

Validated system phase-out without production loss

Two validated weighing stations, integrated with the new formulation software FormWeigh.Net from METTLER TOLEDO, helps pharmaceutical manufacturer CIMEX AG, Liesberg, achieve 100% traceability and high precision.



CIMEX AG has long-standing expertise in the manufacture and packaging of generics. In addition to offering toll manufacturing services, it is also a producer specialised in selected manufacturing technologies for medicines with controlled release of active ingredients, and in dividable sustained release tablets. Its own products are mainly used to help fight high blood pressure, prostatitis and Parkinson's disease. CIMEX AG's customers are generic drug distributors, some of whom are themselves producers. Dr. Thomas Uhlmann, Head of Production and Technology explains: "Because of our global buyers, it is important that our suppliers offer not just a good solution but good service, honesty, reliability and competitive prices to be a competent partner for us." METTLER TOLEDO met all of these requirements.

Integration of existing equipment

Day after day, all the chemical components of a given formulation are weighed at the two central weighing stations, which are protected by special cabinets. In the Swiss production facilities of the

renowned and successful generics manufacturer CIMEX AG, this is nothing new. "For us, it's important to be able to ensure traceability in accordance with 21 CFR Part 11," says Mohamed Ibrahim, Manufacturing Head of the non-penicillin unit. "With the new system from METTLER TOLEDO, this is now 100% guaranteed. That's why we chose the FormWeigh.Net application software. Another key requirement was the ability to integrate our existing equipment into the new system. For us, it was also important not to suffer production losses for the sake of a system change. METTLER TOLEDO flawlessly organised that aspect of the project, as well."

Standard software that comes with countless useful functions

The project began with a process analysis to evaluate CIMEX's requirements in detail. Close cooperation and several on-site discussions resulted in a comprehensive specifications document that contained all needs and requirements, this would serve as the basis for realisation of the project. The task of the interdiscipli-

nary team from METTLER TOLEDO was to fulfill all the requirements of the analysis with a test system. The primary goal was to create a system that was as close as possible to the system they had been using, to introduce new functions and to make the changeover as seamless as possible for the operators. After a short introductory training session, Mohamed Ibrahim could confirm that "With FormWeigh.Net, the components can be easily weighed on the clearly designed operator interface." It often takes time to get used to new equipment, operators know this better than anyone. "The feedback from our weighers is altogether quite positive," said Mohamed Ibrahim after the changeover. The training and Factory Acceptance Test (FAT) were also done on the test system.

Reduction in the cost of validation

Regulations regarding the use of computer systems in the pharmaceutical industry required the FormWeigh.Net formulation system to be validated according to GMP (Good Manufacturing Practice). Despite its own experience with valida-



System layout



Master station

- Maintaining master file
- Order installation

Company network



Weighing stations

- Terminal ID30
- Bar code reader
- Label printer
- Connected up to three weighing platforms



tion processes, CIMEX AG decided to enlist the help of METTLER TOLEDO's validation services. "The standard FormWeigh.Net validation manuals have given us enormous help in minimising our validation expenses. Experience with past validations was brought into the project in the form of validation protocols," says Norbert Waldy, Qualification Manager. METTLER TOLEDO's years of experience in the field of instrument qualification and computerised system validation was also highly valued.

Changeover without production loss

The changeover and validation were carried out completely in two steps to ensure that production would not be interrupted. A second server was procured and operating the new and old databases on the two separate servers at the same time allowed a cabinet to be installed on the new system while the other weighing station worked productively with the existing system. According to Norbert Waldy, "The step-by-step conversion paid off by preventing us from having a production loss."

Additional advantages of the FormWeigh.Net system

An optical filling guide simplifies the manual dosing of the material for the operators at the balances. If necessary, hazard warning symbols or advisories for handling the materials can be displayed. Processing can continue only if the right quantity of the right material is weighed. The system immediately reports any deviations! After a component is weighed correctly, FormWeigh.Net sends a print job to the label printer, which prints a weighing label. When the job is completely finished, the system automatically prints the weighing report, thereby supplying precise process documentation. The header of this documentation contains order information, and all components are listed below, with the actual weight and ID of the operator that completed the action. Tiered access protection aligned to competencies ensures that only authorised personnel see and modify the sensitive data. The new "FormWeigh.Net" software completely supports the use of the touchscreen functions of the ID30.

As its next step, CIMEX AG is planning to upgrade the FormWeigh.Net system in the penicillin unit with a new weighing station based on the IP67-protected ID30 industrial PC.

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