

Streamline Compliance

Efficient Weighing in Regulated Industries



METTLER TOLEDO

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Note:

This interactive PDF is optimized for Acrobat Reader.
Other softwares might block some functionalities.





Why Compliance Matters

Meeting Standards, Enhancing Efficiency

Compliance is essential in regulated industries like pharmaceuticals, food & beverage, and chemicals. Regulatory bodies enforce various standards to protect consumers and the environment. Failure to comply can lead to fines, harm to a brand's reputation, and worse.

This guide outlines key requirements for regulated industries and presents solutions that can help you meet applicable standards while enhancing your operational efficiency.



Data Integrity and Traceability

Safeguarding Accuracy in Data Management

Reliable management of weighing instrument data is crucial in regulated industries. Compliance requires proper handling, secure storage, and prevention of tampering. Examples of regulations with data handling requirements include:

cGMP

Current Good Manufacturing Practices are standards for consistent pharmaceutical, food, and medical device production.

FSMA, Final Rule (204)

The Food Safety Modernization Act is a U.S. law aimed at preventing foodborne illnesses. Final Rule 204 focuses on traceability.



ALCOA++

This U.S. Food and Drug Administration (FDA) acronym represents critical data integrity concepts.

GFSI

The Global Food Safety Initiative is retailer-driven and aims to ensure that facilities process safe food.





Details at a Glance

Pharma vs. Food

Pharma: 10 Principles of ALCOA++

- | | |
|---------------------------|---|
| 1. Attributable | Data must be linked to the party who created it. |
| 2. Legible | Data must be clear and readable. |
| 3. Contemporaneous | Data must be collected at the time of activity. |
| 4. Original | The master data record must be original. |
| 5. Accurate | Data must be unedited and free of omissions and errors. |
| 6. Complete | The record must include all data and metadata. |
| 7. Consistent | Data must be internally consistent (not contradictory). |
| 8. Enduring | Data must survive for required periods. |
| 9. Available | Data must be retrievable for authorized parties when needed. |
| 10. Secure | Data should be protected against unauthorized access, editing, or deletion. |

www.mt.com/ind-data-integrity-ph

Food: FSMA Enhanced Copliance Standards

- | | |
|-------------------|---|
| Retained | Businesses must maintain records for a minimum of two years. |
| Formatted | Records must be kept in an electronic spreadsheet format that can be sorted to facilitate rapid access in the event of foodborne illness. |
| Accessible | Exporters must provide records within 24 hours of an FDA request. |
| Legible | All records must be legible in either electronic or paper format. |

www.mt.com/FSMA-Webinar



Maintain Data Integrity and Traceability

Finding the Right Solutions

Advanced weighing equipment can enhance accuracy, efficiency, and regulatory compliance. Choosing scales and software that can assure traceability helps with compliant recordkeeping, while automated data capture improves efficiency. Solutions include:

Form+ and FormWeigh.Net®

Formulation software gives you complete control over your recipe management process. Features include:

- Automated data capture
- Easily standardized SOPs
- Accessible reporting tools

► www.mt.com/formplus

► www.mt.com/formweigh.net

IND400 and 700 Weighing Indicators

Advanced indicators provide on-demand, verifiable documentation and reporting tools. Features include:

- An intuitive display
- Secure data access
- ALCOA++ support for pharma
- Electronic records

► www.mt.com/ind400

► www.mt.com/ind700





Hygienic Design and Cleaning

Ensuring Product Safety and Purity

Cross-contamination affects product quality and can lead to recalls. Organizations like the FDA and GFSI stress that equipment must be designed to prevent contamination and facilitate cleaning. Examples of hygienic design requirements include:

GMP Cleaning Validation

The FDA and GFSI emphasize effective cleaning through GMP/cGMP, which specify how to assess equipment cleaning for food and pharma applications.

www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations



Hygienic Design Guidelines

The European Hygienic Engineering & Design Group (EHEDG) and NSF International offer guidelines and training in sanitary food equipment design practices.

<https://www.ehedg.org/>



Cleaning Tools/Equipment

Visualize the full production picture to make data-driven decisions for your critical processes. With flexible communication options, easily connect indicators to your ERP, MES, or PLM system.

