

Improved Production Yield through Computer Based Formulation / Recipe Weighing

Fast changing consumer preferences, pressure from regulatory authorities and growing concerns of consumers about safety of nutraceutical products force the manufacturer to improve the supply chain and take care about the correct formulation procedure.

The safety of nutraceutical products is an infeasible issue often in the mind of manufacturers, suppliers and regulators alike. Numerous regional and international standards (e.g. GMP, ISO, FDA, etc.) have been created over years in order to enhance the quality and the safety of nutraceutical products.

The correct formulation and weighing procedures along with the centralized database and relevant documentation process one of the prerequisite to guaranteed consistent product quality, process safety and stability as well as to increased flexibility and productivity. This paper will address the benefits of investing in the formulation system as well as considerations that helps ensure the system enhances manufacturing process.



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1 Increasing regulatory pressure requires traceability

Certain ingredients used in nutraceutical, such as fragrances and preservatives, can trigger an allergic reaction. These ingredients play an important role in the nutraceutical formulations of consumer choice. The correct procedure of the formulation recipe therefore is one of the crucial importances to avoid negative effect of nutraceutical to consumer.

To prevent such situations and protect consumer the regulators worked out the guidelines norms and standards to ensure traceability of all raw materials, intermediates, formulation recipes, and the finished products.

Essentially, nutraceutical manufactures must document all production processes without any gaps. This includes recipe development, quality control, production planning, monitoring, dispensing and packaging as well as shipping and distribution. The computerized and intelligently networked formulation or weighing system helps to improve efficiency, eliminate waste of cost sensitive raw materials, trace the workflow of all intermediates through the whole manufacturing process and improve quality and safety of nutraceutical products.

A traceability system shall be in place which enables the identification of product lots and their relation to batches in direct contact with intermediates, packaging intended or expected to be in direct contact with nutraceutical product itself. The traceability system shall incorporate all relevant processing and distribution records.

2 True traceable formulation / weighing is computer-based

Truly gapless traceability requires that all involved parties recipe – relevant data – ingredients, structures, work instructions, batch and production order information – into a centralized system. A computer-based system's advantages over a paper-based system include data consistency, speed of data analysis and improved recall management.

An electronic system can also document processes, generate weighing and manufacturing reports, and print labels to identify goods-in-process. This corresponds also the main standard and regulations like GMP, FDA, etc. This type of system is also vital for transparent manufacturing processes and providing a proper decision base for streamlining processes.

End-to-End Documentation

Tracking and tracing demands documentation of all production actions from goods receiving to end-product shipment. To be effective, manufacturers must ensure systems provide relevant data quickly. Some

governments request access even within few hours.

For example, in a recall, a manufacturer must identify:

- Who delivered the intermediates used in batch XY of Vitamine recipe Z?
- What quantity was used?
- Who released the recipe?

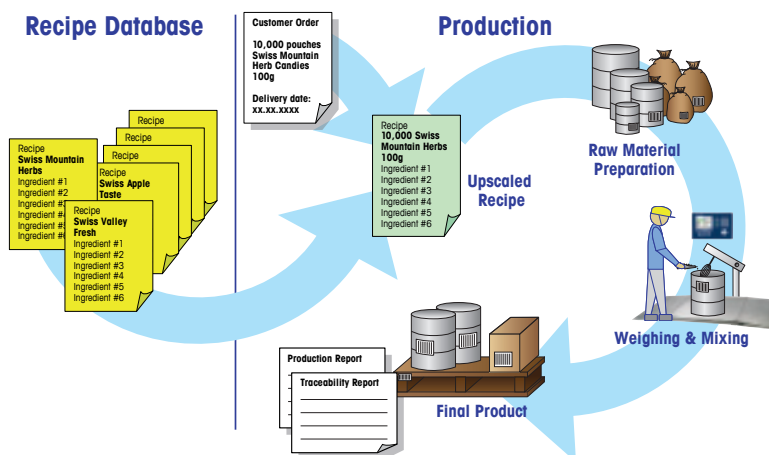
If end-product taste deviates from recipe expectations:

- What area of processing needs to be adjusted?

Most critically:

- How quickly can a manufacturer's current documentation process answer these questions?

In an effective and fully networked system, this information is immediately available when the system offers features such as:



Clearly identified materials via labeling/barcoding.

At each stage a label indicating material and status is affixed. Corresponding entries are made in the database.

Online monitoring. Monitoring functions offer information about exceptional factory situations.

Industry-standard networking. System components communicate with a centralized database via Ethernet LAN. Clients such as dispensing stations and control devices such as balances, scales and other peripherals exchange production data with the server. Windows-compliant applications use standard resources such as network printers for reporting.

