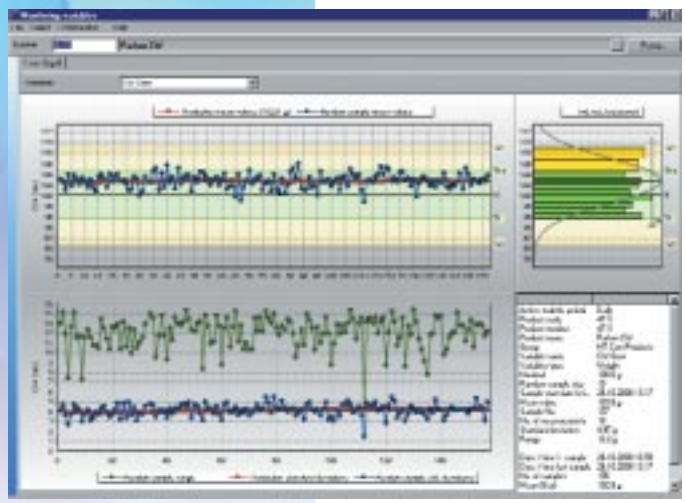
From one source –

the complete solution for quality control in pharmaceutical production:

- Measuring instruments and calibration service
- Terminals and rugged PCs
- FreeWeigh.Net software solution
- Network connectivity
- Compliant with 21 CFR Part 11
- Validation manuals
- Expert consulting



Net weight and in-process control for your pharmaceutical production

METTLER TOLEDO

FreeWeigh.Net – The production reliability you've been looking for!

Based on the software solution FreeWeigh.Net, METTLER TOLEDO has the complete solution for pre-packaged product and in-process control for the pharmaceuticals industry. METTLER TOLEDO offers not only high-precision and easy-to-use measuring instruments and software, but also functions for compliance to regulations such as 21 CFR Part 11 and ready-made validation protocols for IQ, OQ, and PQ project phases.

In-process control of tablet production
FreeWeigh.Net provides a simple and reliable means of checking tablet characteristics such as weight, diameter, thickness, hardness, friability and disintegration – random sample by random sample.

Supported instruments:
- ID30 industry PC with IP67 protection against water and dust.
- METTLER TOLEDO AX (readability up to 0.01 mg, 220g) and PR (readability up to 1 mg, 210g) analytical balances, including LV11 automatic feeder
- Hardness testers, e.g. Schleuniger models 6D, 8M, and AT4
- Various length measuring devices
- Tablet friability (manual data entry)
- Disintegration, dissolution (manual data entry)
- Visual assessment of attributes (e.g. 3 out of 5 tablets scratched)

Many other types of instruments can be integrated into FreeWeigh.Net system using the «Device Integration Utility», with no need for any extra programming.

Test place module
- **Testing**
- **Instrument control**
- **Data acquisition**
- **User guidance**

FreeWeigh.Net

Net weight control and packaging inspection
Product data can be maintained on the master computer and transferred to the GARVENS checkweigher at the touch of a button. FreeWeigh.Net archives production data such as hourly statistics for the duration of the period for which records legally have to be retained. It imports data recorded by the checkweigher and retains stored for the length of time required by GMP.
FreeWeigh.Net can be used with Garvens S-line checkweighers and combicheckers in accordance with 21 CFR Part 11. It supports serial or Ethernet connections.

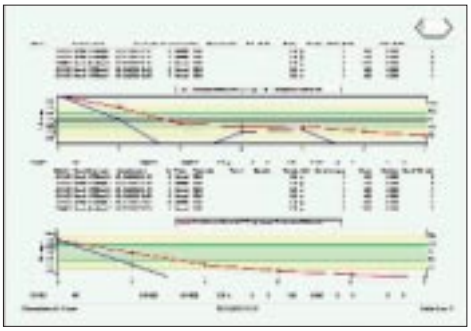
Supported instruments:
S-line, E-line, combicheckers and VS/VO.

Instrument-based test station
For compact net weight control or tablet test stations, inspectors can call up product data right on the balance display and start testing. Calculated statistics and tolerance violators are also displayed here after sampling. These balances can be **integrated directly into your company network** without the need for any extra cabling.
Supported instruments: AX, PR, Viper*.

