

Automation Solutions in Machine and System Building

SOLUTIONS 10



Transparency
in All Phases



MOELLER 

Think future. Switch to green.

The validation process provides verifiable proof that the production system and product meets the high standards of quality required. Manufacturers requiring FDA approval for a product must be able to prove that their manufacturing process is FDA-compliant. Onsite audits by FDA auditors confirm this in the form of a validation.

Handling process data, protecting processes

The freely combinable Moeller components provide flexibly tailored solutions for automation concepts. The project design for the data to be recorded is carried out in the HMI-PLC visualization, where it is possible to assign every operation with a user and password level. In this way, any project design on the server is unnecessary. The database is preconfigured and contains ready-made screens. The administrator just has to define the users involved.

The system offers a range of different versions. These range

from the stand-alone system with an autonomous function up to the multi-PLC or multi-client concept. Ethernet TCP/IP is used as the communication medium. HMI-PLC names and IP addresses are used to guarantee that the data is unambiguous in the system.

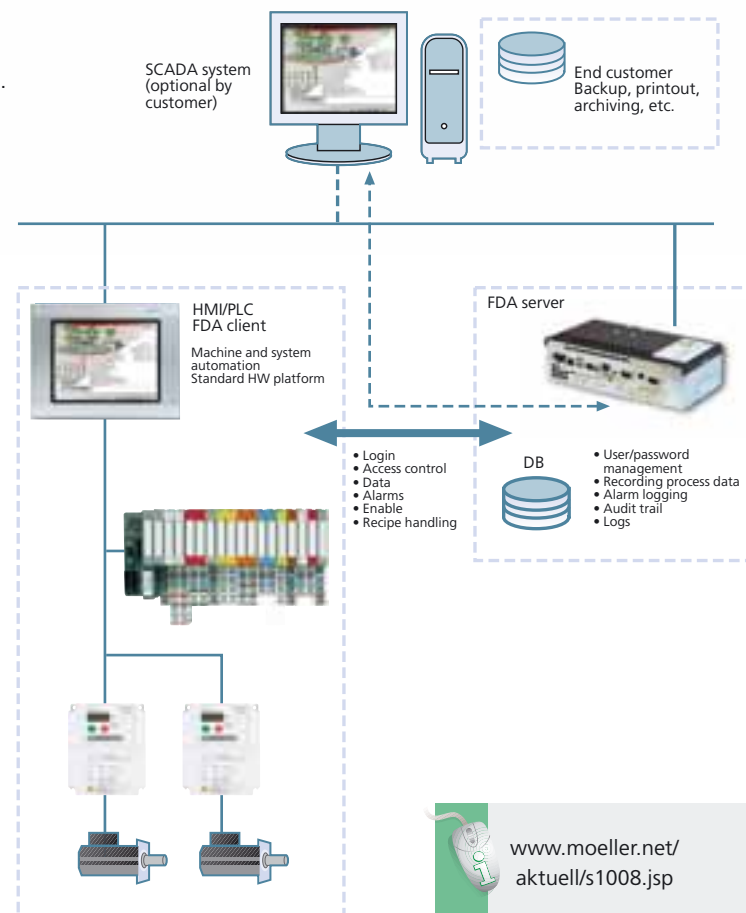
For operating data acquisition, batch traceability and FDA compliance with an audit trail, the Moeller concept integrates extensive user/password handling facilities, the recording of all operations in the event log, the logging of individual values and alarms, as well as the data allocation of the batches (batch history).

The automation concept can be expanded and adapted easily. Only a client has to be added and registered with the server, and the same goes for the addition of a subsystem below the client.

A powerful real-time database with open, standardised interfaces for all data formats links the system to the IT world.

21 Code of Federal Regulations Part 11 Electronic records; Electronic signatures

Subpart A	General Provisions
§ 11.1	Scope
§ 11.2	Implementation
§ 11.3	Definition
Subpart B	Electronic Records
§ 11.10	Controls for closed systems
§ 11.30	Controls for open systems
§ 11.50	Signature manifestations
§ 11.70	Signature/record linking
Subpart C	Electronic Signatures
§ 11.100	General requirements
§ 11.200	Electronic signature components and controls
§ 11.300	Controls for identification codes/passwords



CONCLUSION

With this pragmatic approach, Moeller is offering its customers an outstandingly simple but powerful concept for meeting the requirements of different regulations, in particular, the FDA regulations. The range of versions available covers a broad spectrum of automation concepts. General certification is not possible due to the range of versions available. However, Moeller provides extensive documentation for supporting users in the validation of their machine or system.

