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Fast track shop floor integration and central electronic Batch Reporting in a new pharmaceutical manufacturing facility

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Fast track shop floor integration and central Electronic Batch Reporting in a new pharmaceutical manufacturing facility

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This article describes the integration strategy for recording of all production-related data centralized and in a standardized electronic format for a newly-erected pharmaceutical production plant of Novartis. Although the project has been realized in the specific environment of pharmaceutical production, all its fundamental approaches are industry and application independent; they provide a generic approach to the problem of quick and standardized integration of package units in line or cell structures of discrete or batch production. The implemented concept is described based on a discussion of the options of possible integration scenarios and common industry standards, particularly underlining the high degree of standardization of data communication from the shop floor up to MES level. Basis for the integration was the manufacturer-independent OPC technology. A Historian has been used as central "Production Data Warehouse" for collection of all data. The article concludes with references to further exploitation of the gained experiences as well as their use in other application areas, such as by supporting the FDA Process Analytical Technology (PAT) initiative.

ERP / MES / SAP / PAT / OPC / Fast track integration

1. Introduction

Continuous, seamless horizontal and vertical information flow is one of the central requirements on modern production concepts. Production strategies such as Lean Production, Six Sigma, Performance Monitoring and Right-the-first-Time cannot be realized in a beneficial, practical way without IT-linked systems. What we realize today is that companies strive for this goal in very different ways.

As a rule, modern MES systems are used today as connectors between ERP level and shop floor. Integration of the MES system and lower-level machinery and equipment is a crucial cost factor of every MES project. At the same time, it is key with regard to future performance and flexibility of the complete system.

This article describes a concept for standardized communication on the shop floor by means of a fully integrated pharmaceutical production within the scope of a new investment. The concept is application and manufacturer independent and builds on the open OPC standard. With this strategy, it stands out from other concepts which are based on a manufacturer-specific, proprietary approach.

The production is a solids secondary production starting with the supply of API and raw materials up to finished tablets in bulk form. Under the aspect of a green-field project realization, the production buildings as well as the machinery have been structured according to the latest, state-of-the art manufacturing concepts.

The machinery consists of newly acquired machines with modern control systems. SAP R/3 is used as enterprise-wide ERP system. With regard to MES software, Novartis selected PAS X of Werum Software & Systems as a global MES standard.

2. Outset and discussion of options

With the entire plant to be newly designed, constraints for automation systems were limited. Based on the global IT strategy of NOVARTIS, ERP and MES vendors were predefined; final purchase of the machinery and choice of suppliers were still to be decided during the design phase.

As a first approach to tackle the generation of a concept for the shop floor and for connection to MES a fundamental design study was compiled. This pilot study first had the purpose to establish the basic requirements on communication, integration and reporting. At the same time, it provided a manufacturer-independent analysis of various possible solutions. Basic requirements from the point of shop floor communication are shown in Fig. 1.

Requirements shop floor communication

- MES connection with batch and recipe management
- Creation of an interface between shop floor and higher-level IT systems
- Handshake mechanisms for media requests from utility units

