

# Pharmaceutical Preparations

Industrial weighing and measuring



# 2 News

## Each Tablet a Winner through Best-Practice Quality Control

**Tablet quality is assured by using a paperless and wireless in-process control system, which visualizes and documents real time product quality data from several compression booths into one 21 CFR part 11 compliant batch record.**

In each of the six tablet compression booths a METTLER TOLEDO XP balance is used to sample 10 tablets every fifteen minutes. The weight is transferred by WLAN communication to the FreeWeigh.Net® Quality Assurance system located in the in-process control lab.

### Improved tablet quality monitoring and process control

Results of the analysis, such as mean values, standard deviations and tolerance ranges are immediately available on all supervisor stations. This allows real time process control options, such as compression and punch adjustment before any tolerance violations can occur. Compared to procedures where net weight data acquisition requires

time-consuming manual data collection and transfer operations on each balance, FreeWeigh.Net® allows for labor-saving automation and more efficient data analysis.

The FreeWeigh.Net® system displays SOPs directly on the balance screens, ensuring fast and error-free tablet weighing operations. Furthermore, it automatically manages calibration of all six connected weighing instruments, including documentation of daily performances.

Additional tablet testing devices, such as analyzers of hardness, thickness, diameter, etc., can be integrated in a future step with the Device Integration Utility.



Courtesy Novartis

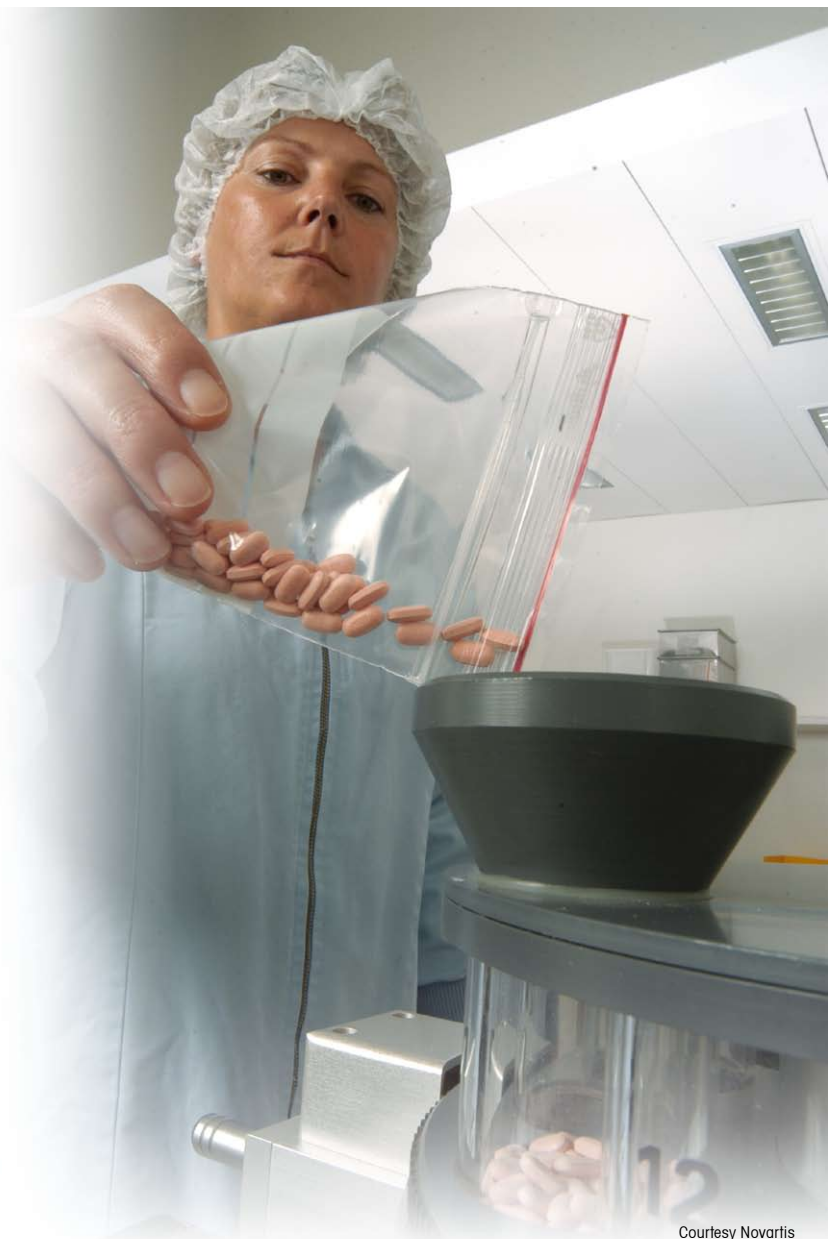
**METTLER TOLEDO**

**Automated electronic batch reports, 21 CFR Part 11 compliant**

At the end of the batch FreeWeigh.Net® automatically generates a report with all relevant statistical data. The functions implemented into FreeWeigh.Net®, such as audit trail, electronic signatures, user profiles and password management ensure full compliance to 21 CFR Part 11. The report is reviewed and released by Quality Assurance as a part of the entire manufacturing batch record.

