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CiP Article: When the Recipe Becomes a Recall: Controlling Ingredient Risk at Weigh and Dispense

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Most manufacturing systems are good at repeating instructions. That is precisely why ingredient control matters. If the wrong formula, material, lot or quantity—or an uncorrected potency variation—enters the process, the equipment downstream can efficiently and consistently make the wrong product.

Final quality control remains essential, but it is an expensive place to discover an error. By then, further materials, production time, laboratory capacity and release effort have already been committed. The outcome may be quarantine, investigation, rework or destruction. If the problem is not detected before release, the exposure can extend to patient or consumer harm, product recall, supply interruption, regulatory action, litigation and lasting damage to confidence in the manufacturer.

The dispensary is therefore not simply a preparation area. It is one of the points at which the intended product becomes the physical batch—and where a preventable error can become embedded in it.

The consequences are already on record

The following cases are cited to illustrate historical failure modes. They do not imply anything about the companies' current systems or standards, and no single technology should be presented as capable of preventing every type of manufacturing failure.

At GSK's former Cidra facility in Puerto Rico, the US Department of Justice reported that Avandamet tablets did not always contain the FDA-approved mix of active ingredients and could contain too much or too little of the therapeutically active component. The same case included longstanding product mix-ups involving different drug types or strengths. In 2010, subsidiary SB Pharmco agreed to plead guilty, with a resolution comprising a $150 million criminal fine and forfeiture and a $600 million civil settlement. The case shows how failures of formulation and material control can move beyond a batch deviation into major criminal and civil exposure. [1]

The scale of the company is not the deciding factor. In 2012, compounding pharmacy ApothéCure and its owner pleaded guilty in connection with two lots of compounded colchicine injectable solution. FDA testing found some vials at 640% of the declared colchicine

level and others below 62%. Three patients died from colchicine toxicity. The published record does not reduce the event to one weighing action, but it demonstrates the extreme consequence of losing control of potency when a highly active ingredient is being compounded. [2]

A more recent UK example involved Eaststone Limited. In January 2026, the MHRA issued a National Patient Safety Alert after the manufacturer reported that the formula used for all batches of its unlicensed quetiapine oral suspensions was incorrect. The active content was twice the intended amount, creating a risk of overdose. A total of 166 bottles manufactured between October 2025 and January 2026 had been distributed to healthcare customers. This is an important reminder that digital execution cannot compensate for an incorrectly governed master formula: recipe creation, review, approval and change control have to be part of the control strategy. [3]

The same exposure exists outside pharmaceutical manufacturing. Following its 2019 dog-food recalls, Hill's Pet Nutrition received an FDA warning letter concerning products marketed with unsafe levels of vitamin D. FDA testing of two samples found levels more than 33 times the recommended safe upper limit. The agency reported that a vitamin premix had been accepted and used without being tested and reviewed against specification, contrary to the firm's receiving procedures. The initial recall covered 25 canned dog-food products and was later expanded. This was not simply the absence of a written procedure; the documented control already existed but was not consistently followed. [4]

Together, these cases show several distinct routes to the same commercial and safety outcome:

- an incorrect or outdated formula is authorised for use;
- the correct formula is used with the wrong material, strength, lot or status;
- the correct material is dispensed in the wrong quantity or unit;
- a released ingredient has a valid but non-nominal potency and the dispense is not adjusted using the approved factor;
- an unsuitable incoming ingredient is accepted without the required evidence;
- an exception, substitution or correction is made without effective review; or
- the records are too fragmented to identify the error before release or reconstruct it afterwards.

Dispensing is a control point, not an administrative step

Regulators are explicit about the importance of this stage. EU GMP Chapter 5 states that starting materials should be dispensed by designated people under a written procedure, with the correct material accurately weighed or measured into properly labelled containers. The material and quantity should be independently checked, the check recorded, and the materials for each batch kept together and clearly identified. [5]

US requirements are similarly direct. Under 21 CFR 211.101, dispensed components must be identified with their name or code, control number, quantity and intended batch. The regulation requires verification of component status, quantity and identification, either by a second person or through appropriately controlled automated equipment. [6]

The record is part of the control, not evidence to be assembled later. FDA's data-integrity guidance describes complete, consistent and accurate data as attributable, legible, contemporaneously recorded, original or a true copy, and accurate. It also states that system design and controls should make errors, omissions and unusual results readily detectable across the data lifecycle. [7]

A dispensing management system can turn those expectations from instructions that people must remember into a workflow that the process actively enforces.