<https://www.brcgs.com/our-standards/food-safety/>





Preventing Material Accumulation and Cross-Contamination

While some variations exist between food, pharma, and chemical regulations, in general, weighing equipment used in highly regulated environments must be:

Cleanable

Scales and balances must allow effective cleaning to prevent bacterial growth.

Made of compatible materials

Equipment must be compatible with the product and cleaning chemicals used.

Accessible for inspection, maintenance, and sanitation

All equipment parts should be accessible without tools.

Designed to prevent product or liquid collection

Weighing equipment must self-drain to prevent accumulation.

Hermetically sealed

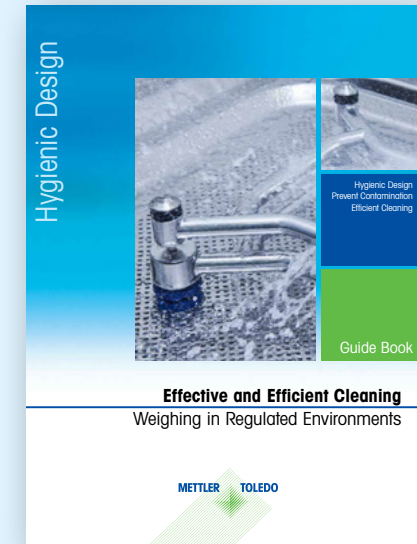
Hollow areas must be sealed or minimized; attachments must be welded.

Without cracks or pits

Equipment parts must be free of deformations that can harbor bacteria.

Compatible with other systems

Design must be compatible with electrical and hydraulic systems.



www.mt.com/ind-hygienic-guide



Meet Hygienic Guidelines

Finding the Right Solutions

In regulated environments, scales are regularly sprayed with high-pressure water or flooded with water and chemicals during cleaning. Weighing solutions that help facilitate cleaning and regulatory compliance include:

Bench Scales

Hygienically designed bench scales improve cleaning efficiency by up to 40 percent.

Features include:

- Open construction
- IP69K protection
- Hygienic foot design

► www.mt.com/BBA4-BBD6

Floor Scales

Hygienically designed floor scales enable ease-of-use, making it a natural for minimizing risk in clean rooms.

Features include:

- 360° cleaning
- 100% visual inspection
- Certified hygienic design
- Reliable lifting

► www.mt.com/PHD779

Weigh Modules

A range of hygienic weigh modules have been optimized for tank applications.

Features include:

- Certified hygienic designs
- Faster, thorough cleaning
- Easy integration

► www.mt.com/SWB805



Statistical Quality Control and Performance

Fulfilling Net Content Rules

Product bottles, boxes, and other packages typically display net weight or volume. Underfilling is prohibited and overfilling can become expensive. Additionally, items like pills or vials must contain stated ingredient amounts to ensure safety. Net content regulations include:

Net Compliance USA

The National Institute of Standards and Technology provides comprehensive guidelines for verifying the net content of packaged goods through NIST Handbook 133.

www.nist.gov



Net Compliance Europe

WELMEC Guide 6.5, which offers controls for 'e' marked prepackages, provides for the harmonized implementation of Directive 76/211/EEC.

www.welmec.org



USP

The USP sets guidelines for identity, strength, quality, and purity. Items like capsules and pill bottles as well as food and pharma ingredients must contain amounts consistent with labeling.

www.usp.org





Net Content Control

Examples of Guiding Regulatory Principles

Net Content Compliance – NIST

NIST sets rules for packaging, including:

- The average net content of the packages in a lot must not be below the value declared on the label.
- Packages underfilled by more than the Maximum Allowable Variation (MAV) are considered unreasonable errors.
- No unreasonable errors are allowed for lots of up to 3,200 units, and only one is permitted for lots over 3,200 units.

Net Content Compliance – WELMEC

WELMEC defines permissible errors:

- The actual contents shall not be less, on average, than the nominal quantity (Q_n).
- The proportion of prepackages with a content below the tolerable negative error (TNE, T1) must not exceed 2-2.5% of the batch (dependent on country).
- No prepackage shall have a content that is below $2 \times \text{TNE}$ (T2).