**Key benefits of FreeWeigh.Net® quality control system**

- Saving resources by getting paperless and automating weight data recording
- Faster and more efficient quality monitoring through on-line data availability
- Effective in-process control prior to the occurrence of deviations
- System is in compliance with 21 CFR Part 11 and GAMP 4
- Full validation support from METTLER TOLEDO allows effective cGMP system validation



Courtesy Novartis



**XP Precision balances**

- High productivity thanks to MonoBloc<sup>HighSpeed</sup> technology
- Ease of use with large colored touchscreen display
- Hands-free operations with SmartSens and ErgoSens sensors
- Complete flexibility through seven interfaces including Ethernet and Bluetooth

**ErgoSens**

Individually configurable sensor for hands-free operations of the XP analytical balance.



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## Schering-Plough's Recipe for Success: Integrated and Paperless Batch Manufacturing

**Reliable formula weighing system, SAP integrated and 21 CFR Part 11 compliant: with this combination, Schering-Plough K.K. succeeds in continuously satisfying their customers.**

Schering-Plough K.K. is a global science-based health care company with a focus on healthcare products treating allergy, respiratory and infectious diseases, skin disorders, cancer, cholesterol, and cardiovascular problems. For Schering-Plough K.K. data

integrity, accuracy and traceability are critical for the product quality, and compromises cannot be accepted. During an expansion of production capacity, a new weighing system was integrated into SAP and validated according to cGMP.

Schering Plough K.K.'s decision to choose METTLER TOLEDO was triggered by a very positive experience at another plant in Spain where FormWeigh® has been running successfully for more than two years.



**Processes are more reliable and efficient due to integration into the ERP system.**

METTLER TOLEDO provides a certified interface to integrate the formulation software FormWeigh® into the PP-PI module of SAP. After releasing a production order in SAP, the recipe is submitted electronically to the weighing stations. Stock levels are automatically adjusted in SAP after each weighing step. This process minimizes manual transactions in SAP, accelerates the work process and prevents potential human mistakes.

**Correct product quality is ensured**

The correct raw material is verified via barcode scanning. All relevant data about the raw material status such as the expiration date, as well as its target value, are downloaded from the warehouse of SAP to FormWeigh® and checked by the system. The target quantity to be weighed is adjusted automatically according to the potency of the ingredient, thus ensuring error-free calculations. Finally, the software guides the opera-

tor through the whole dispensing process so that it becomes easy to follow and fail-proof.

**The process complies with 21 CFR Part 11 requirements**

Electronic weight records and audit trails implemented in FormWeigh® ensure traceable paper-free formulation in compliance with 21 CFR Part 11.

**System validation performed fast and efficient**

With the ready-made protocols from METTLER TOLEDO, the GSV (Computer System Validation) packs, equipment qualification and software validation was performed smoothly and efficiently according to GAMP 4 guidelines and specific requirements from Schering-Plough.



Courtesy Schering-Plough K.K.



### FormWeigh® formulation management solution

FormWeigh® is a software-based formulation solution for batch manufacturing. It consists of a weighing terminal connected to up to three scales, a barcode reader and a label printer.

At Schering-Plough K.K., five central weighing stations are equipped with FormWeigh® for the formulation of a wide range of raw materials, in both sterile and non-sterile areas. The weighing range covers 0.01g up to 1500kg.

Courtesy Schering-Plough K.K.

### SAP Production Planning PP-PI Module (PCS Interface)



Download bill of materials after order release in the ERP system



Upload consumption data for stock adjustment

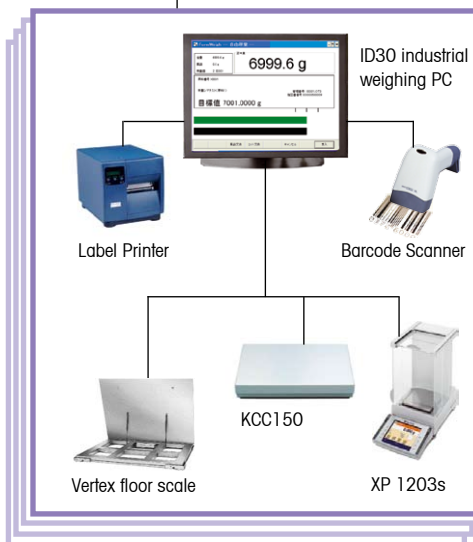
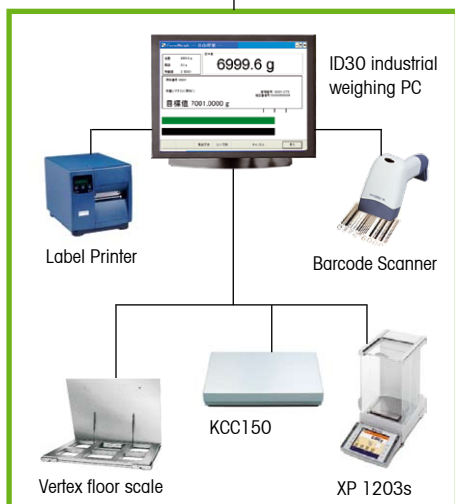