Validated oversight can replace routine two-person checks

The traditional control is for a second person to check the material, lot, status, quantity and destination before the dispense proceeds. That can be effective, but it consumes skilled labour and still depends on the check being genuinely independent, accurate and contemporaneous. Under operational pressure, a second check can deteriorate into a signature applied after the event.

A validated dispensing management system provides a different form of oversight. It can verify the material and lot through barcode scanning, obtain the actual weight directly from the balance, compare it with the approved target and tolerance, confirm the intended batch and prevent the transaction from progressing when a defined check fails. The evidence is captured at the time of execution rather than reconstructed later.

For dispensing checks covered by the validated system, site risk assessment and approved procedures, this automated verification can remove the need for the routine two-person check. The control has not disappeared; it has moved from repetitive human confirmation to objective, rules-based oversight with a traceable electronic record. This can release operator and supervisor time while improving the consistency of the check. [8]

It does not follow that every human approval should be removed. Master-recipe approval, deviations, substitutions, overrides, unusual events and final quality decisions may still require appropriately authorised personnel. The boundary between automated verification and human approval should be defined in the user requirements and demonstrated during validation.

The correct weight can still deliver the wrong potency

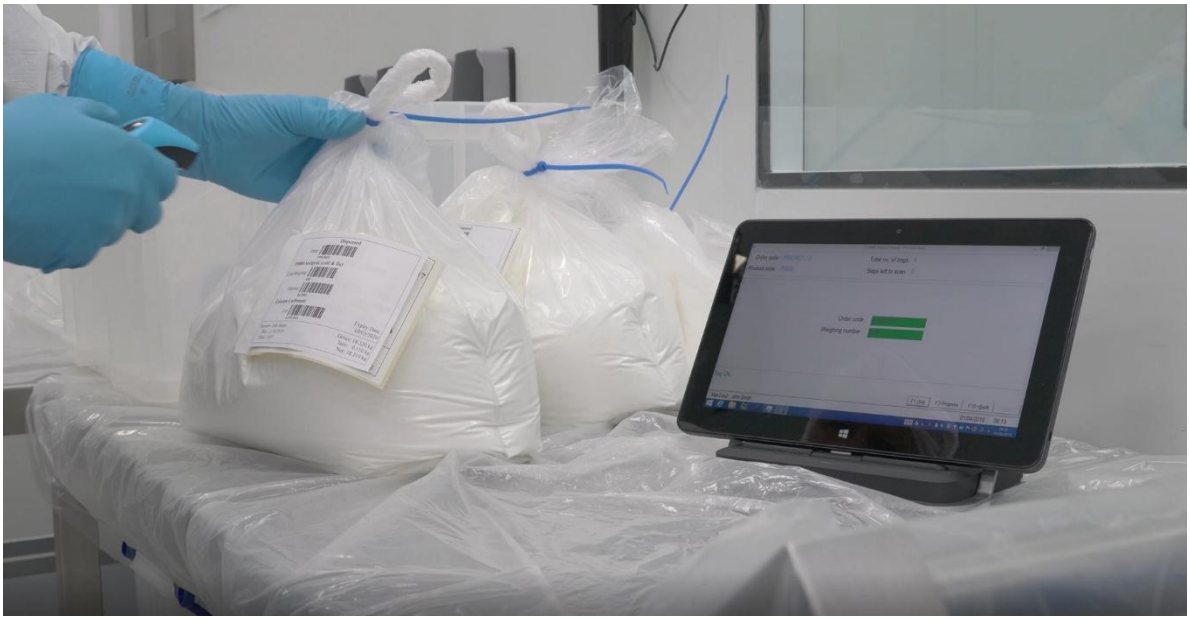
Not every formulation error begins with the wrong ingredient or an obvious weighing mistake. A raw material can be correctly identified, released for use and weighed precisely, yet still contribute the wrong active quantity if its actual potency is not reflected in the dispense target.

