

Weighing Solutions for Pharma Manufacturing

# **9 Ways to Ensure Efficient Compliance** Design Quality into Your Pharma Process



### Introduction

### **Designing Pharma Manufacturing Processes for Quality**

Pharma and biopharma manufacturers face many challenges, such as:

- · Achieving quality in every batch
- Complying with stringent GMP regulations
- Ensuring data integrity
- Reducing the cost of compliance

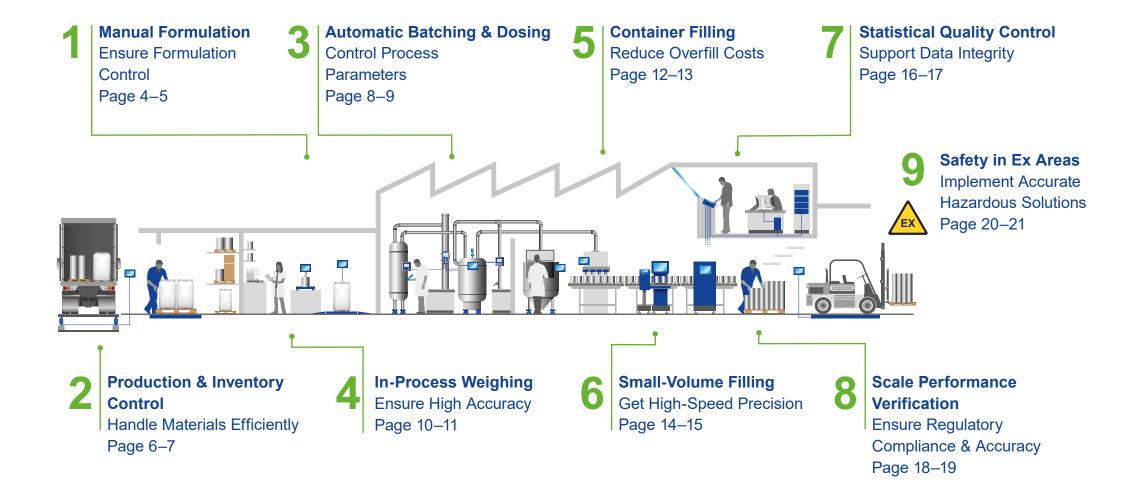
METTLER TOLEDO creates comprehensive weighing solutions and reliable services that help you meet these challenges while improving productivity and profitability.

www.mt.com/pharma



## 9 Ways to Ensure Efficient Compliance

Ensure quality, enhance compliance and increase productivity at critical points in your production process. Explore solutions from METTLER TOLEDO designed with pharma and biopharma manufacturing in mind.



## 1. Manual Formulation

### How can I ensure precise formulation control and full traceability?





#### Tight process control for consistency

Maintaining efficient and compliant workflows at multiple workstations can be challenging. Formulation management with tight process control ensures repeatable batch quality.



#### Process efficiency in complex set-ups

Creating production orders, planning workflows and instructing operators can be time consuming. When done efficiently, operators are freed up for value added tasks.



#### Automatic & traceable documentation

For quality critical process steps, full batch documentation is required. Solutions that create this documentation automatically help you achieve GMP compliance more easily.

## 1. Manual Formulation

### Manage process complexity, avoid operator errors, and stay compliant

Your solution will depend on the complexity of your formulation and batch size. Step-by-step guidance for manual workflows helps you prevent errors. Our networked software solutions can deploy instructions to multiple workstations and automatically capture data for efficient recipe management.

www.mt.com/ind-formulation



#### **High-precision scales**

Our floor and bench scales can measure very small quantities with great precision, even with a high preload. Scale consolidation allows you to create efficient workflows.





#### Networked software for full control

Our formulation software helps streamline processes in the dispensing room and eliminate many reasons for out-of-spec batches. Simplify your software validation in line with 21 CFR Part 11 or EU Annex 11.