www.moeller.net/aktuell/s1008.jsp

FDA Solution Based on Standards



The regulations of the US Food and Drug Administration are particularly stringent. Its Code of Federal Regulations (CFR) now has legal status, and so does Part 11, which applies to the processing of data in electronic form. However, it is often the

case that only parts of this law applicable to the pharmaceutical and food industries are fulfilled. Moeller's comprehensive solution, based on inexpensive standard components, enables machine builders to design projects easily that are still fully compliant with the legal requirements.



pester pac automation, one of the leading manufacturers of final packaging machines, uses Moeller's FDA solution for its PEWO-pack Compact 250 stretchwrapping machines.

FDA 21 CFR Part 11: safety as the top priority

The recording and traceability of production data are essential requirements in the production of pharmaceuticals and cosmetics, and increasingly in the food industry. After all, the safety of the consumers using these products must be ensured. As early as 1997, the FDA issued a directive prescribing the complete and secure documentation of all processes in electronic form. These requirements are set out in FDA 21 CFR Part 11. Although this is only legally binding for the US market, globally operating pharmaceutical and food companies in Europe are also affected by these regulations. Manufacturers requiring FDA approval for a product must be able to prove that their manufacturing process is FDA-compliant. Onsite audits by FDA auditors confirm this in the form of a validation.

Manufacturer's aim: 100 percent compliance

"As machine builders we must create the conditions to achieve the production goal of 100% compliance," said Stephan Remer, responsible for software and electronics development at the Bavarian company. pester pac automation achieves this on the one hand by the careful selection of the materials processed and GMP-compliant machine design in accordance with the quality standards of the pharmaceutical industry. On the other hand, the automation system must

be designed so that it meets the requirements of FDA 21 CFR Part 11. Previously this was only possible through the use of cumbersome process visualization systems. Apart from this, some other display solutions are available on the market, but these only cover some aspects of the FDA regulations. The proprietary developments of machine builders often involve a lot of time and money, and are not available for a wide range of uses due to their speciality.

FDA client and FDA server in the network

Moeller therefore looked at this area thoroughly and worked out a comprehensive solution. Practical suitability was a key priority in addition to compliance with all the necessary regulations. Standard machines and machines for the pharmaceutical industry are mostly built compliant to FDA requirements, and this is also the case at the plant in Wolfertschwenden. A machine builder requires engineering that is standard regardless of whether systems have FDA functions or not.

The FDA client, consisting of a Moeller XVC601 HMI forms the basic unit for the FDA solution. This client can be used for both types of applications – with and without FDA functionality – and is within the standard price range for a visualization device. FDA functionality simply requires an additional component, the FDA server, and client and server are linked via Ethernet. Retrofits are also always possible.

The server itself consists of a Moeller XCC601 Box PC and integrated with a powerful SQL database. The data can be viewed via pre-configured screens on a flat-screen display

connected to the XCC601. An HTML interface is available for headless versions without a display. This system is then simply set up via a web browser on a PC connected to Ethernet. Major cost benefit for complete production systems: several FDA clients can be connected to the FDA server. Data exchange with higher-level systems is possible as an option for storing or further processing the logged data.

Flexibly scalable functions

For integration into existing control concepts, the FDA client can provide either visualization and HMI functions for the machine, or can also provide as an HMI-PLC the entire open and closed-loop control of the system. For this purpose, the XVC601 is equipped with a powerful processor, and can be supplied with 10.4" to 15" displays. If necessary, the PLC functions can be programmed with CoDeSys from 3S in compliance with the industrial standard IEC61131. Moeller also uses standard programming packages for designing the visualization functions. EPAM (EasyPageMachine) is the name of the visualization tool, which offers a powerful development environment that is fully integrated in MS-Excel. For data recording in compliance with FDA requirements, the data points that have to be processed via the server are simply marked in EPAM.