Pharmacopoeia Guidelines

Content control depends on the product attributes being considered. For example:

- The USP permits overfill in injection vials to aid withdrawal and ensure the labeled volume can be administered. The net quantity on the label reflects the minimum product amount.
- Eurasian pharmacopoeias set tests such as Content Uniformity and Mass Variation for tablets, granules, and powders.



www.mt.com/ind-sqc-guide



Net Content and Statistical Quality Control

Finding the Right Solutions

Manufacturers often overfill products to avoid underfilling, leading to higher costs. Dynamic and static checkweighers can help you meet regulatory requirements, optimize filling processes, and keep costs in check. Solutions that can help include:

FreeWeigh.Net® for SQC

Static scales enabled with FreeWeigh.Net® software ensure compliance with packaging regulations.

Features include:

- Operator-assisted random sampling
- Requires less production space
- Allows fast product changes

► www.mt.com/FreeWeigh

Automatic Checkweighers

Dynamic checkweighers ensure products are accurately filled and meet regulations 100 percent of the time.

Features include:

- Continuous weighing
- High throughput
- Sort-out for rejected packages
- Less operator intervention required

► www.mt.com/checkweighing



Hazardous Areas and Safety

Ensuring Faster, Compliant Weighing

Hazardous areas are subject to stringent regulations for obvious reasons. However, safety protocols can slow down weighing processes. Achieving reliable weighing quality can also be challenging. Key hazardous-area standards producers must meet include:

ATEX

ATEX comprises two EU directives for explosive atmospheres: ATEX 114 focuses on equipment design to prevent ignition risks, while ATEX 153 requires risk assessments and safety measures for worker protection. Together, they set safety standards to minimize explosion risks.

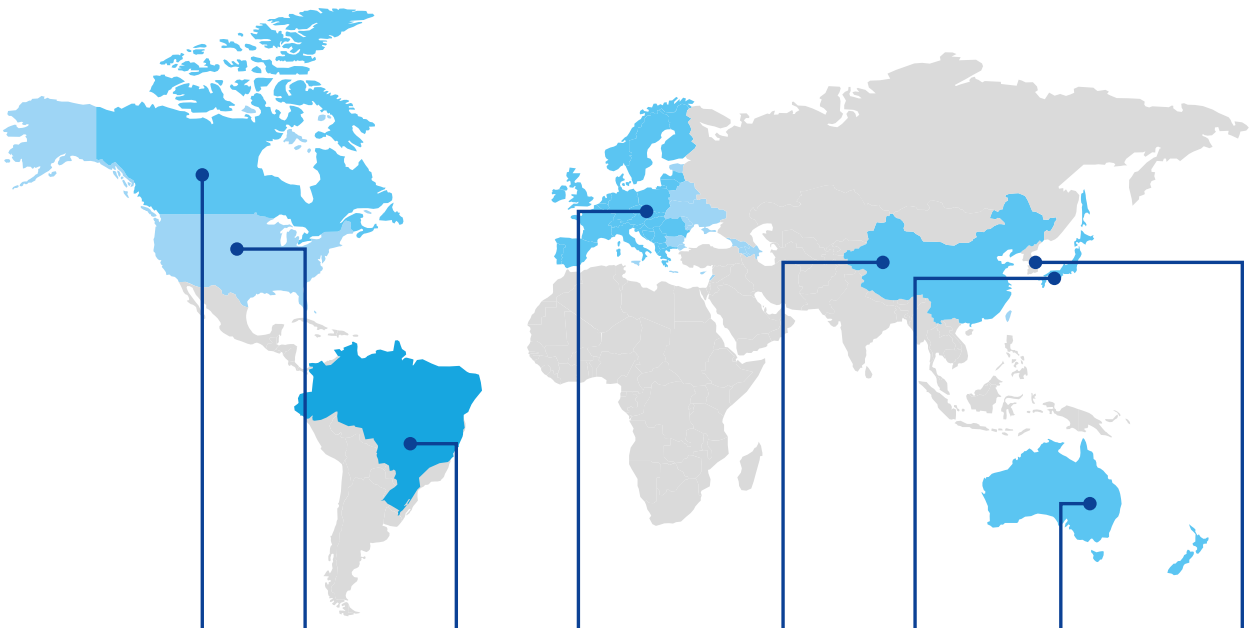
<https://single-market-economy.ec.europa.eu>



IECEx

IECEx is an international system that provides standards and certification for equipment and services in explosive atmospheres. It harmonizes global certifications so manufacturers can demonstrate compliance in hazardous environments.