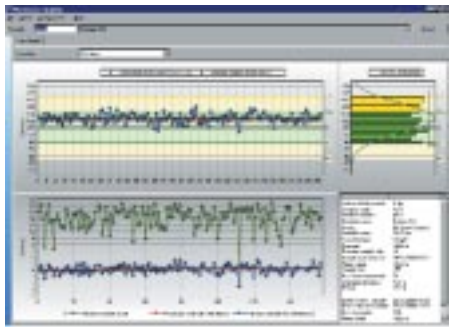
Networked test stations directly on the production lines

* available Q4/03

From your own workstation you can define cross-departmental quality tests. Using simple and clearly laid out masks, you can maintain product catalog data such as nominal weight, tolerance system, resolution, sample size, etc. The test plans are available for execution at all weighing/test stations after release with an electronic signature. On completion of testing, the measurement results and statistical evaluations are available to quality assurance personnel and production managers in real time via the company network. Deviations and activities at the filling stations are clearly displayed, ensuring that production managers and quality assurance are always kept up-to-date about the running process.



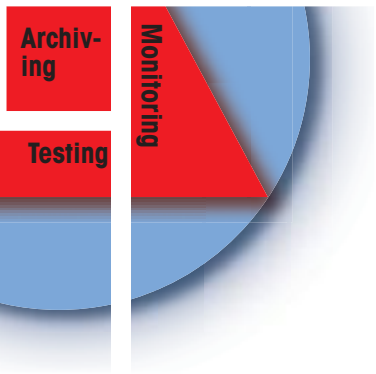
Quality documentation
FreeWeigh.Net includes ingenious evaluation algorithms and flexible reports that can be configured to your own requirements, guaranteeing complete, long-term control and documentation in accordance with net weight control legislations:
- samples, statistics, batches, jobs, alarms, and activity reports
- special checkweigher reports



SPC evaluation and monitoring
FreeWeigh.Net offers a number of different evaluation options for various periods, such as:
- mean value, standard deviation and range
- SPC and Cpk, Cp, and CuSum capability
- histogram, 6-sigma display
- HACCP monitoring
- Control limits for mean value

… as well as machine-specific and filling head-specific options, of course.

Visual inspection and attributes
With FreeWeigh.Net you can detect and record production defects by frequency of attributive, visual inspection. Possible parameters include:
- Best before date correct?
- Label affixed correctly?
- Package insert present?

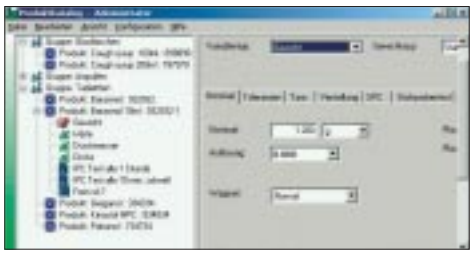


FreeWeigh.Net

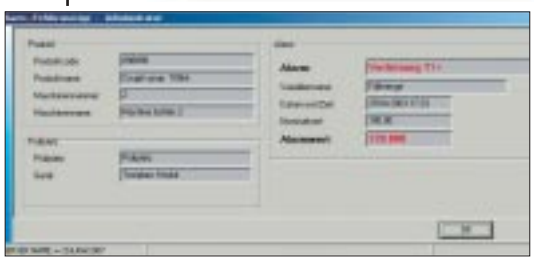
Secure MS SQL Server 2000 database – the database that your IT department knows.

FreeWeigh.Net

Master station
- **Tests planning and allocation**
- **Maintain basic data**
- **Print reports**
- **Monitor lines**



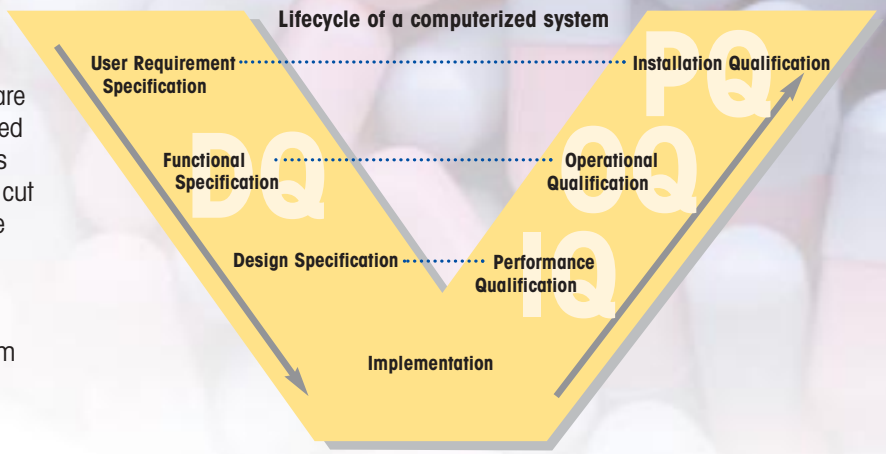
Master data maintenance and host connection
At your own workstation you can define cross-departmental test schedules or machine and job data. Using clearly laid out masks you can maintain product catalog data such as nominal weight, tolerance systems such as US Pharmacopeia, sample size, etc. You can accurately import test schedules and job data from production planning systems such as SAP, and export test results again – guaranteeing seamless data integration.



