Pharma and Biotech Manufacturers

5 Solutions to Ensure Compliance and Quality

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METTLER TOLEDO

Data Integrity Built into Your Process
4 Proven Solutions

These well-established data integrity solutions improve the quality of data for easier compliance, but also help to build a more robust, streamlined and efficient pharma manufacturing process.

Dispensing Room

Challenge

Inaccurate measurements, addition of wrong materials, false labeling or lost documentation are some of the reasons for inefficiencies. Experience has shown that manual inputs are more error-prone than automatic methods. Our software solutions help you take control of workflows for ensured and consistent quality.

Solution

FormWeigh.NET® offers full formulation control with visual displays that guide operators easily through the recipe-weighing process. It captures weight values automatically, storing them in a central database. Qualification manuals and checklists complete the package and speed up your validation process.

www.mt.com/Formweigh

Scales in Production

Challenge

Scales are at critical points throughout the manufacturing process. They assist in capturing relevant data including verification of when it was recorded, as required by GMP regulations. Our solutions allow for collecting and storing data electronically to fulfill ALCOA principles more efficiently.

Solution

IND780 terminals can be integrated into a networked system allowing for operator access control and automatic data capture and transfer. They support a wide range of automation protocols and can be easily customized to your manufacturing process.

www.mt.com/IND780

Filling Line

Challenge

Quality parameters of medication are captured at the filling line such as fill weight, tablet hardness or pH. These are batch release criteria that must be accurately documented for a truly comprehensive quality control process. If a statistical method is used, test plans, test methods and all results have to be recorded without undocumented modifications.

Solution

FreeWeigh.NET, a networked software solution for Statistical Quality Control, meets all these demands. Centralized management of test plans, central user management, and electronic signatures make for a compliant and efficient quality control process.

www.mt.com/Freeweigh

Serialization and Aggregation

Challenge

Mandating of serialization in the industry has applied significant pressure on manufacturers to meet compliance requirements. Legislation states that all serialization data must be held in a secure location so that other entities along the supply chain can verify product authenticity. This requires investment in suitable hardware and software solutions.

Solution

METTLER TOLEDO solutions meet serialization and aggregation requirements. Systems apply package codes and labels, check and verify code readability and capture data to provide regulatory compliance. Data is collected and held in a secure database with full connectivity and integration with ERP systems.

www.mt.com/PCE

When Quality is Critical
Rely on a Competent Partner

When the Spain-based Reig Jofré Group, a leading European pharmaceutical development and manufacturing company, decided to start exporting to the United States market, adapting its processes and facilities to comply with U.S. Food and Drug Administration (FDA) regulations became a key challenge.

The Reig Jofré Group focuses on four areas: industrial services, pharma, research and development and biotech services. At its main production site in Barcelona, the company manufactures freeze-dried and sterile vials as well as liquids, syrups, solids and semi-solids.

Versatile weighing areas provide enhanced flexibility

According to Luis Alonso, Reig Jofré engineering manager, one of the most important projects in this endeavor was to develop a new weighing area that provided sufficient versatility for collaboration with third-party customers. The design of the new weighing areas had to account for material and personnel flows as well as international compliance requirements. Furthermore, seamless connectivity of the weighing equipment and easy integration into existing formulation and inventory management systems were critical.

Safe weighing in hazardous areas

Based on these prerequisites, METTLER TOLEDO designed three weighing cabins. The first cabin is specifically equipped to weigh products in a sterile environment that can be potentially active in medium degrees. Furthermore, this cabin is adapted to allow the weighing of photosensitive materials. The second weighing cabin is classified as Hazardous Area ATEX Zone 2/22 and enables the weighing of highly flammable materials, such as alcohol. The third weighing cabin is used to weigh oral and topical products. In addition, a separate room has been set up to weigh closed drums that do not need to be opened. That room, in contrast to the three weighing stations, is not under laminar flow.

Reig Jofré already used METTLER TOLEDO products and hose the company to help plan and implement this ambitious project due to its existing relationship

The METTLER TOLEDO weighing system includes floor and bench scales as well as a weighing terminal.

and METTLER TOLEDO's excellent reputation. Existing KC120 weighing platforms from METTLER TOLEDO were adapted and extended with the application weighing terminals and X4002SX laboratory balances. That setup is fully compliant with Hazardous Area Zone 2/22 and is seamlessly integrated with existing inventory management and formulation systems.

Furthermore, all equipment and software solutions meet the required certifications to comply with FDA regulations. The METTLER TOLEDO Service Team performed all of the calibrations. The team also was awarded the overall service contract.