<https://www.iecex.com/>



Country	Canada	USA	Brazil	Europa	China	Japan	Australia	Korea
Guideline	CEC	NECTM	INMETRO	ATEX	CCC	MHLW	IEC	KOHS
Standard	CSA	FMUL	INMETRO	CENELEC	GB 3836.x	JNOSHI	IECEx	KCs
Testing marks (nationally accredited Testing labs or official mark)	Examples:  	Examples:  					 	



The Basics of Explosion Protection

Flammable or explosive substances may be present in certain production areas in the form of gases, vapors, mist, or dust clouds. To eliminate explosion risk, one of the three elements of the “Triangle of Fire” – flammable substances, oxygen, and ignition source – must be removed. Mitigation generally takes one of two forms:

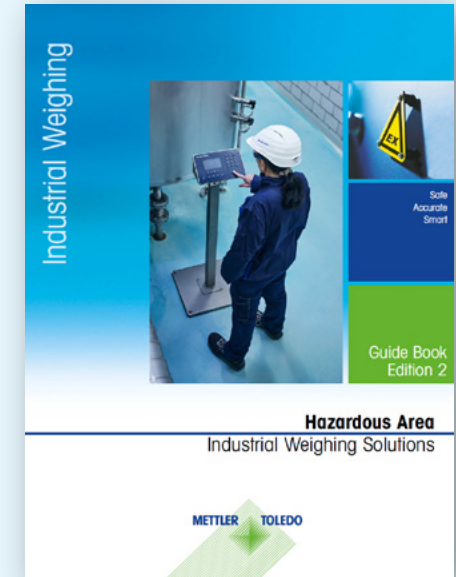
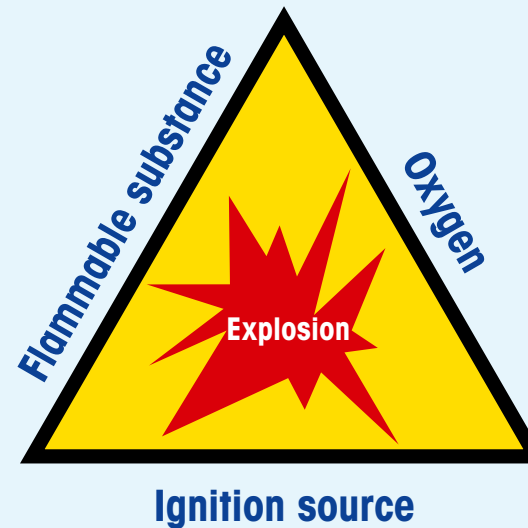
Primary explosion protection

Prevents the formation of a potentially explosive atmosphere. Substituting non-flammable substances for flammable ones, using gas detectors, and ventilating key areas are part of primary explosion protection.

Secondary explosion protection

Removes ignition potential in hazardous areas. This includes utilizing spark-resistant housing, implementing proper earthing and conductivity, and avoiding hot surfaces through intrinsically safe circuit design.

3 Components of Explosions



www.mt.com/ind-hazguide



Hazardous-Area Weighing

Finding the Right Solutions

Meeting international safety standards helps to ensure safe operation in explosive environments, and certified weighing equipment is crucial for compliance. The right solution will also enhance reliability and user confidence while reducing error risk.

Approved Indicators

Our hazardous-area approved weighing indicators deliver consistent quality in Ex-areas.

Features include:

- Process control
- Error-free operation
- Filling and formulation applications

► www.mt.com/ind500x

Secure Platforms

Hazardous area scales and platforms enable safe and reliable weighing in explosive environments.

