



Weigh Dispense Optimization

*Rockwell Automation's open,
modular weigh and
dispense solution.*

**Rockwell
Automation**

Overview

Improving business performance through increased focus on manufacturing operations is getting more and more attention in the pharmaceutical industry. A combination of advances in technology, the global economy, and the increasing difficulty in discovering new blockbuster drugs is changing the business model by which pharmaceutical companies operate. Patent protection cannot be relied on as the primary engine that drives profitability for the future.

Evidence of this, pharmaceutical companies are working with the FDA on the Process Analytical Technologies (PAT) initiative as an effort to facilitate the introduction of new technologies to the manufacturing sector of the pharmaceutical industry. Process Analytical Technologies are systems for analysis and control of manufacturing processes based on timely measurements of critical quality parameters and performance attributes of raw and in-process materials.

PAT focuses on processes to assure acceptable end product quality at the completion of the process. One of the key factors identified by the PAT advisory committee is information management tools and/or product/process optimization strategies related to the manufacture of pharmaceutical products. The PAT advisory committee is comprised of FDA and pharmaceutical leaders and has stated “such systems will improve the efficiency of pharmaceutical manufacturing processes, thereby significantly benefiting the public health, as well as the pharmaceutical industry and the FDA.”¹

Weighing and dispensing input materials with the precision required by the product specification is extremely important in pharmaceutical production. Product efficacy, potency and overall consistent quality are dependent upon proper proportioning of tested, approved materials. As the first step in the production process, controlled execution and documentation of dispensing operations is particularly significant. Significant business benefits are dependent upon how well the weigh and dispense operations are integrated with planning and logistics, material, quality, and production management throughout the facility. Opportunities to improve the consistency of product quality, improve the efficiency of the quality process, and to reduce on-hand input and finished goods inventory are all enabled through well designed and implemented weigh and dispensing operations.

This white paper provides an overview of typical weigh and dispensing operations found in the pharmaceutical industry today. This helps uncover and put in perspective the benefits of a well-designed system and some of the opportunities that can be realized. Finally the paper details Rockwell Automation's Weigh and Dispense Optimization solution and how it will provide the functionality that enables improved business performance as a cornerstone of an effective quality management and production process strategy.

¹ FA Center for Drug Evaluation and Research Office of Pharmaceutical Technology “Introduction to the PAT initiative “

2) Weigh and Dispense in Pharmaceutical Today

Despite the prevalence of computerized control and manufacturing execution systems (MES) in process industries, pharmaceutical manufacturers have traditionally relied on paper-based methods for a great deal of the tracking of vital production information. There are several factors that have contributed to the reticence of pharmaceutical manufacturers to adopt computerized systems. Until 1997, the United States Food and Drug Administration (FDA) had no policy in place for the acceptance of electronic records and electronic signatures. Now that the FDA has adopted Part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11), that policy is in place and compliance is being enforced. Paper-based systems need not be replaced, but electronic records and signatures are now accepted by the FDA as binding².

The implications for drug manufacturers in meeting 21 CFR Part 11 are far reaching and after more than five years, the industry and the FDA are still working to come to a mutual understanding of the extent of the rule. Converting paper-based systems to computerized systems provides many benefits, but must be done based on understanding of 21 CFR Part 11. Regulation on such issues as security, authenticity, version control and electronic audit capability are absolute requirements for those systems covered by the rule².

Pharmaceutical manufacturers have expended tremendous effort evaluating existing systems. Meanwhile computer system and software vendors have been diligently working to increase functionality to address the needs of the industry. Expense has been substantial, but there are great opportunities for pharmaceutical companies to use technology to eliminate errors inherent with paper-based methods. Business benefits related to the adoption of electronic recording/electronic signature (ERES) systems may include increased production efficiency, improved product consistency and quality, inventory reduction, and greater visibility of plant floor operations to the rest of the enterprise.

Paper-based methods persist in those parts of the process where automation is not practical for technological, logistical, or cost reasons. Weigh and dispense is a good example of an area in which automation is not always practical. Often times, production orders, material information, work instructions, and operator process observations are all paper based. This setup produces very large quantities of paper documentation for the weighing process, much of which must be carried through the rest of the production process and reviewed for quality release of finished product.

² Refer to www.fda.gov for copy of 21 CFR Part 11 and latest FDA guidance documents

2) Weigh and Dispense in Pharmaceutical Today cont.