Expandability and connectivity. System expansions are possible without disturbing other components unless software is updated. A dedicated ERP Gateway can offer a configurable interface between the solutions and an ERP system such as SAP.

Benefit in Terms of ROI

Virtually any company blending different materials in a well-defined recipe can benefit from a computer based formulation system to streamline procedures. More expensive or higher risk materials will produce the fastest return on investment; however, nearly any processor should be able to prove ROI on an appropriately scaled system in 12 months or less through:

- Reduced consumer risk
 - Enhanced regulatory compliance
 - Less product waste
 - Lower disposal / rework / recycling costs
- all leading to substantial bottom-line enhancements.

3 System components / configuration

A standardized configurable system that has been tuned to manage critical weighing process parameters has many advantages over client-specific systems with custom programming.

Standard interfaces allow a high degree of customization while offering expert system maintenance and support over the life of equipment and software. The initial investment better maintains its value and can secure optimal production performance well into the future.

Master Data Management

In a networked system, a master station allows overall data management and maintenance. This can include tracking of:

- Materials
- Instructions

- Recipes
- Orders
- Preparation batches
- Warehouse status
- Containers
- Operators
- Consumption data
- Exceptions
- Production activities
- Password activities
- User connections
- Database activity log
- Weighing / calibration
- Audit trail
- Electronic and hardcopy reporting on the above

Reliability and security are critical. While processes can be controlled at individual process weigh stations, all process data is gathered at the master station.



Barcodes guarantee simple, fast verification with the connected reader

4 Real-world tracking / tracing

In every production step from goods entry to shipment, database entries correspond to in-process materials. In a computerized system, barcode-reader enabled labels assist with component identification and overall traceability during processing.

Nutrihealth Corp.	
Weighing	
Product name:	Nutrihealth Capsules 350
Order:	20091006-04
Lot:	20091006-04-01
Material:	ethanol
Lot No.:	061009004
Tare Weight:	250.4 g
Target Weight:	1.000 kg
Real Weight:	1.004.2 g
Operator:	FG
Date:	06.10.2009 13:52:40

A newly printed weighing label helps guarantee component identification

Printers connected to weighing workstations can print labels at the point of identification that enable fast materials recognition. Label types include:

- **Stock labels.** These ensure stock is known upon arrival and becomes traceable. Descriptions, lot numbers, quantity, delivery date, expiry and status is entered. The material enters the database and is available for processing.

- **Weighing labels.** Dispensed materials for an order are marked. Order, batch and lot number help guarantee processors do not mistake components.
- **Pallet labels.** These identify a pallet and its contents, particularly when materials are placed on a pallet before they are moved into production.

Scans help avoid confusion as materials are brought into production and ensure that the right material is added to a mixture at the right moment. Recorded results help manage stock, FEFO (first expired, first out),

FormWeigh.Net		995.1 g	
Order No.	20091006-04	Material	Nutrihealth Capsules 350
Product No.	350	Lot	01
Batch No.	20091006-04-01	Weight	995.1 g
Material	ethanol	Target Weight	1.000 kg
Decomposition	ethanol	Real Weight	1.004.2 g
Target Weight	1.000 kg	Operator	FG
Batch No.	061009004	Date	06.10.2009 13:52:40
Dispensed material		Target weight: 1.000.00000 g	
Real weight: 995.1 g		4.2 g	
Lot: 01		Status: OK	

Company logo and safety / danger symbols, as well as important status information

5 Summary

In the modern era of computerization where the safety of the consumer products are in the line with the increased regulatory scrutiny, a well- designed formulation and weighing process results in straight forward, efficient and fully traceable nutraceutical production

With easily integrated, standardized weigh stations, label printers and barcode scanners, materials mix-ups and wrong quantities become history. The resulting active stock management makes sure that components flow into the production process

timely and that available materials are fully exploited. The results are less waste, less rework, less recycling, and lowered production costs. Productivity is significantly improved at the same time compliance with international regulations regarding materials traceability is assured.

Enhanced output and higher yield from available raw materials should result in ROI on initial system investment in 12 or fewer months.

6 Additional resources

- 21 CFR Part 11
Controls Used for Manufacturing, Processing, Packing, or Holding Dietary Supplements
for FDA 21 CFR Part 111 CGMP Regulations
www.mastercontrol.com/21_cfr_regulations/21_cfr_part_11/
- METTLER TOLEDO Formulation
www.mt.com/formulation

www.mt.com/formulation

For more information

Mettler-Toledo AG

Industrial
CH 8606 Greifensee
Switzerland
Phone +41-44-944 22 11
Fax +41-44-944 30 60

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