#### www.mt.com/Formweigh



## 2. Production & Inventory Control

### How can I accurately measure materials and avoid contamination?





#### Ensure accurate, repeatable results

Many level measurement techniques are influenced by temperature or physical state that can adversely affect accuracy. When precision matters, weighing is the best way to ensure repeatable results regardless of material type.



Reduce downtime with condition monitoring

Sensors in storage tanks can be difficult to reach and inspect. Remote monitoring allows for much more efficient maintenance and can significantly increase uptime.



#### Eliminate contamination risks

Production environments have become increasingly complex and so have the challenges to ensure a contamination-free process. Hygienically designed equipment speeds up and simplifies cleaning.

## 2. Production & Inventory Control





www.mt.com/ind-tank-weighing





#### Hygienic weigh module

SWB805 Hygienic MultiMount™ reduces the risk of contamination and shortens cleaning time due to its highly polished self-draining surfaces. Easy integration is possible.

www.mt.com/ind-SWB805



#### Indicators with a hygienic metal keypad

Our metal keypad consist of one solid stainless steel plate without any physically accessible buttons. This eliminates the risk of residue or water accumulation on the surface.

www.mt.com/ind-metal-keypad







www.mt.com/ind-video-sanitary-wm

## 3. Automatic Batching & Dosing

### How can I optimize batching and dosing processes?





# Save production cost and reduce downtime

Long batching sequences can create production bottlenecks. Optimizing the speed and timing of dosing steps leads to better operational efficiency and plant utilization.



#### **Optimize accuracy, speed & quality**

Automatic dosing depends on the interplay between scale, valves and material flow properties. Working with the right solution helps you hit targets more easily.



# Obtain flexible & user-friendly system integration

Dosing systems are often part of a plantwide automation system. Standardized interfaces and protocols make integration faster and reduce training effort.

## 3. Automatic Batching & Dosing

## Ensure precise dosage with smart weighing systems

A completely automated system creates a reliable and robust production process by enabling the fast and accurate sequencing and dosing of expensive materials. In such a system, diagnostic tools are required to ensure continuous uptime, minimize waste and improve accuracy.

www.mt.com/batching

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#### **Automation terminals**

For fast and efficient automatic batching and dosing of materials, our range of automated terminals offer high performance and versatility for a wide range of applications.

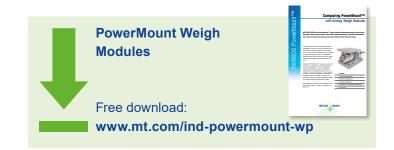
www.mt.com/ind-tank-silo-hopper



PowerMount<sup>™</sup> weigh module

Provide repeatable accuracy and the industry's highest reliability in hazardous and non-hazardous areas. Performance of POWERCELL load cells can be monitored and provide alerts prior to serious trouble.

www.mt.com/ind-powermount





## 4. In-Process Weighing

### How can I optimize my production workflow?





#### Avoid cross-contamination

In multi-purpose plants, various materials are handled at different workstations. Highly functional, hygienically designed equipment prevents cross-contamination while increasing process efficiency.



#### **Ensure error-free production**

Operators have to follow complex SOPs at many workstations. Smart equipment provides operator guidance to ensure that every step is followed exactly as intended in order to prevent quality-critical errors.



#### Create mobile and adaptable workflows

Single-use and mobile equipment helps to increase production efficiency and lets you more easily adapt to changing demands. Low-profile and mobile equipment supports the trend towards greater production flexibility and removes obstacles in production flow.