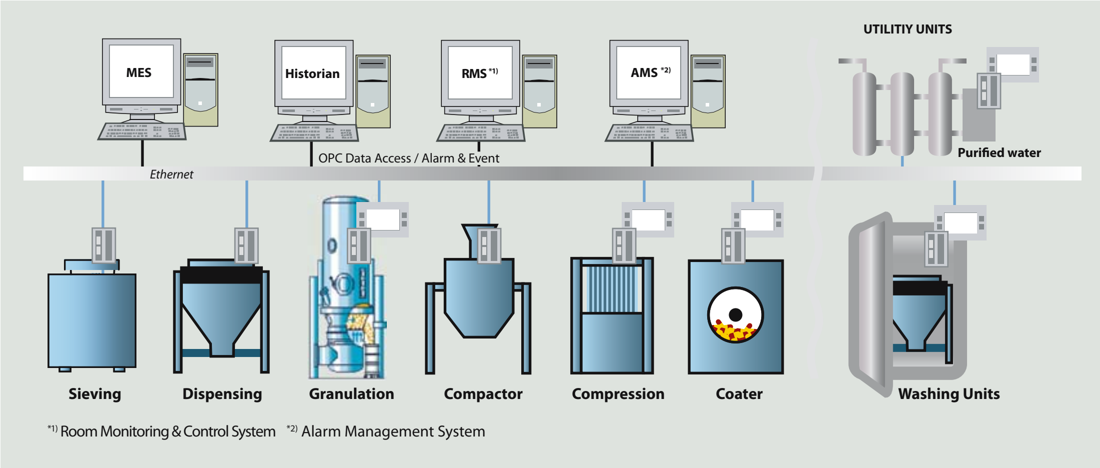

Fig. 1: Basic requirements from the point of shop floor communication.

- Safe and reliable data transfer from package units to Historian
- Connection to a central monitoring & alarming system
- Time synchronization of all communication services

Communication requirements mainly comprised highly technically dominated aspects. With regard to Electronic Batch Reporting, the requirements of the later users were predominant. Main requirements on Electronic Batch Reporting are shown in Fig. 2.

Requirements Electronic Batch Reporting

- Generation of the EBR as a deviation report in MES
- Detailed machinery reports through central report system (Historian)
- No data storage on the package units
- Data storage in the Historian up to fifteen years
- Central user model on the shop floor
- Central audit trail for the shop floor

On the basis of these requirements, the following concepts have been analyzed:

- Direct connection to the MES via PU/MES-specific interfaces
- Common intermediate layer consisting of an OverallConsolidated SCADA (OCS) by integrating all PUs into the same SCADA layer
- Use of open communication standards together with standardization of MES and PU interfaces

Direct connection of the PUs to MES generally implies high costs for adaptation of the various interfaces and implementation of data exchange. As a rule, interface implementations of this kind also preserve any PU specifics up into the MES. As individual solutions, only a minimum of functionalities determined by MES or PU data structure is implemented. This high variance of vendor-specific solutions requires high amounts of maintenance during plant operation, especially during system upgrades.

To limit the number of interfaces between MES and shop floor an alternative is to design an OCS as a common SCADA layer. This means that all PUs independent of the supplier's standard have to be integrated into the SCADA application. Benefits of this approach are a harmonized machine handling for all PUs, standardized data handling based on the used SCADA application, a common batch processing standard and a reduction of the software systems involved.

Disadvantages are mainly given for systems of a different vendor than the provider of the OCS. To integrate these systems, the often long-time proven SCADA solution of the supplier has to be removed and be replaced by the OCS. This results in high integration efforts for OCS integrator, supplier and operating company. An additional critical point is to define and agree on the boundary for warranty between OCS integrator and equipment supplier.

As a third solution, standardization of interfaces and data exchange as a generic approach has been examined. In this approach, the goal is not to harmonize machinery, manufac-

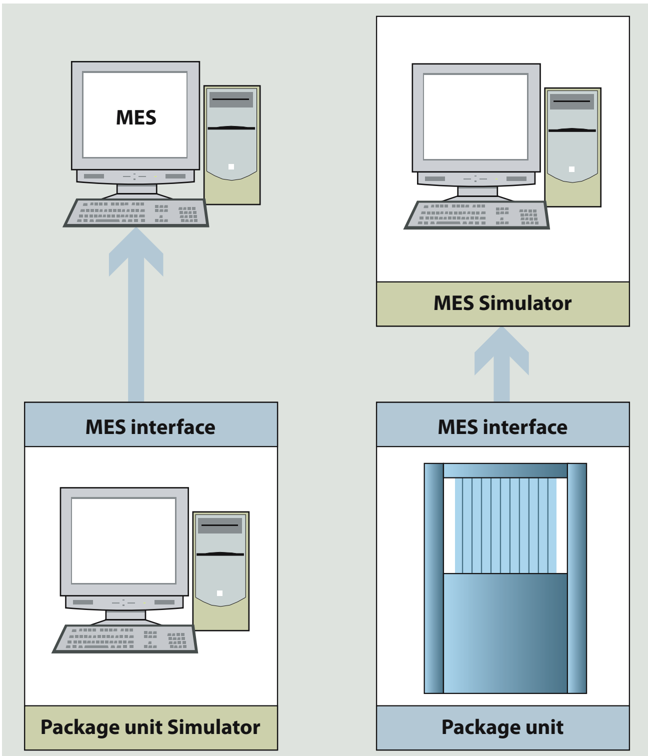

Fig. 2: Main requirements on Electronic Batch Reporting.