Regardless of the level of automation, integration of weigh and dispensing operations with plant floor control and information systems throughout the production facility is essential to realizing the most from investments in plant assets. Isolated weigh and dispense operations cannot provide the benefits of a well-integrated system. Weigh and dispense operations should integrate with such plant and enterprise systems as:

- ERP systems
- Material and warehouse management systems
- Batch recording systems
- Quality management systems
- Plant production operations and control systems

Many pharmaceutical companies have invested in Enterprise Resource Planning (ERP) Systems that provide some level of production planning. With paper-based and/or isolated dispensing operations, it becomes difficult to integrate the ERP production schedule with plant floor activities. The production order request is often printed out or transcribed to a plant floor system to be passed on to operations. Results from operations, such as material consumption information, are needed by the ERP for planning and costing purposes. Isolated manual weigh and dispense systems introduce a delay in getting this critical data distributed as needed as well as introducing potential for errors and incorrect information.

All aspects of dispensing operations that could potentially impact product quality and safety must satisfy FDA regulation no matter the level of automation. Operators must have proper authorization and training, equipment must be in the correct state e.g. cleaned and ready for use, and all material information must be available for quality review. Calculations may be required to adjust formula values based on material test results. Paper-based dispensing requires operators to write this information down, date the document, sign as required, and ensure that the paper record is properly handled as production continues.

Optimization through online production order processing is difficult if not impossible using isolated manual work centers. Furthermore, each time a human is required to write an entry, sign and/or date a record, there is an opportunity to introduce error. Eventually, these errors must be investigated and rectified, which is time consuming and costly.

An ideal weigh and dispensing system allows ease of operation in an open system architecture that allows integration with other plant floor systems as well as business systems. Removing as much potential as possible for introducing errors reduces waste as it increases the efficiency of production and quality processes. Optimizing the weigh and dispensing operations is a critical step in realizing increased return on drug manufacturing assets.

3) Rockwell Automation Weigh and Dispense Optimization

Rockwell Automation's Weigh and Dispense Optimization (WDO™) solution enables maximized efficiency of dispensing operations while enabling overall manufacturing operations to drive greater business performance. WDO is one of the solution modules that comprise Rockwell Automation's Pharmaceutical Manufacturing Optimization. As such, WDO is architected to serve as a basis for and integrate seamlessly with plant-wide optimization solutions such as Electronic Batch Recording Systems and Plant Warehouse and Material Management Systems. WDO leverages Rockwell Automation's industry leading 21 CFR Part 11 compliance enabling Propack Data and Rockwell Software standard software as part of this modular, open, scalable dispensing solution.



WDO is a complete solution that is secure, operators find intuitive to use, can be rapidly validated, and easily maintained. Our experienced professionals provide a complete breadth of consulting, engineering, and validation services to help ensure that the WDO project is successful and delivers sustainable value. WDO enables you to reduce risk while improving your return on plant assets.

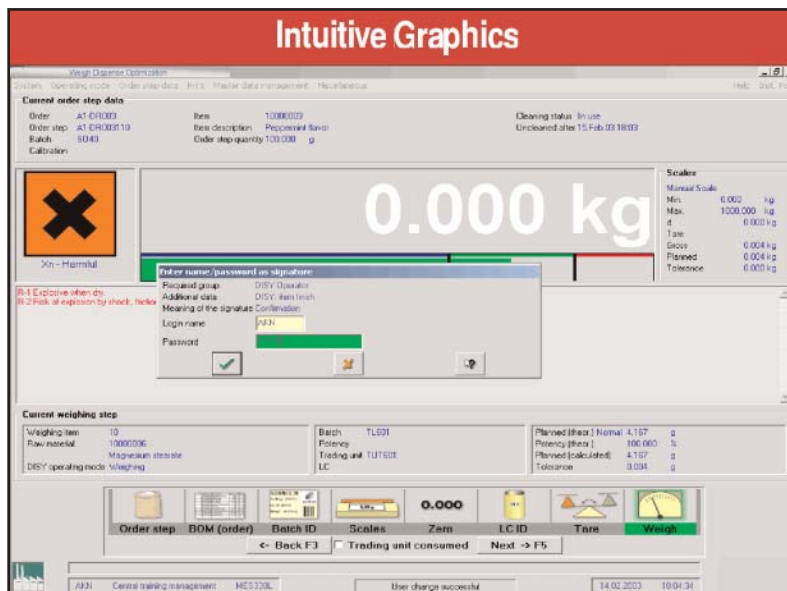
WDO is modular and is easily integrated into a centrally managed plant production information system. Full weigh and dispense reporting is standard with the system, and vital weigh and dispense production information is readily available for analysis and review. WDO supports industry standards for database management and communications, allowing you to specify which data are needed for reporting as part of the batch record.