## 4. In-Process Weighing

### Adapting workflows efficiently

Accurate weighing helps you document every production step, ensure compliance with regulations and improve your product quality. Our high-precision weighing solutions offer industry-leading metrological performance and ensure consistent weighing results when tolerances are tight.

www.mt.com/ind-precision-weighing



#### High-precision hygienic floor scales

Contamination can have costly or even lethal consequences. Hygienically designed low-profile floor scales with electropolished surfaces, approved steel grades, and liftable load plates prevent cross-contamination.

www.mt.com/ind-ss-floorscales



#### **PowerDeck<sup>™</sup> floor scales**

POWERCELL<sup>®</sup> technology eliminates errors and helps improve yields with clear operator guidance to ensure proper placement. Loadcell performance monitoring keeps your process in control and avoids faulty batches.

www.mt.com/powerdeck



## 5. Container Filling

### How can I ensure an accurate and efficient filling process?





#### **Optimize cost**

Pharmaceutical ingredients are costly and even small amounts of overfill add up. Using the full functionality of your weighing devices can ensure accuracy, help avoid product waste and stay compliant easily with net content regulations.



#### Automated data collection

If a quality issue occurs, easy tracking and tracing of product and container data ensures quick identification of faulty batches. Automatic data transfer to central databases helps you create process improvements and ensure more efficient recall management.



#### **Increase uptime**

Many filling processes have very narrow specifications yet require rapid throughput. Process control technology helps you avoid the kind of unnoticed equipment failure or improper handling that can negatively impact production quality.

## 5. Container Filling

### Streamline filling processes for every type of container



When filling intermediate bulk containers, totes, drums or big bags, you need fast, precise, and repeatable results. Our platform and floor scales provide predictive maintenance for increased uptime and peak operational efficiency.

#### www.mt.com/filling



#### **IND570:** Automated filling

www.mt.com/ind570

The IND570 offers easy-to-configure software routines, discrete I/O, material storage tables, and more to enable accurate control of filling operations. All data is easily transferred to your MES or PLC.



#### Versatile floor scales

An array of reliable, precise, and robust floor scales can be tailored for your application. Whether you need hazardous-area accuracy, a specific size, or a certain diagnostic function, we have a solution.

#### www.mt.com/floor\_scales



## 6. Small Volume Filling

### How can I ensure precise filling of small containers?





#### Create 100-percent in-process fill control

Equipment breakdowns in vial filling processes are not an option. Measuring devices must be robust, reliable and able to accurately record the smallest weights at high speed for full in-process control.



#### **Ensure full sterility**

Many filling machines are in clean rooms that require the highest levels of sterility. Clean-in-place solutions allow for efficient cleaning protocols that avoid contamination while increasing uptime.



#### Gain high throughput and variable filling

Filling in pharma is fast but it must also be adaptable to accommodate various container sizes. As medications become more personalized, both adaptability and machine speed are critical to ensure you meet throughput demands.

## 6. Small Volume Filling

### Accurate and fast filling of small containers

Weighing is the easiest, most accurate, and hygienic method for filling syringes, vials, ampoules and tubes. Our comprehensive range of weighing solutions can meet the most challenging small volume filling requirements with respect to speed, accuracy, variability and automation.

www.mt.com/ind-small-volume-filling





#### Sensors for automated weighing

Our high-accuracy weigh modules measure at the fastest speeds and highest resolutions. With their robust design and integrated electronics, they fulfill the highest requirements of machine manufacturers.

www.mt.com/APW



#### WMF high-precision weigh modules

With its compact design, fully integrated electronics and industrial Ethernet interface, the WMF module performs in challenging applications and tight spaces. Fast real-time data transmission to PLC is possible.

www.mt.com/WMF



## 7. Statistical Quality Control

**METTLER TOLEDO** | 16

### How can I ensure precise filling and prove it to auditors?





#### **Monitor fill control**

SQC solutions provide automated reporting and allow immediate trend recognition. Quality parameters can be efficiently monitored and managers can be alerted when process deviations arise.



#### Be compliant with net-content regulation

Net-content laws mandate that every package contain the amount declared on the label. SQC solutions ensure regulatory compliance with comprehensive documentation.



#### Ensure data integrity efficiently

Documenting quality critical attributes for every batch is a must. Software that provides user management, electronic signatures, audit trail and many other functions ensures data integrity more efficiently.