Combining a broad portfolio and global reach

"First, we had to meet carefully planned project deadlines to prevent production disruptions when changing from the old to the new system," says Ramirez. "Second, we required an equipment portfolio that fulfills both regulatory requirements and Reig Jofré's high quality standards. Finally, we required the ability to provide equipment globally while also offering local support at a sales and technical level as well as extensive software knowledge. "As important as those abilities is our relationship of mutual trust with METTLER TOLEDO that certainly helped make this project a success."

www.reigjofre.com
www.mt.com/pfk9

From Standalone to Fully Networked
Compliant, Efficient, Adaptable SQC

FreeWeigh.Net® software solutions can fulfill all of your quality control needs, whether you work with a single station or fully networked production solution. FreeWeigh.NET Compact provides a highly capable, convenient SQC and SPC system on a single station. With production growth, it is easy to upgrade to the fully networked system.

www.mt.com/SQC

Our Solutions

Our standalone solution

FreeWeigh.Net Compact is a PC-based standalone software solution that allows you to control and fine-tune your processes. The base package contains a batch management module, as well as a multicomponent horizontal and vertical weighing functionality. Benefits include:

- Single station SQC solution that is easy to set up, operate and adapt to your process.
- Validation support and compliance with GMP, EU and FDA regulations.
- Fast and easy upgrade to full FreeWeigh.Net to grow with your process.

www.mt.com/Freeweighnet-compact

Our fully networked solution

FreeWeigh.Net is a powerful, networked SQC solution for factory-wide data acquisition with an MS SQL database and vast expansion capabilities. In addition to avoiding batch waste, FreeWeigh.NET allows ad hoc reporting of any asset to demonstrate compliance with legal requirements. Benefits include:

- Complete quality and process control with a flexible and scalable client-server network.
- Automated batch release and extensive reporting capabilities.
- Connectivity to third-party devices, including tablet testers, PLCs or controllers.

www.mt.com/Freeweighnet

Your benefits from both solutions

Benefit from precise production control

With a quick response to any deviations and immediate notifications via email or SMS, FreeWeigh.Net helps to prevent raw material waste. Additionally, content control can be amended with attribute control and data from Critical Control Points. Finally, with the trend monitoring of the optional SPC module, process interruptions can be avoided.

Ensure compliance and data integrity

FreeWeigh.Net provides full support for FDA 21 CFR Part 11 and EU Annex 11 compliance, including complete user management, electronic signatures and audit trail. Comprehensive documentation and complementary services are provided for efficient software validation.

Compliant, Start to Finish
Traceable Filling and Reporting

An Indian pharmaceutical company needed to secure safe data printing from scales in hazardous filling areas. A customized intrinsically safe weighing solution ensures worker safety while providing traceable recordkeeping, resulting in better productivity and more time for value-added activities.

A pharmaceutical company based in India develops, produces and sells raw materials, intermediates and APIs for anti-infectives and other therapies. This includes handling of potentially explosive materials. Workers prepare those substances for shipment in hazardous areas classified as ATEX Zone 1/21 and Zone 2/22.

Inefficient manual documentation

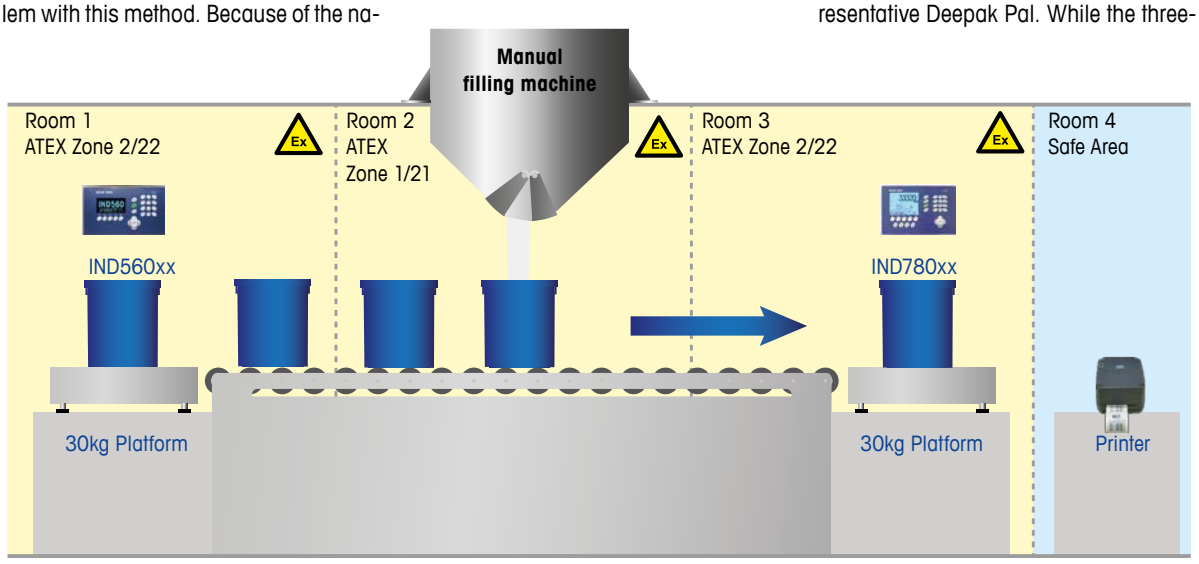
Before shipping, operators must capture the weight of each outgoing container. They keep one report for internal records and send a copy with dispatched material. While effective, there was one problem with this method. Because of the nature of the hazardous-area handling, all records were completed by hand. Those handwritten logs then had to be entered into spreadsheets after the shift. This process not only came with a risk of human error, it also took a significant amount of time that operators could have put to use completing other value-added tasks.