FDA integration with the PEWO-pack Compact stretchwrapper

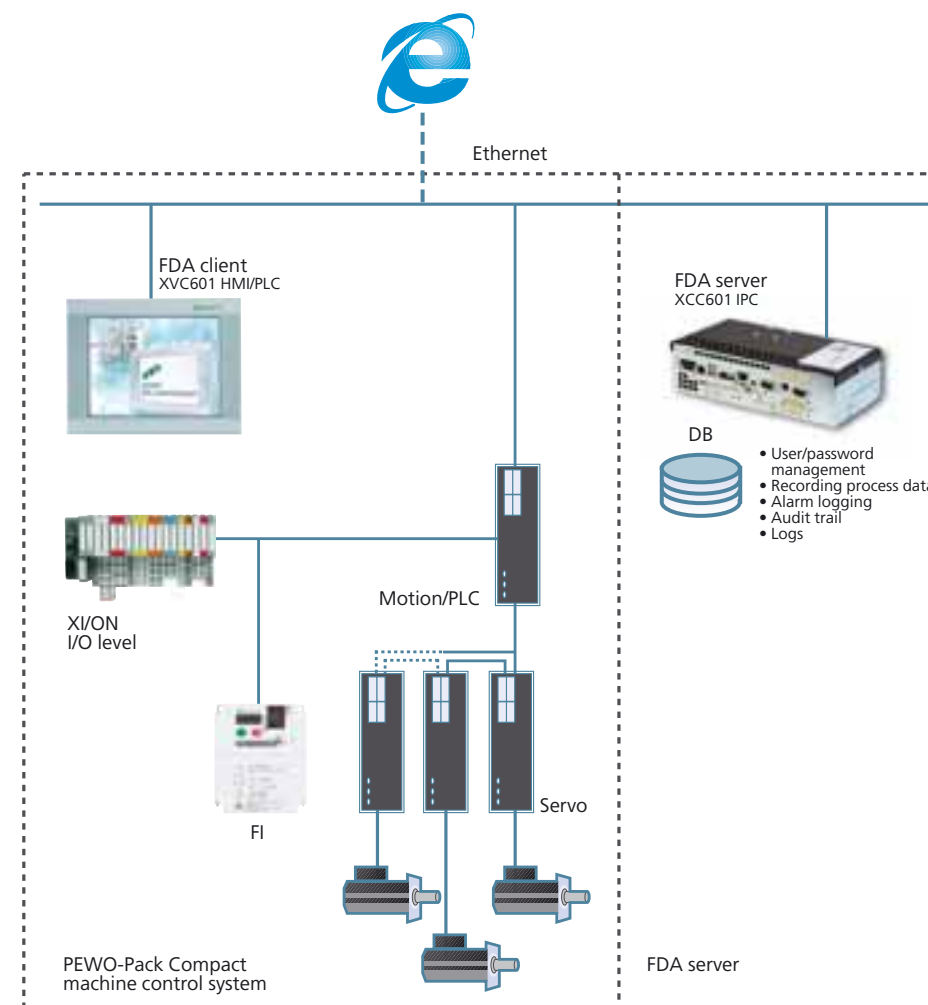
The PEWO-pack Compact series of machines are designed for the stretchwrapping of collations. The cartons coming from an upstream cartoning machine are fed via a conveyor belt to the Compact 250. Three servo axes ensure that the cartons are sealed with a polyethylene foil as finished packages. The pester pac automation machines are available as stand-alone units and as components in a packaging line, with possible cycles of 60 units/minute. Thanks to the balcony construction, the low-wearing sealing system, the swing-design control and pneumatic cabinet, a GMP compliant

machine construction and intelligent recipe management for swift size changeovers, these machines meet the demanding requirements of the pharmaceutical industry.

pester pac automation, which had been confronted by this sector with the FDA regulations, had for a long time been looking for a system based on standard components whilst still offering flexibility. As Stephan Remer noted about the Moeller concept: "The Moeller components can be integrated in our control philosophy without any problems. The price performance ratio is very good, and the system enables us to be equipped for further or modified FDA requirements in the future."

FDA 21 CFR Part 11 functions:

The Moeller concept offers extensive functions for implementing the large number of requirements of the FDA regulations: password management, unlimited access levels, and audit trail with complete and secure event logging, alarm archiving, version management of software and recipes, creation of reports and interface to the IT environment (end user). Functions such as operating data acquisition and batch logging (data logging) are available as additional products.



CONCLUSION

As well as an appealing solution made up of product and know-how, machine builders require competent advisory support. As an FDA expert, this is something that Stephan Remer from pester pac automation appreciates. "We also require our suppliers to provide customer support and consulting. With Moeller, we have a partner that can meet these requirements to the fullest."

THE COMPANY

The family based company was founded by Emil Pester in 1888 and now looks back on over thirty years of experience in the building of packaging machines. At Wolfertschwenden in Bavaria, 280 employees make sure that high quality components and machines meet specific customer requirements. The machines are used in applications for walleting, foil packaging, cartoning and palletising, especially with global players in the pharmaceutical, cosmetic and food industry.