Real-time alarm messages
If the batch mean value drops below the target, or a single value violates the tolerance limits for example, an alarm message is immediately displayed on the line and on all master stations. Production interrupts can be minimized, as the system can use trends to detect tolerance violations in advance. Use the monitoring functions of FreeWeigh.Net to minimize your machine downtimes.

Impressively simple, clear, and efficient.

We can help you to save time and money on validation.



Statistical quality control systems (SQC) that are used in the GMP environment must be validated by law. Using ready-made validation protocols and services from METTLER TOLEDO you can cut down this time-consuming and labor-intensive process dramatically, saving you time and money. Our validation engineers have an intimate knowledge of FreeWeigh.Net, test procedures, and the whole issue of computer system validation.

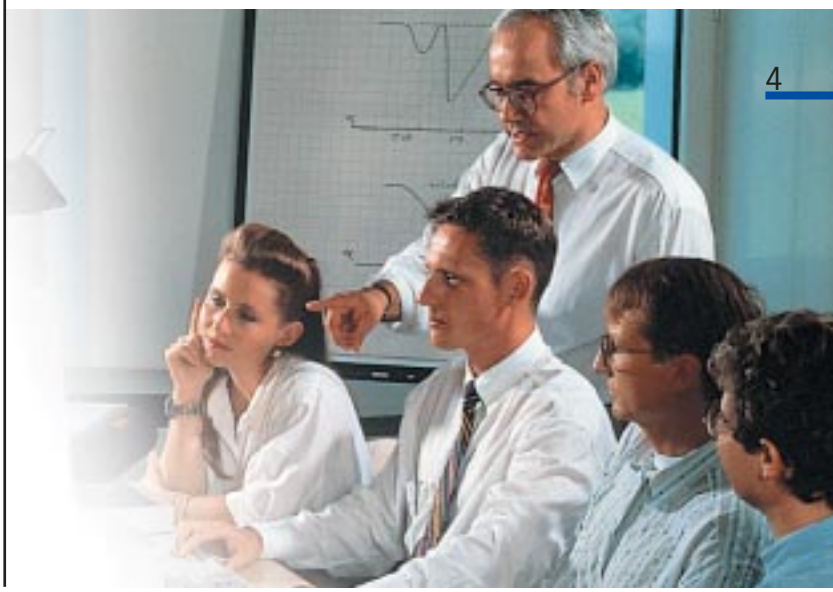
For the validation of the entire FreeWeigh.Net system, in other words software, hardware, documentation, and operation, we can supply ready-made validation documents that have been tried and tested in various projects worldwide.

Validation manual I
Pharmaceutical companies are required to qualify their suppliers. So the first manual describes METTLER TOLEDO's quality management system. It contains software development documents such as specifications and test reports to enable the quality of METTLER TOLEDO's software development to be assessed.

Validation manual II
The second manual contains detailed protocols for the system definition, installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) phases. This saves the drug manufacturer the trouble of preparing documents, and ensures that proven validation methods are used.

Professional support from our project and validation engineers
METTLER TOLEDO's engineering team is on hand to provide professional support along with systems and process expertise drawn from a variety of different projects. We can support you in the following activities:

- Process analysis
- Preparation of specifications
- Detailed operational definition
- Project and validation scheduling
- Design and installation planning
- Software and hardware installation
- Installation qualification (IQ)
- Operational testing (OQ)
- Acceptance testing (PQ)
- Training on site and in the METTLER TOLEDO training center
- Maintenance and hotline support



FreeWeigh.Net: the system solution FDA 21 CFR Part 11 ready!

Computer systems are increasingly taking over batch recording. Electronic records, complete with electronic signature are replacing many paper GMP documents. The fact that electronic batch records now do not also have to be printed, filed, and then removed from the files after a retention period saves time and labor for pharmaceuticals operations. Production plants are thus becoming increasingly paper-free. The United States FDA defines the legal basis for this in 21 CFR Part 11.

As of February 2003, the FDA has changed its approach to 21 CFR Part 11, which now includes fewer types of electronic records. The quality data recorded by an in-process control system such as FreeWeigh.Net is considered to be highly relevant to the quality control process, and so it still falls under 21 CFR Part 11.