A complex process

The company's process necessitated the use of three rooms, which added complexity. In room 1, which is classified Zone 2/22, empty containers are weighed and placed on a conveyor belt. The belt moves the containers to room 2 – a Zone 1/21 hazardous area – where they are filled to a 20 kilogram capacity. Finally, filled containers are conveyed to another Zone 2/22 area, room 3, where they are weighed again. Could company management find a cost-effective way to bring electronic recordkeeping and traceable report printing to this multi-step, paper-based process? In a word, yes.

Integrated documentation

The solution, which involved report generation directly from intrinsically-safe scales, came from METTLER TOLEDO India representative Deepak Pal. While the three-



Pictured is a fill line with IND560xx and IND780xx hazardous-area weighing terminals and a safe-area printer, according to customer requirements.

room process remains unchanged, today the new equipment configuration for the fill line (Figure 1) includes:

- A PBA430 platform with 30 kilogram capacity and IND560 weighing terminal are installed in room 1, where the attending operator tares empty containers.
- The scale is connected to an IND780 weighing terminal with another PBA430 weighing platform in room 3 via RS485 cabling. Here the attending operator obtains and accepts the net weight after automated filling in room 2.
- Data from both scales is stored in the IND780 terminal.
- Printouts are generated in a nearby safe area via an Epson printer connected via RS232 cabling.

Safe and compliant processing

With the intrinsically safe nature of the new set-up, the operation adheres to hazardous-area standards, keeping workers safe. With the new scales and reporting capabilities, the operation also maintains airtight traceability. All product details, batch numbers, processing date/time and tare/gross weight are catalogued for internal quality control and client recordkeeping.

A consultative service approach with Pal and other METTLER TOLEDO representatives working alongside the company's process experts has helped ensure that management has a solution they feel confident about. In addition, the company is saving two man hours per day on operations plus the added savings from eliminated operating and documentation errors.

"Company management was able to secure the budget, and the equipment they chose will provide returns many times over in the coming years," Pal says.

www.mt.com/ind560x
www.mt.com/ind780

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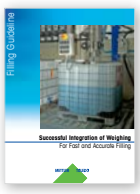
www.mt.com/ind-large-volume-filling-guideline



Passing the Audit
Risk-Based Process Verification

Do you have an informed response when an auditor asks, "Why are you using this weight to calibrate the scale?" Klosterfrau Healthcare Group always has a competent answer regarding their routine balance testing and weighing processes, making it easier for them to pass audits in the highly regulated pharmaceutical industry.

For more than 200 years, the German-based company Klosterfrau Healthcare Group has been developing, manufacturing and selling pharmaceutical products. Its portfolio combines traditional remedies with modern drug therapies and encompasses more than 30 brands and nearly 220 over-the-counter products.

At its Berlin site, the company runs state-of-the-art production lines. Scales and balances, whether in quality control or production, are an integral part of the process. Every piece of weighing equipment in use must be regularly calibrated and qualified to ensure regulatory compliance.