Released raw-material lots do not always have identical strength. An API or other potency-critical ingredient may comply with its specification while its assay differs from the nominal value used in the master recipe. Depending on the authorised formulation method, the required physical weight may therefore need to be adjusted so that the batch receives the intended active equivalent.

In a simple potency-only example, delivering 1.000 kg of active equivalent from material assayed at 98.0% would require an adjusted dispense of approximately 1.0204 kg, before any other authorised correction is applied. The arithmetic is straightforward. The process around it may not be. Someone has to obtain the correct result for the correct lot, interpret its basis, apply the approved calculation, transcribe the result and ensure that the adjusted target follows the material if dispensing spans more than one container or lot.

Paper records and standalone spreadsheets leave opportunities to select the wrong assay result, invert a factor, misplace a decimal point, use a superseded value or lose the relationship between the calculation and the physical lot. A second signature may detect an error, but only if the check is genuinely independent and occurs before the material is used.

Ci-DMS can track material across multiple containers and lots and offers the option to adjust required weights automatically for potency. The approved lot-specific value can be used to calculate the target presented to the operator, with the connected balance capturing the actual result. The electronic record can retain the recipe requirement, potency information, adjusted target, source lot, measured quantity, user actions and approvals as one traceable transaction. This moves potency compensation out of an isolated calculation and into controlled batch execution. [9]



Automation does not remove the need to govern the data. The potency or assay result, its calculation basis and the adjustment rule must all be correct, approved and controlled. A dispensing management system can execute and document that rule consistently; it cannot make an incorrect laboratory result or an unsuitable formulation rule scientifically valid.

What effective dispensing management should control

An effective system should address the full transaction, not just display a target weight.

Controlled formula execution. Operators should only be able to use the approved formula and current version for the selected product and batch. Creation, amendment and approval of master data should be restricted and traceable.

Material identity and status. Barcode verification can check that the presented ingredient and lot match the requirement and, where integrated with the relevant business systems, that the material is released, in date and permitted for use.

Quantity and tolerance. A direct connection to the balance captures the value without manual transcription. Defined targets, tolerances and units can prevent an out-of-tolerance dispense from progressing as though it were acceptable.

Lot-specific potency. Where the approved method requires an adjustment, the system should associate the authorised potency value with the material lot, calculate the revised target using the validated rule and preserve both the nominal and adjusted quantities in the record.

Guided sequence and exception handling. On-screen instructions can control the order of work and require authorised review of substitutions, adjustments, rejected attempts or other deviations.

Recipe-specific safety and handling instructions. The workflow can present the instructions and health and safety warnings relevant to the material, recipe and process step at the point the work is performed. These may cover required personal protective equipment, containment, transfer, exposure precautions, cleaning or other handling requirements. Critical notices can require acknowledgement before the operator continues.

Validated automated verification. Barcode, balance and recipe data can be checked against approved rules in real time. Where this control is included within the validated scope, it can replace routine manual second-person checks while retaining evidence of every verification and failed attempt.

Container identification and onward traceability. Automatically generated labels can link each dispensed container to the material, source lot, quantity, product and batch, reducing the risk of handwritten or detached information.

Accountability and review. Individual user authentication, role-based permissions, electronic approvals and a secure, time-stamped audit trail establish who performed and approved each action, when it occurred and what changed.

Reconciliation and record availability. Dispensed quantities, losses, returns and stock movements should be reconcilable. QA should be able to review a coherent electronic record rather than reconstruct the event from batch sheets, balance printouts, labels and spreadsheets.

Rebuild the method before configuring the system

Software should not be used to reproduce a weak paper process screen by screen. If unnecessary hand-offs, duplicated entries, informal workarounds or poorly positioned checks are carried into the electronic workflow, they become faster and more consistent—but they remain weaknesses.