Ease of integration also enables increased visibility of plant operations to the rest of your enterprise. WDO enables efficient integration between manufacturing operations and control with Enterprise Resource Planning (ERP) systems. Rockwell Automation's experience integrating dispensing operations with ERP systems is unsurpassed and our rich set of standard interfaces enable ease of integration with a broad range of business systems. This allows you to accurately, securely, and robustly transact with your ERP system according to your needs for such things as execution of the production plan and material consumption reporting.

Intuitive User Environment

Weigh Dispense Optimization enables system managed and controlled operation of the dispensing area. The system guides users through the weighing process in a secure environment. All materials, containers, and scales are verified by the system helping ensure quality and safety. Support of standard interfaces for bar code label printers, bar code scanners, and scales increase operator efficiency by reducing human error, and enables more rapid execution of production orders.

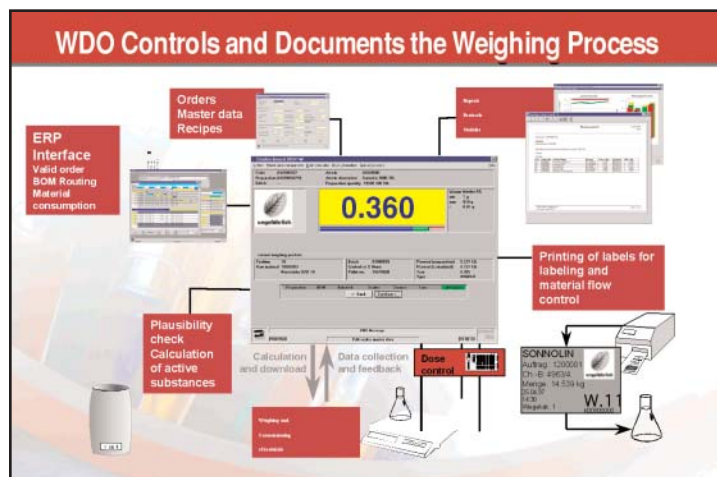
Operators find the intuitive screens easy to navigate and easy to find the information they need to do their job effectively. Weighing status is provided in the main weighing screen enabling operators to determine whether weighing is within tolerance and make appropriate adjustments using the dynamic, color-coded, weigh status.



Operator comments can be input and incorporated as part of the weigh and dispense information report. Proper authorization through single or double electronic signatures where appropriate, help reduce risk and streamline operations. Deviations, weighing amounts that are outside the tolerance, are highlighted and require immediate correction in order to continue the dispensing operation.

System Managed Weighing

Recipes are defined as part of the WDO master data definition. When production orders are issued, WDO extracts the dispensing production procedures and operators are directed step by step through the procedure. Weighing specific production information may include deviation specifications, formula values, and operating procedures. System managed master data helps eliminate human error and streamline the operation of the dispensing area.



The system displays hazardous symbols for the selected material as well as R*S (Risk and Safety) information according to the material. Material specific instructions may also be displayed according to the requirements of the process. Operators are provided necessary material information by the system, which enables them to focus on the process. This enables higher productivity and more consistent quality.

At startup, WDO initializes all scales' interfaces and activates and checks the scales connected to it. All materials are identified prior to weighing and direct data collection allows the calculation of consumed quantities and yields. The automatic collection of the data and the plausibility checks run on it preclude reading errors on the part of the operators. Material labels and target container labels are printed directly by the system.

The weighing control board provides the ability to use standard operating modes for various areas of application.