The compliance challenge

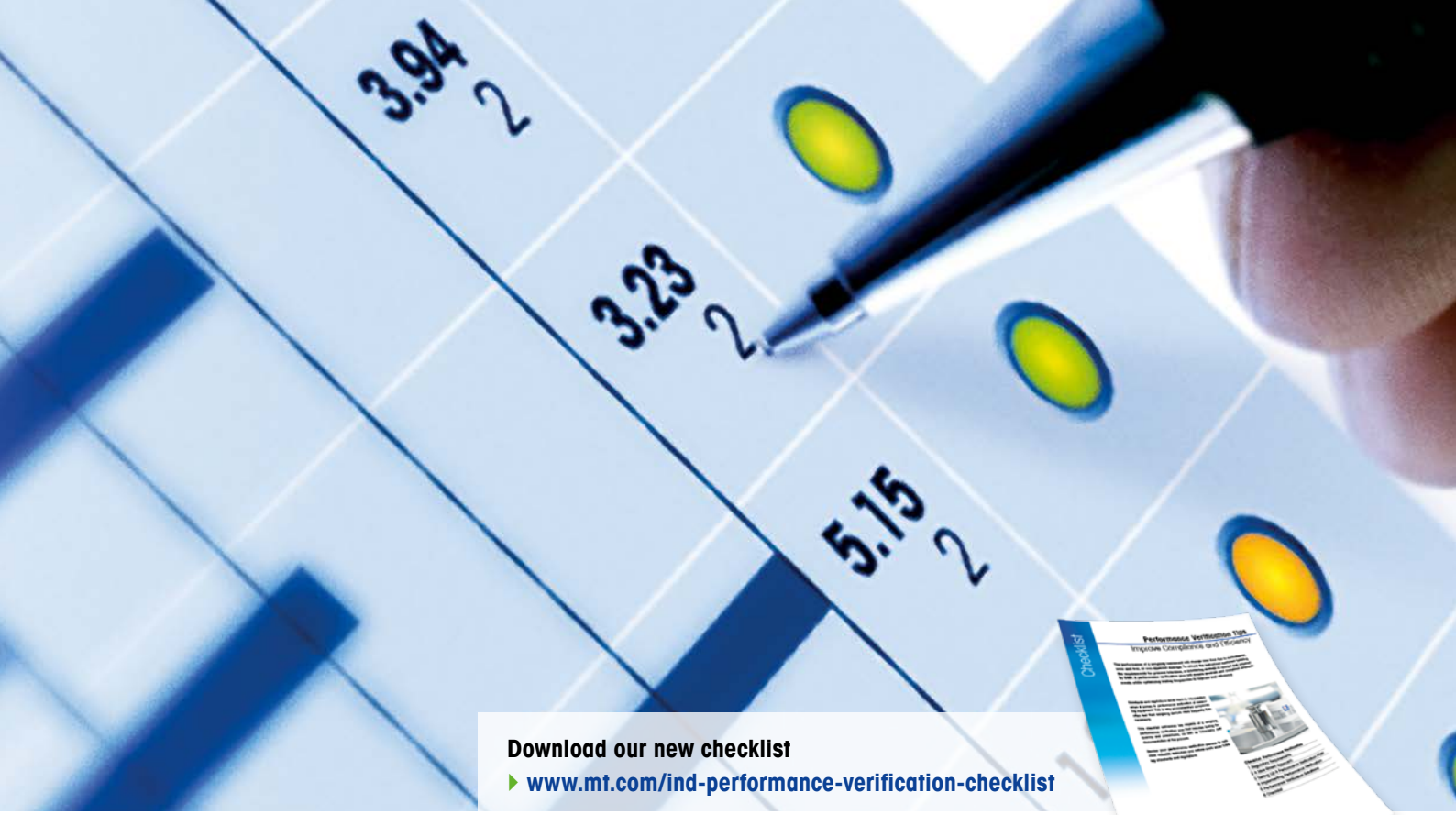
The challenge for Claudia Brostmeyer, Head of Quality Control at the Berlin site, is to ensure that all workplaces – with their variety of processes and responsibilities – calibrate and qualify weighing equipment according to stringent Good Manufacturing Practice and Good Laboratory Practice standards.

Running a compliant weighing station is more complex than it may seem. In addition to making sure that a scale or balance is suitable for the application, sound documentation must prove that suitability to auditors. Operators also must be trained according to valid standard operating procedures to ensure periodic equipment testing, calibration and qualification is done accurately.

When Brostmeyer learned about Good Weighing Practice™ (GWP®) Verification from METTLER TOLEDO, she immediately recognized that this approach would make her life easier. "GWP is a well-thought-out and accepted concept that provides a scientific basis for our weighing equipment verification needs," she says.

Risk-based process assurance

After METTLER TOLEDO conducted a GWP Verification assessment at Klosterfrau's Berlin site, Brostmeyer received a risk-based assessment and testing recommendations for each scale and balance.



Download our new checklist

www.mt.com/ind-performance-verification-checklist

"What I like about the verification document is that it clearly states whether the equipment is suitable for the given process. It also provides recommendations on which tests should be conducted at which intervals with which test weights," says Brostmeyer. "That makes it easy for me to instruct operators and maintenance personnel on appropriate testing procedures." Shortly after METTLER TOLEDO verified the weighing equipment, a production audit put the new process to the test, leaving no questions unanswered.

www.klosterfrau.de

www.mt.com/gwp-verification

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Explore our Resource Center on compliant weighing in pharma with a range of tools such as white papers, videos, webinars and more.

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Guides:
The latest information to help you comply with regulations more easily and efficiently.

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