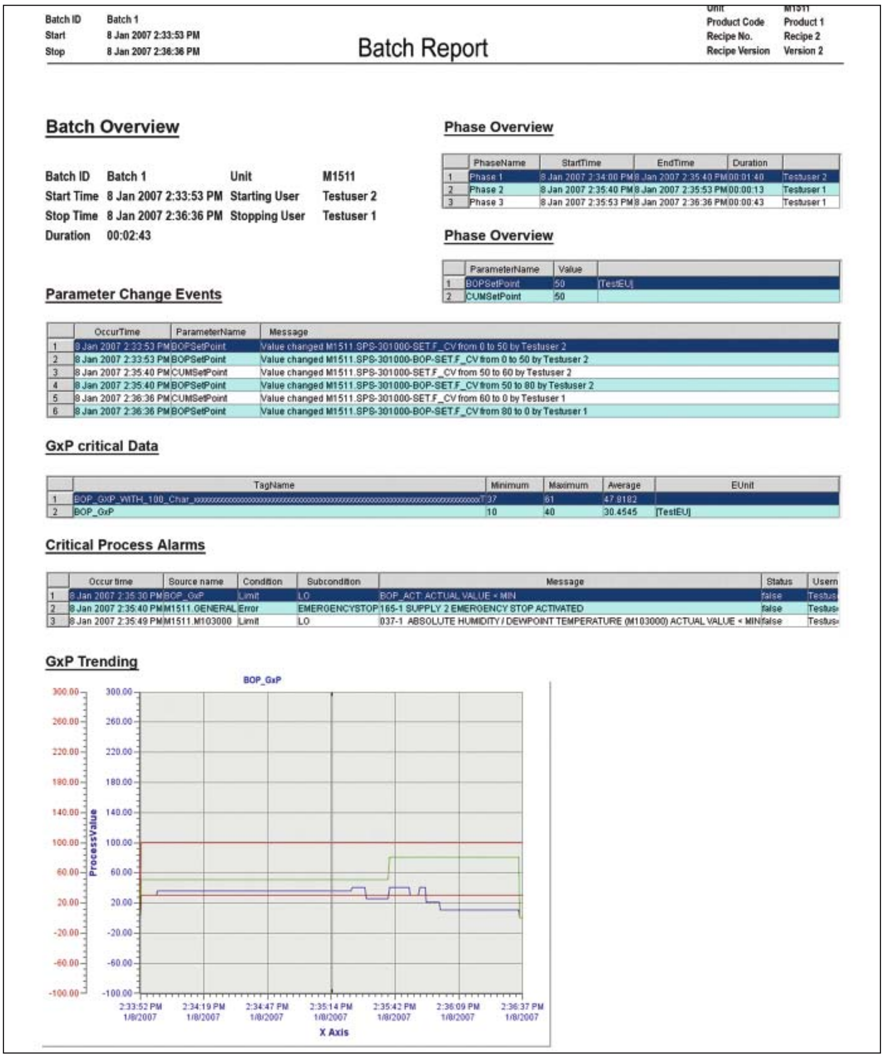

Fig. 3: Reference model by use cases.

turers or software products and control systems with each other, but to define a uniform, typified view on the data interfaces. As communication standard, OPC as a world-wide available and accepted industry standard meeting the needs of automation technology was chosen. Since the OPC Foundation has already defined all details required with regard to interface structure and actual communication, no further specification tasks were needed. As OPC is provided as an integrated functionality of all main SCADA applications as well as a stand alone tool by some manufacturers today, maximum freedom with regard to the selection of systems and manufacturers is ensured. OPC as de-facto industrial standard has proved its practical potential in a wide range of applications. This makes OPC a safe and proven solution, particularly when compared to project or manufacturer-specific alternatives. In the pharmaceutical environment, this in turn is a special benefit for reducing necessary validation efforts.