The following operating modes are pre-defined with the system:

- Weighing - Order-oriented weighing of the BOM items of an order step.
- Weighing without order - Weighing of any objects not related to orders, order steps, batches, etc. and also without documentation.
- Weighing campaign (raw material-optimized weighing) - Raw materials are selected from the BOMs of several order steps. This results in a BOM related to several order steps, for which the weighing process is then executed.
- Cost center-related weighing - Cost center-related weighing of the BOM items of an order step. These items are not assigned to a (planned) weighing item but to a cost center.
- Weighing for inventory check - Weighing of trading units for inventory check of materials before delivering them back to the warehouse
- Yield Weighing – Determining yield from manufactured products

21 CFR Part 11 Capability

Standard WDO functionality provides security, version protection, and audit trail capability. Password protection methods are consistent with the requirements of 21 CFR Part 11 and are designed to allow you to enforce your administrative policies. Required single and/or dual electronic signatures can be configured ensuring proper authorization and documented actions. Full attention is paid to enabling compliance with the FDA 21 CFR Part 11 regulation, including the following standard functionality:

- Reporting of Electronic Records
 - Support for PDF format
 - Track who printed, when printed, and how many printed copies
- Authority Checks
 - Execution and Certification
 - Hierarchy of groups with users defined by administrator
- Archiving
- Audit Trails
 - Version controlled files/documents
 - Tracking of versions and changes
 - Who made change, when change is made, why change was made with optional electronic signature (with support for dual signature)
- Electronic Signature per 21 CFR Part 11 requirements
- Controls for Identification Codes / Passwords

Open System Architecture

Weigh Dispense Optimization leverages industry standards for data exchange and communication to ease development and maintenance as well as provide efficient data interaction with other systems. Rockwell Automation is a founding member of the OPC foundation and a leader in industry standardization efforts including the ISA (SP95, SP88), ISO, and IEC committees.

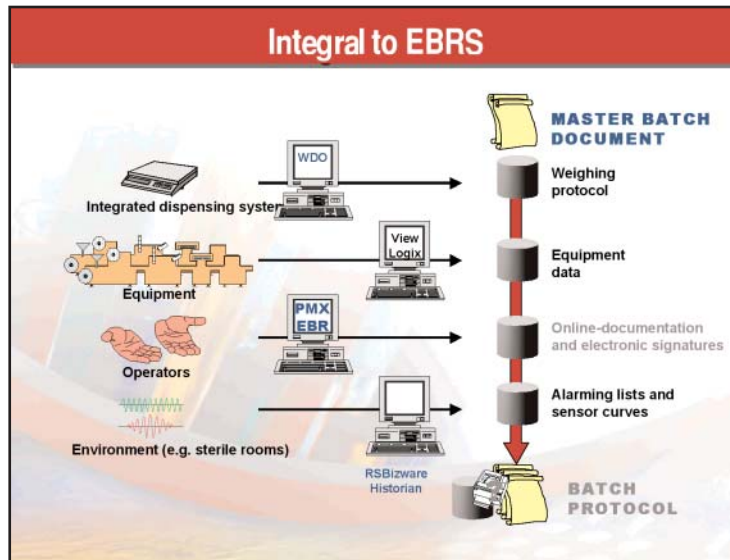
WDO standard interfaces provide connectivity with plant floor devices and control systems as well as with manufacturing execution and business systems. Rockwell Automation's Weigh and Dispense Optimization solution integrates easily with systems such as:

- Weigh scales
- Bar code label printers and Scanners
- Enterprise Resource Planning Systems
- Warehouse and Material Management systems
- Electronic Batch Recording Systems
- Product Specification and Recipe Management Systems
- Process Control Systems

Bi-directional communications with plant floor control systems allows operations to rely on a single interface for carrying out their dispensing tasks. Embracing open standards means that WDO communicates with virtually all plant floor automation and control systems allowing you to increase productivity while preserving existing investments.

The combination of leading technology and vast experience with pharmaceutical weigh and dispense applications are the keys to WDO's ability to reduce maintenance and validation burden. Leveraging WDO's robust security model in a web-based architecture reduces the complexity of the system while providing greater flexibility. This provides greater visibility to plant operations, which results in higher operational efficiency.

Integral to EBRS



The open, relational database allows structured archiving and evaluation of the data relevant for batch documentation and batch tracing. User authorizations, password protection, and an electronic signature guarantee regulation-compliant and nearly paperless production documentation. Standardized definitions for further processing make the connection to production logistics transparent and efficient.

Central management of the production data allows fast review of deviation information for quality review by authorized personnel. Workflow oriented operator screens are designed to remove virtually any possible sources of human error.