### FormWeigh® Server Dispensing System



Booth 1, sterile dosing station

Booths 2-5, non-sterile dosing stations



**FormWeigh®**  
Accuracy  
Reliability  
Compliance

# Inspected, Marked, Released

## How do you increase your operational capacity while complying with Good Manufacturing Practice?

The answer: with the S2 PharmaLaser from METTLER TOLEDO. Embedded into your production line, the S2 PharmaLaser allows increased throughput of tablets and capsules while maintaining high quality standards.

### Optimized process control

Both checkweigher and laser marking unit are merged into one integrated solution for trouble-free in-process quality control.

### Major advantages are:

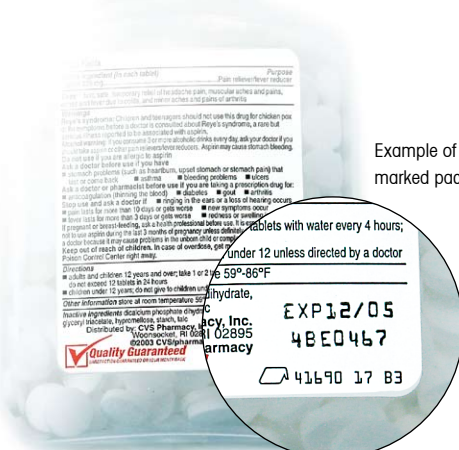
- Minimisation of errors thanks to embedded statistical analysis programs and intervention software module
- High production throughput is reached due to fast weight data processing
- Fail-proof work through clear operator guidance with easy-to-use touchscreen
- Open flap and askew package detection prior to laser marking
- Automatic rejection of out-of-tolerance products

### GMP compliance at your fingertips

- Full qualification from setup and calibration to system configuration delivered by METTLER TOLEDO
- Following 21 CFR part 11 by implemented audit trail
- Easy tracking and tracing due to process data transfer to MES/ERP systems

### Unique product identification

- Clear marking of texts, logos, special characters and graphics on the package
- Redundant safety through the OCR (Optical Character Recognition) camera system



Example of a laser-marked package



S2 PharmaLaser



Courtesy Novartis

# Keep an Eye on the Output Nothing Escapes the X-Ray System

## No compromises on quality

To guarantee compliance with the strict quality requirements of the pharmaceutical industry, thorough inspection of all your products is needed before they leave the factory.

Integrated into your production line, the METTLER TOLEDO Safeline® X-Ray inspection system detects metal, glass, bone, and stone contaminants and monitors portion control, product and packaging integrity. And you can be sure that the leaflet insert is also inside!

In a glimpse several stacks of multiple blister cards are checked by the careful eye of the Safeline® X-Ray. Promptly, any defective product is rejected by an automated mechanism

and eliminated from the production line. With X-Ray solutions from METTLER TOLEDO Safeline®, you can put your mind at rest: trouble-free operations and highest quality are guaranteed.

## Safety is crucial – protect the operator and the product

All Safeline systems use low energy, electrically generated X-rays that are fully contained to the highest safety standards in the industry. Every X-Ray system is also tested by approved and certified auditors before leaving the manufacturing facility. With Safeline® systems safety comes first for both operators and products.



Series 20 X-Ray Unit



Relevant process information at your fingertips. Clearly arranged and easy to operate touchscreen for quick and smooth handling of the scanning process.

# Pure Protection through Highest Levels of Accuracy and Hygiene

**Howorth Pharma is a world leader in the design and manufacture of containment equipment for pharmaceutical industries.**

Through innovative design and skilled manufacturing capabilities Howorth Pharma offers a comprehensive containment service, providing customers with solutions that exceed the varied and ever increasing demands of potent compound manufacturing and handling. The company has recently been awarded a \$5 million US contract – the largest in its history. The contract for a total of 29 glovebox isolators was secured after Howorth Pharma successfully demonstrated that it could provide unique retrofit

containment solutions to a number of complex existing pharmaceutical machines.

METTLER TOLEDO has effectively provided the split-second high-precision weighing capability that lies at the very heart of the \$5 million order.

#### **Our contribution to success:**

As Howorth Pharma's preferred partner for reliable weighing equipment, the Modulo Automated Precision Weighing Sensors by METTLER TOLEDO have played a key role ensuring:

- Highest accuracy: down to 0.1mg with Modulo digital weigh modules
- Minimised cross-contamination
- Easy to clean due to smooth stainless steel design
- Optimised handling process through high-performance equipment



**howorth**  
pharma



#### **Modulo Series**

- 120g/0.1mg up to 6kg/0.01g
- Stainless steel, IP66 protection
- Internal calibration device
- Broad data interfaces: RS232/422, DeviceNet™, Profibus® DP, Ethernet

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