3. Solution concept and reference models

The solution concept is based on a few basic assumptions and principles which were the fundamental guidelines along the project. They include the following points:

- Completely manufacturer-independent concept design on the basis of use cases
- Use cases for batch control, reporting and machine synchronization
- Compliance with GMP requirements on electronic records, user management and audit trail (21 CFR Part 11)
- Historian as central data storage for all types of shop floor data
- No local data on the package units
- Mapping of communication and interface functions by means of OPC as mandatory interface

Based on the preliminary study, OPC was specifically required in the contract specifications during the purchase process. In parallel, all project members were informed and involved at a very early stage.

The basics of the technical concept were explained in workshops in order to raise awareness and ensure suppliers' acceptance and support for the strategy from the start. Encountering a highly different level of familiarity, the specialists actively supported the knowledge transfer to all parties. Overall, a very high level of acceptance for the approach was present in all project participants from the outset.

As OPC is a communication standard and does not standardize applications, the next step was to create reference models. These reference models use the OPC Data Access and Alarm & Event specification of the OPC Foundation.

Single reference models for the mapping of functions or data structures as well as for functional descriptions by metadata were created.

The Functions reference model supports the following use cases (Fig. 3):

- Remote batch control by evoking the respective recipe on the PU by MES
- Upload/download of recipe parameters between shop floor and MES
- Upload of process values by the MES
- Upload of all process trending data for reporting in the Historian
- Upload of all process alarm & events for reporting in the Historian
- Report of quality-relevant events by the MES
- Handshake functions for synchronization of the package units with the utility equipment (e.g. Purified Water (PUW))
- Handling of Wash-in-Place (WIP) requests of the package units
- Connectivity to a central monitoring & alarming system

The reference model for the data structures includes all elements necessary to map events, parameters, alarms, measurement values and account information such as:

- Order/batch information
- Order/batch events
- Recipe parameters
- Process alarms
- Modifications of recipe parameters by the operator
- Trending of measured values
- Account information (login, logout with name of operator)
- Machine identifier
- S88 defined machine states as basis for KPI calculations

Based on this reference model, all shop floor data is mapped to the data structure of OPC Data Access (DA) and Alarm & Event (A&E). Machine identifiers, for instance, are described by areas and sources. Event categories are defined and mapped onto the use cases. For handling of machine states, respective tags were defined. Without requiring any special knowledge, all this information is directly available for every user through the OPC browsing mechanism.

In total, all project requirements could be met successfully on the basis of OPC DA and A&E.

Underscoring the capacity and flexibility of the concept is the fact that within the scope of the project, integration comprised 25 PU manufacturers, grouped in ten PU classes with in turn up to ten different PLC/HMI or batch and recipe systems (Fig. 1).

The number of DA and A&E tags differs from around 200 (Compactor) to around 700 (Compression) for these systems, all using the same reference model.

4. Simulators and conformance test

Availability of the reference model now allowed standardized tests of the single system parts such as MES, PUs, room monitoring, alarm system and Historian against the specification. A special simulation tool was developed to this end. This tool firstly served the purpose of testing the various PUs against the specified MES interface; at the same time it could also be used in principle as an MES simulator for PU suppliers. The tool was provided to all parties to the project at an early project stage. It enabled all suppliers to verify their implementations in advance and then maintain tests continuously throughout the entire project run. Furthermore, it permitted clear attribution of responsibilities while also reducing system test complexity. Communication and functional failures could be identified more quickly and in time, resulting in higher implementation quality and stability from the start. This in turn led to shorter commissioning times on site. The simulator can be configured via parameterization interface and was used for all PUs. If the specification is modified, additional tests can be carried out at any time. As another benefit, the simulators can be reused in other projects. At the bottom line, cost savings due to shorter test and commissioning times clearly outbalance relatively low costs for simulator development.