Our instruments are designed for:

- Highest accuracy
- Peak throughput
- Unmatched efficiency

► www.mt.com/powerdeck

Mobile Applications

Connect to an external battery for mobile applications or to a power supply for installation in Division 1.

These solutions are:

- Intrinsically safe
- Flexible
- Cost Effective

► www.mt.com/ind256x

Scheduled Maintenance and Service

The Cornerstones of Ongoing Compliance

Choosing the right weighing equipment is only part of the equation for compliant production. Regular verification, testing, and calibration from certified service technicians further minimizes compliance risks. Service solutions for compliance can include:

Accuracy Calibration Certificate



The METTLER TOLEDO ACC Certificate evaluates a scale's entire weighing range to ensure accuracy.

Preventive Maintenance



Regular maintenance and performance verification assure accuracy and uptime.

Good Weighing Practice™



METTLER TOLEDO's GWP® is a tool that demonstrates a scale can produce compliant accuracy in its intended application.

Equipment Qualification



Professional installation and equipment qualification can ensure compliance performance.



www.mt.com/gwp



The Right Service Package Makes the Difference

METTLER TOLEDO service packages are designed to enhance accuracy, productivity, and compliance in a wide range of regulated applications so that you can be confident that your operations comply with local and international regulations. Our comprehensive range of products and services offers you:

Spare parts and kits

All our parts meet high-quality specifications, ensuring reliable operation and compliance.

Safe installations

Our certified service technicians are trained to ensure safe installation and calibration so your production sites remain compliant and agile.

Equipment qualification

Our care packages support equipment qualification and performance verification for efficient, compliant weighing.

Operator training

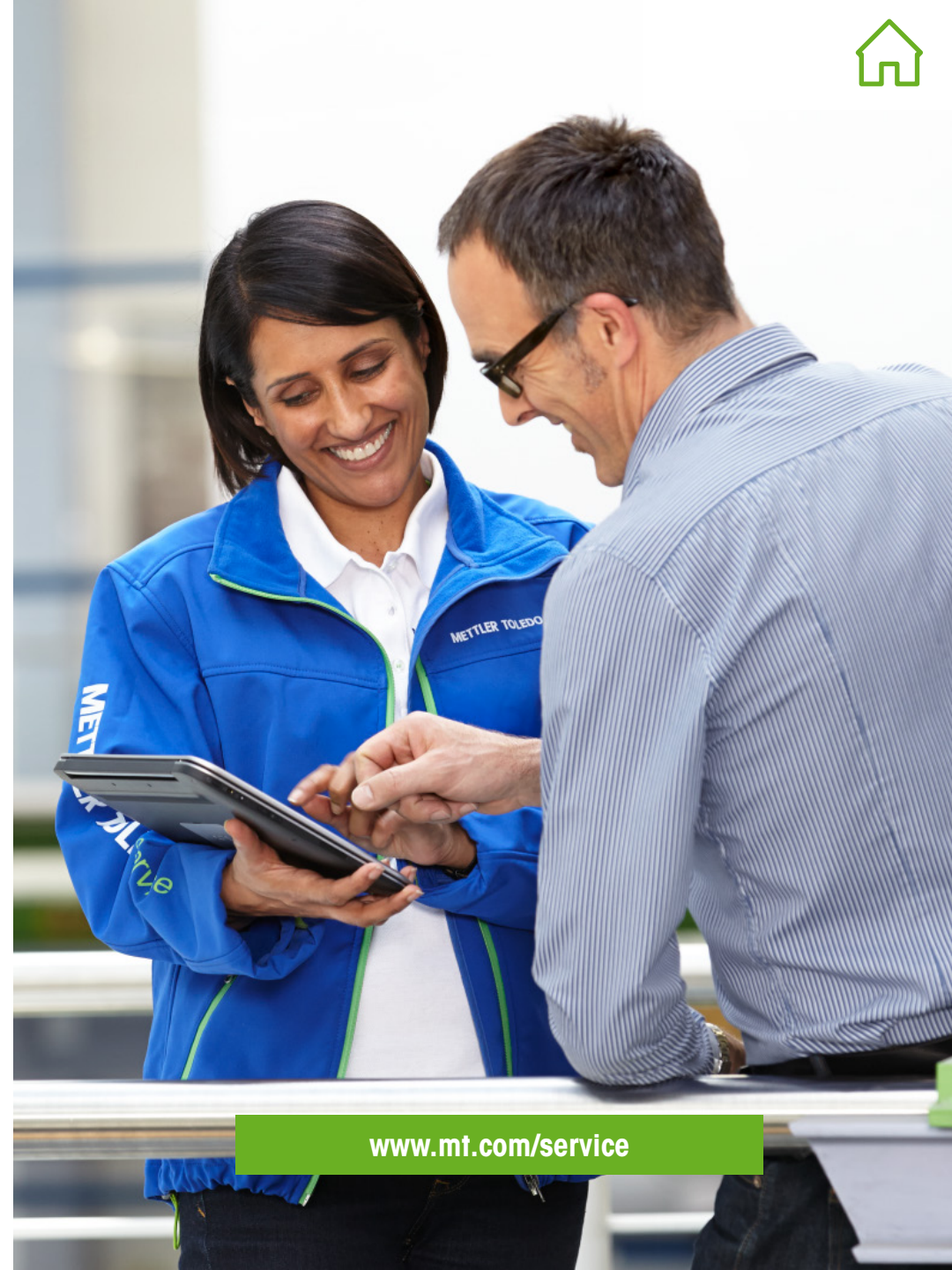
We offer training for both basic and advanced equipment use so that you obtain high performance and ongoing accuracy.