Everything from audit trail to E-signature
FreeWeigh.Net has implemented all necessary 21 CFR Part 11 functions. Time-consuming exemptions procedures are no longer necessary. The validation board will grant permission to install the system in your production process without the need for lengthy discussion and with pleasure.

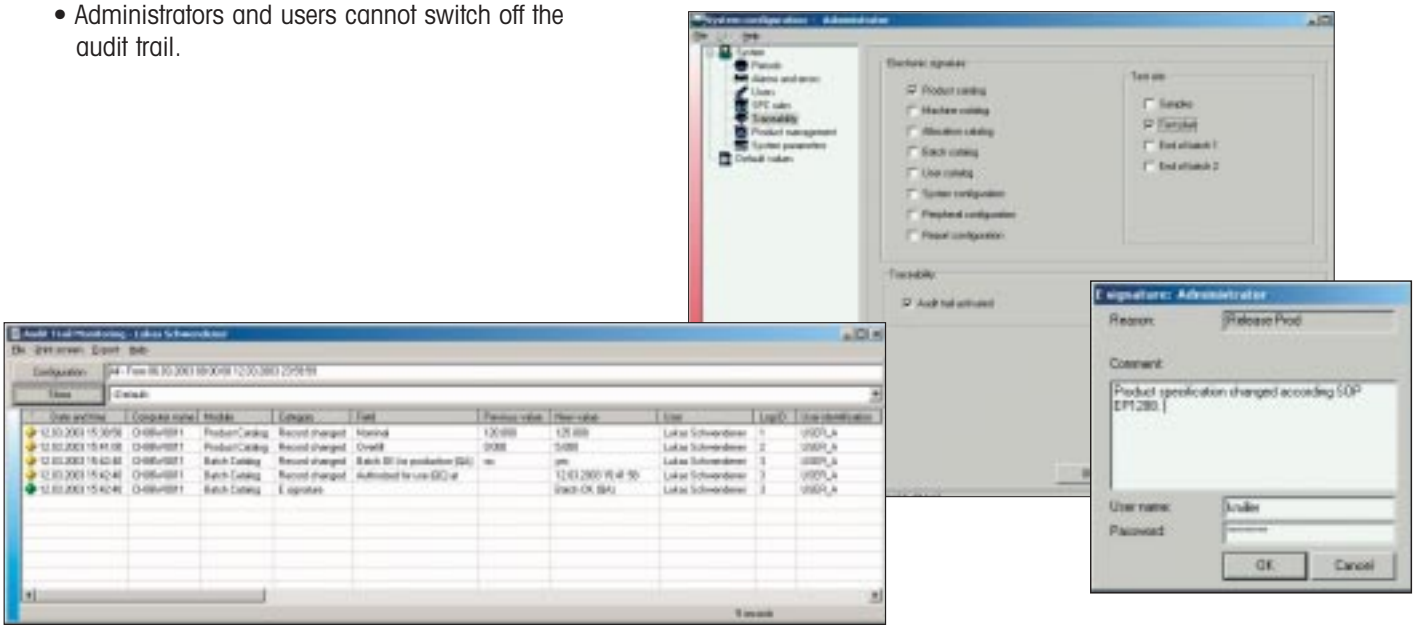
Audit trail – traceability of all changes to the system
- Complete event recording of all new, modified and deleted data.
- Reports and data export in ASCII and PDF format with selection criteria (filters) such as time period, product number, batch number, user, etc.
- Administrators and users cannot switch off the audit trail.

Controlling system access – the right way
- Unlimited number of user groups with over 50 individual authorization options.
- Record of all system log-ins, including in particular all unsuccessful log-ins.
- Automatic log-out mechanism after e.g. 12 minutes (configurable for the test stations).
- User is locked out of system after 3 unsuccessful log-in attempts.

Password management
- Configurable minimum password length (recommended 6 characters).
- Encrypted password storage.
- Users can change their password at any time.
- The user's full name is stored (not just the user ID).
- Users have to change their password after a specified, configurable period, e.g. after 30 days.
- Passwords have to be changed after a new one is issued by the administrator.

Electronic signatures
for 12 different releases or authorizations.

Control
of measuring instrument serial numbers and software versions.



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Quality certificate.
Development, production, and tests to ISO 9001. Environmental management system to ISO 14001.

Global service.
Our extensive service network, one of the best in the world, ensures maximum availability and prolongs the operating life of your product.

«Conformité Européenne».
This symbol proves that our products meet the very latest guidelines.

On the Internet too.
Important information about our products and services, and about our company, can quickly and easily be found on our website at:
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