Overview of systems and vendors

Project:
Novartis Singapore Pharmaceutical Manufacturing
Project Manager Automation: Dr. J Zobel

Werum Software & Systems: Olaf Aurin
Trebing & Himstedt: Steffen Himstedt

Software systems:	
ERP	SAP
MES	Pas-X, Werum
Historian	iHistorian, GE Fanuc
Room monitoring system	Vista, TAC
Monitoring & alarming system	Vista, TAC
Machinery and utility units:	
Sieving – Glatt	iFix, GeFanuc
Dispensing – Glatt	iFix, GeFanuc
Granulation – GEA	iFix, GeFanuc
Compactor – Bepex	WinCC, Siemens
Compression – Fette	OCIF, Fette
Purified Water – Christ	WinCC, Siemens
Washing Units – Glatt	iFix, GeFanuc

5. Historian and reporting

The communicative substructure provided the main basis for powerful and flexible reporting. Besides the MES system, the reporting constitutes the most vital interface between users and the real production process. MES systems focus on GxP-compliant process control and documentation in the form of the overall Electronic Batch Report. The Historian-based central reporting concept presents the real window into processes for the user team. Reports can be generated for each machine, every process step, across the entire plant – by anyone involved in the process at any level, including shop floor workers, head of production or quality assurance. The concept has been designed in a way that the Historian not only stores time-related data of single process values. Instead, all shop floor data are collected at one central point. To do so, the reference model was implemented in the Historian as well. As a consequence, runtime data as well as respective alarms and events are recorded and will be available for later reporting. Structured records exist for the following information (extract):

- Batch attributes (batch ID, start, stop, duration, product code of batch, recipe version, …)
- Phase information (phase name, start, stop, duration, parameters, users, …)
- Parameter change event (time stamp, old value, new value, user name, reason, …)
- GxP-critical data (GxP value name, min value, max value, engineering unit, …)
- Critical alarms (time stamp, source, condition, sub-condition, message, status, user name, …)
- GxP trend information (GxP-critical value, set point, upper limit, lower limit, …)

With the collected data, the Historian constitutes a "Process Data Warehouse" as equivalent to the IT Business Warehouse. This concept raises report quality to an entirely new level:

- Wholistic electronic machine report generation throughout the entire production process
- Directly comparable machine reports of single process steps instead of vendor-dependent, fixed PDF documents
- Independence of report details and formatting from manufacturer-specific tools of subsystems (PU, AMS, MES, …)
- Data mining and ad-hoc reporting for better process understanding
- Finally this provides the basis for a future standardized machine reporting throughout all production processes within Novartis

Exploitation of the benefits of central reporting required further conceptual prerequisites. Data transfer to the Historian is based on the "Store and Forward " principle using the standard functionalities of the Historian collectors.

Ethernet communication of production systems and the Novartis office world in NSPM are concentrated on the same physical LAN using the concept of virtual private networking (VPN) with firewalls for data segregation. This allows the connection of all production systems to a centralized Domain Controller for central user and password management. The Domain Controller additionally serves as central time synchronization server for all PUs.

6. Results and outlook

At the moment, the project at Novartis Singapore is in its last implementation phase. The results of the FATs and Installation Qualifications (IQs) conducted so far have all confirmed the concept strategy. Significant cost reductions and savings are expected with regard to integration and commissioning of shop floor and MES. The good cooperation of all project partners and their willingness to break new ground smoothly solved some minor problems mainly due to the varying performance of the manufacturers' OPC implementations. For suppliers not yet providing a flexible OPC A&E server, participants did not resolve to proprietary solutions undermining and weakening the concept. Instead, respective OPC A&E servers were developed by Trebing & Himstedt within the scope of the project. As a consequence of the extremely positive experiences, this concept will be applied as standard approach for new projects at global level whenever possible. It is equally applicable for liquids, packaging or fermentation processes.

Application of the same principle for the Novartis PAT initiative is another evident, immediate result. This project includes the integration of spectrometers via OPC allowing spectral raw data to be transported via OPC arrays into the Historian for further analytical investigations.

With this described approach, integration projects can be implemented much more speedily, based on clearly defined standards, and at a higher quality level.

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Steffen Himstedt (Dipl.-Ing., 40) founded Trebing & Himstedt Prozessautomation GmbH & Co. KG together with Stefan Trebing in 1992. He is an active member of ISPE, GAMP SIG 21 CFR Part 11, furthermore he is an associate member of working groups for the validation of PROFIBUS networks or VDMA Germany. As a board member of the OPC Foundation Steering Committee, he helped launch the OPC concept in Europe.

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