## 7. Statistical Quality Control

### **Optimize cost while maintaining compliance**

Strict process control is required when filling hundreds of containers in order to comply with net content regulations. Our SQC solutions help you to ensure precise filling, improve process control, provide full documentation and save costs.

www.mt.com/sqc

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**Standalone solution** 

FreeWeigh Compact is our user-friendly PCbased standalone SQC solution that allows you to control and fine-tune filling processes. It is easy to set up, operate and upgrade when production expands.

www.mt.com/FreeWeighnet-compact



#### **Networked solution**

Freeweigh.Net is a powerful, networked SQC software solution for factory-wide data acquisitions that enables tight and compliant production control. Automated batch release and reporting capabilities ensure quality.

www.mt.com/FreeWeighnet





### 8. Scale Performance Verification

### How can I maintain compliance and increase uptime?





# Achieve high uptime with optimal maintenance efficiency

All precautions must be taken in order to avoid downtime in pharmaceutical production. Regular equipment checks following recommended procedures ensures maximum uptime at minimal cost.



# Optimize service intervals with preventative maintenance

Preventive and predictive maintenance according to manufacturers' procedures ensure efficient and consistent performance throughout the life of your weighing equipment.



# Maintain compliance and be prepared for audits

ISO9001 standards and GMP regulations require regular calibration and control of measuring and monitoring devices. Leverage world-class service to confidently pass future audits.

### 8. Scale Performance Verification

### **Ensure equipment is fit-for-use**

Robust and fit-for-use equipment, documented data integrity, and standardized performance verification are musts in pharma manufacturing. Periodically scheduled scale calibrations and routine testing enhance scale longevity and facilitate streamlined compliance with pharma regulatory standards.

www.mt.com/service



**GWP® Verification** 

GWP<sup>®</sup> Verification is based on a calibration service that documents the measurement uncertainty of weighing equipment under real operating conditions. Learn how this service can ensure process accuracy.

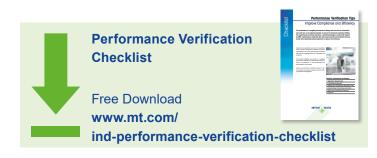
www.mt.com/gwp-verification



#### **Regular calibration**

Calibration determines industrial weighing equipment performance. Our comprehensive calibration services help you to achieve compliance, cost savings and quality.

www.mt.com/calibration-competence



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## 9. Safety in Ex Areas

### How can I ensure safety without compromising functionality?







#### Create an accident-free workplace

Pharmaceutical companies track accidents and achieving a zero rate is their number one priority. Equipment designed with safety in mind is a first step towards achieving this goal.



#### Gain high functionality

Designing processes in hazardous areas requires special equipment, know-how and care. With our Ex-products, you can rely on approved solutions without compromising accuracy or efficiency.



#### Comply with global safety standards

Safety guidelines and regulations are different in each country. Choosing an approved equipment supplier with global reach will ensure easier compliance.

## 9. Safety in Ex Areas

### Designed with safety in mind

When handling explosive materials, weighing equipment must comply with extensive regulations and be installed and maintained correctly in order to ensure safe operation. Choose solutions that help you fulfill your safety standards without compromising functionality.

www.mt.com/hazardous

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Hazardous poster

The easy and quick identification of markings and protection methods help engineers ensure equipment complies with appropriate regulatory hazardous-area standards.

www.mt.com/ind-haz-poster



#### **Hazardous services**

Our experienced, factory-trained service specialists make sure hazardous area weighing equipment is safely installed, inspected, maintained, calibrated and repaired.

#### www.mt.com/ind-ex-service





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## Knowledge at Your Finger Tips

Explore our Knowledge Center on compliant pharma weighing and discover useful white papers, videos, webinars, and more.

#### Webinars:

Learn the latest in regulatory compliance, safety requirements, and technical trends.

#### **Guides:**

Download the latest information to help you comply with regulations more easily and efficiently.

#### Videos:

Quickly gain an understanding of how you can improve efficiency and accuracy in all your weighing applications.

### Visit your Knowledge Center today! • www.mt.com/ind-pharma-compliance

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