CI Precision's business process review approaches the dispensary at method-study level. It examines how the work is actually performed, not only how the procedure says it should be performed. That means following the physical movement of ingredients and containers alongside the flow of instructions, status information and records.

The review considers each process step, decision and hand-off: who performs it; where the information comes from; what equipment is used; what must be checked; what evidence is created; where people wait, copy or re-enter data; and what happens when the normal route cannot be followed. It also identifies the safe-handling information needed at each point, including material-specific warnings, personal protective equipment, containment and

acknowledgement requirements. The exception paths are brought into view—partial containers, multiple lots, potency changes, returns, substitutions, rejected dispenses, corrections, cleaning decisions and work split across shifts.

At that level of detail, the review can distinguish a regulatory or safety control from an activity that exists only because systems are disconnected. Each step can then be challenged: must it happen, should it happen at that point, can it be removed or combined, should a person or the system verify it, and which application should hold the authoritative data?

The aim is a future-state method in which roles, equipment, master data, approvals and electronic records work together. The outputs inform the user requirements, Ci-DMS configuration, equipment and interface scope, approval structure, validation strategy and training plan. This allows the project to rebuild a more robust and integrated operating method rather than simply digitising the existing paperwork.

CI Precision begins this work before implementation, investing time in understanding the customer's weigh-and-dispense processes and their wider business context. Detailed requirements are then mapped to specific project deliverables so that the intended operational and compliance outcomes can be traced through design, implementation and validation. [10]

That support continues through validation, go-live and routine use. CI Precision states that its pharmaceutical MES experience extends over more than 40 years, with project and validation documentation, staff training and support for measures such as disaster-recovery planning. These are important parts of risk control: the software has to remain validated, understood and recoverable after the implementation team has left the site. [8]

Where Ci-DMS fits

Ci-DMS is a focused Manufacturing Execution System for pharmaceutical weigh-and-dispense operations. It can control the weigh, dispense, addition, discharge, yield-reconciliation and cleaning processes, as well as recipe management. It guides operators through controlled process steps using on-screen instructions, barcode scanning, connected weighing equipment and automatic label printing. Process- and recipe-specific operating instructions and health and safety warnings can be presented at the relevant stage, with acknowledgement required where appropriate. Weighing results and the batch details of each ingredient are captured automatically and retained in a secure database for reporting, review and audit. [9]

The system supports controlled access, approvals, audit trails and traceable electronic records. Every process step, weighing result and ingredient-batch detail can be tracked and recorded automatically, supporting ALCOA+ data-integrity principles and making the resulting record readily available for operational review, reporting and audit. As with any regulated system, compliant use still depends on appropriate configuration, procedures, infrastructure, training and validation.

Ci-DMS includes dedicated integration capability for sharing live data securely with connected equipment and wider MES and ERP systems. Its interfaces can be configured to exchange the formats required by different systems and adapted as the customer's IT landscape evolves. This reduces isolated data entry and creates a connected record from the production requirement and material selection through to the completed dispense and subsequent batch review.

The configurable architecture also allows Ci-DMS to support different operating scales, from research organisations and personalised-medicine production to large-scale manufacturing. It is designed to be delivered, integrated and validated quickly, while its specialist focus on pharmaceutical weigh and dispense allows it to operate as a defined part of a broader MES and ERP strategy. The business process review remains central to deciding what the system should control, where information should originate and how users, equipment and other systems should interact. [8]

The practical value is not merely the replacement of paper. Ci-DMS can reduce dependence on memory, manual transcription and retrospective checking at the point where the cost and consequence of an ingredient error begin to increase.

Risk reduction can also deliver an operational return

The same controls that reduce ingredient risk can remove significant non-value-adding activity. Automatic data capture reduces manual recordkeeping and transcription. Validated system checks can reduce routine second-person checking. Integration can remove repeated entries between dispensing, MES and ERP records, while clearer electronic evidence can shorten reconciliation, review and investigation.