Much of the dispensing activity is vital to product quality and safety. Standard reports providing details on material, personnel, and equipment are available. Analysis of dispensing information enables you to uncover opportunities for improvement and to help assure quality processes are being followed properly.

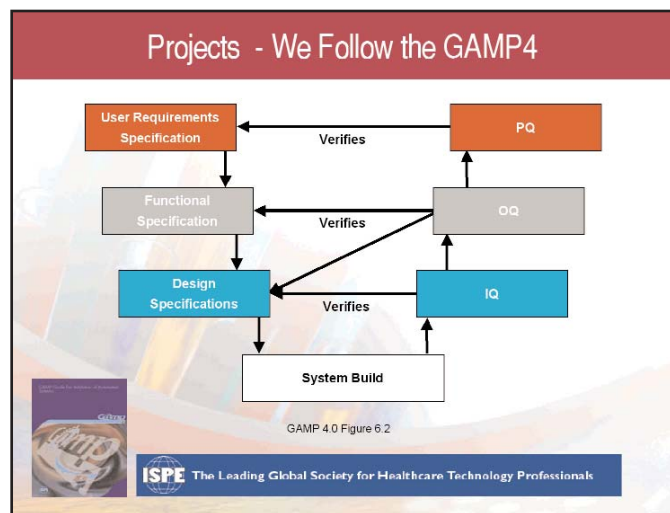
As an integral part of an overall plant information management system, WDO allows you to accurately track material usage based on lots and sublots as well as on which material containers were in use. This is an enabler to a comprehensive material tracking and genealogy capability that a plant wide information solution, such as is provided with Rockwell Automation's Pharmaceutical Manufacturing Optimization (PMO).

Professional Consulting, Engineering, and Compliance Services

Only Rockwell Automation can offer the powerful combination of a large central consulting, project management, regulatory compliance, and engineering team with highly trained professionals located locally throughout the world. Our global expertise and experience implementing validated weigh and dispense solutions for the pharmaceutical industry allows you to design, create, and roll out company wide standards across your entire enterprise.

Successful projects begin with the important task of understanding the needs of all those that will use and interact with the system. Rockwell Automation's experienced experts have implemented hundreds of weigh and dispense solutions for pharmaceutical companies worldwide. Leveraging our vast experience with weigh and dispense, your plant operations, maintenance, engineering, quality, and the business planning personnel will improve performance in an efficient, intuitive, open system environment.

Strict adherence to standard project methodology is what makes Rockwell Automation's professional services invaluable to our clients. All WDO projects are thoroughly documented consistent to the requirements of qualification testing of the system. The following figure provides a basic outline of the project methodology, illustrating the importance of the GAMP guideline in our approach.



Our expert consultants are available to assess your current weigh and dispense methods, evaluating the dispensing operations themselves as well as how the dispensing operations fit into overall plant operations. Working with you to identify the ideal dispensing practices for the future, we will document the proposed project in accordance with GAMP standard methodologies.

4) Summary –

Pharmaceutical companies are placing more importance on manufacturing operations as a key contributor to overall business performance. With full support of the FDA as evidenced in the PAT initiative, drug manufacturers are focusing more and more on operational excellence. This will improve the bottom line of pharmaceutical companies, and will also enable more rapid availability of lower cost drugs, thus benefiting the general public health.

Rockwell Automation's Weigh Dispense Optimization is a modular solution in our Pharmaceutical Manufacturing Optimization solution portfolio. In addition to being able to realize efficient, compliant dispensing operations, WDO's scalable, open architecture environment can lay the foundation for a plant-wide optimization and quality strategy.

Ease of integration with plant floor automation and control provide operations with an easy to use, centrally managed dispensing system. Standard interfaces to ERP systems enables efficient production order execution and raises the visibility of plant operations to the rest of the enterprise.

All facets of your weigh and dispense project from initial consulting through validation and qualification testing are available as part of the WDO solution. Standard solutions reduce validation and lower cost while ensuring ease of maintenance and operation.

WDO leverages Rockwell Automation's industry leading 21 CFR Part 11 compliance enabling software, which leads to reduced validation costs and helps ensure sustained regulatory compliance. Virtually eliminate human error, reduce administrative cost, and increase the inefficiency of information flow with Rockwell Automation's modular, scalable, open system.

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