Full asset control

We offer detailed service reporting for full transparency so that you can proactively manage your weighing asset maintenance.

Response times you can rely on

A defined maintenance strategy is crucial for uninterrupted operation. Our standardized service levels and remote support maximize uptime and productivity.



www.mt.com/service



Choose The Right Care Package

Assuring Accuracy in Regulated Industries

Equipment validation, maintenance, and documentation are essential—and scheduling these services is the best way to ensure ongoing compliance. Our care packages let you match service level to application so you can maintain asset control and product quality.

	No Contract	BasicCare	StandardCare	ComprehensiveCare ExtendedCare
 Performance				
Planned Preventive Maintenance	✗	✓	✓	✓
Operational Testing	Functional Testing only	✓	✓	✓
 Compliance				
Calibration and Verification	On request	Added to service contract according to your requirements and regulations		
GxP – Good Measuring Practices	On request	Recommended, preferred rates may apply		
Planned Calibration	✗	✓	✓	✓



Additional Resources

Tools for Optimizing Compliance

Hygienic Solutions Video

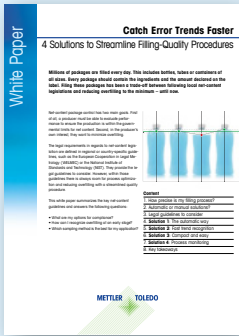
Hygienically designed equipment enables avoidance of contamination and improvements in cleaning efficiency. Learn how hygienic weighing solutions play a critical role in protecting both consumers and products.



Hygienic Solutions Video

Quality Control White Paper

This White Paper describes 7 key considerations including 4 solutions for filling processes that allow producers to catch error trends faster while remaining compliant.



www.mt.com/ind-catch-trend-faster

Hazardous Area Equipment Marking Poster

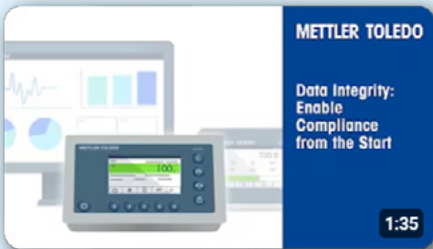
Easy and quick identification of markings and protection methods can help operators ensure weighing equipment complies with appropriate regulatory hazardous-area standards and avoid negative safety consequences.



www.mt.com/ind-haz-poster

Data Integrity Video

Learn how partnering with experienced vendors like METTLER TOLEDO simplifies the process of ensuring data integrity with advanced solutions and support that help maintain high standards throughout production.



Data Integrity Video

METTLER TOLEDO Group
Industrial Division

Subject to technical changes
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