS-X software, content and services.

PAS-X is a mature software product with full-scope functionality that is easy to operate. Its fast implementation is ensured by PAS-X Content Packages: pre-configured templates that – with the assistance of Werum consultants – facilitate the set-up of the PAS-X MES with unprecedented speed. Werum's broad range of services supports and guides pharma and biotech companies in all phases of the implementation process and during the entire lifecycle of their PAS-X MES solution.

PAS-X MES covers all key life cycle stages in pharmaceutical and biopharmaceutical manufacturing from process development to commercial manufacturing and packaging. It supports all major pharmaceutical industry segments, e.g. for vaccines, biopharmaceuticals, solids and liquids.

About ABB
ABB (ABBN: SIX Swiss Ex) is a pioneering technology leader in electrification products, robotics and motion, industrial automation and power grids, serving customers in utilities, industry and transport & infrastructure globally. Continuing a history of innovation spanning more than 130 years, ABB today is writing the future of industrial digitalization with two clear value propositions: bringing electricity from any power plant to any plug and automating industries from natural resources to finished products. As title partner of Formula E, the fully electric international FIA motorsport class, ABB is pushing the boundaries of e-mobility to contribute to a sustainable future. ABB operates in more than 100 countries with about 135,000 employees. www.abb.com

Appendices

About ABB Ability™ Manufacturing Operations Management
ABB Ability Manufacturing Operations Management (MOM) is a comprehensive, scalable and modular software suite maximizing visibility, knowledge and control throughout the complete manufacturing domain. It is the natural extension and complement to the real-time control system. By turning large amounts of industrial data into actionable information, the MOM software helps daily operations improve, by ensuring subsequent shifts run more efficiently than the last.

MOM directly supports stakeholders working in the plant and business side of a company, by collecting, storing, combining and translating industrial data from business, control and monitoring systems into meaningful, actionable information. Such users work with the overall plant operations in the areas of data analysis, reporting, production planning/execution, quality and asset management.
www.abb.com/mom

About ABB Ability™ System 800xA Batch Management
ABB Ability™ System 800xA Batch Management is a powerful application software package for configuring, scheduling, and managing batch operations improving batch production profitability, consistency and traceability. System 800xA Batch Management is aligned with industry standards such as ISA88, ISA95, IEC 61512, and IEC 62264. It is further enhanced by ABB's extensive batch automation expertise. For manu-facturing processes subject to licensing and inspections by regulatory bodies such as FDA, MHRA, TGA, System 800xA Batch Management provides the tools needed to achieve compliance.
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