CI Precision reports examples of dispensing costs being reduced by more than 50% and return on investment being achieved in under nine months. Those figures should not be treated as a universal promise: the result will depend on the starting process, production volume, labour model, number of dispensing areas, integration scope and validation effort. The method-study-

level review and business-case work provide the basis for establishing what is realistically achievable at an individual site. [8]

Is the current process carrying avoidable risk?

The warning signs are usually familiar:

- formulae or batch instructions are printed, emailed or copied from more than one source;
- ingredient codes, lot numbers, expiry dates or weights are transcribed by hand;
- potency or assay values are copied from certificates of analysis or spreadsheets and adjusted targets are calculated manually;
- dispensing across more than one lot relies on a person to reconcile different potency values;
- a second check can become a signature added after the activity rather than an independent verification;
- safe-handling instructions are held in separate documents rather than presented for the specific recipe and step;
- balances operate separately from the batch record;
- an out-of-tolerance result can be repeated, changed or overridden without a controlled reason and approval;
- shared user accounts make actions difficult to attribute;
- container labels are handwritten or produced outside the dispensing transaction;
- stock and quality-status changes are entered after the physical material has moved; or
- QA needs several records or systems to establish what was actually dispensed.

These conditions do not mean that operators are careless. They mean the process still depends on careful people performing repetitive, high-consequence tasks without sufficient engineered protection. Training and vigilance matter, but neither is a permanent control against distraction, time pressure, ambiguous labelling or transcription error.

What a dispensing system cannot do

Digitising a weak process does not make it compliant. A dispensing management system cannot prove that a correctly labelled container chemically contains the correct material, detect an unknown contaminant, repair an incorrectly approved master formula or compensate safely from an incorrect potency result. Nor can it replace supplier qualification, incoming-material testing, cleaning and segregation, process validation, final quality control or authorised batch release. Automated oversight must be validated for its intended use and should not be used to remove a human approval that remains necessary under the applicable requirements or the site's control strategy.

Those controls have to operate together. The role of a dispensing management system is more specific: to reduce the probability of selection, quantity, identification and recording errors; stop defined exceptions from passing unnoticed; and create reliable evidence of what physically entered the batch.

It avoids the false promise that software eliminates risk, while recognising that paper procedures and retrospective signatures leave preventable gaps at one of manufacturing's most consequential stages.

Prevent the error before it becomes a release decision

A recall begins long before the recall notice. It begins when a process allows a material decision to proceed without enforced verification and a trustworthy record.

Businesses at risk do not necessarily lack procedures or capable people. More often, their controls are fragmented across paper, standalone balances, spreadsheets and disconnected systems. Each element may appear reasonable on its own, while the gaps between them remain dependent on perfect human performance.

A well-designed and validated dispensing management system closes many of those gaps. Ci-DMS links the approved instruction, safe-handling requirements, material, lot, lot-specific potency, adjusted target, measured quantity, operator, approval and time of execution before the material moves forward. It can also replace routine two-person verification with validated, rules-based oversight for the checks within its approved scope. That gives operations stronger prevention, QA better visibility and the release decision more defensible evidence.

The technology alone is not the starting point. A method-study-level review exposes the weak hand-offs, duplicate records, manual calculations and disconnected decisions that have to be addressed. Ci-DMS can then be configured around a redesigned and integrated operating method, rather than preserving the limitations of the process it replaces.

The real business case for dispensing management is therefore not simply paperless production. It is reducing the likelihood that the wrong product is made—and improving the chance that any problem is contained before it becomes a recall, an audit finding or a legal case.

Sources

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About CI Precision

CI Precision specialises in precision weighing technologies for the pharmaceutical and related life science sectors. Our systems are designed to support robust, data-driven quality control where measurement integrity, process understanding, and defensible decision-making matter.

We are proud to be the only manufacturer of an off-the-shelf semi-automated high precision implant weight sorter. Built specifically for the challenges of development, tech transfer, and operational quality control of medicated implants in both pharmaceutical and veterinary pharmaceuticals applications.

#PharmaceuticalManufacturing #GMP #DataIntegrity #MES #WeighAndDispense #QualityRiskManagement #CiDMS

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