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CiP Article: The Impact of Machine Change Parts in OSD Manufacturing & R&D

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One machine. Fewer change parts. Lower GMP risk.

Why “universal” OSD weight sorting is becoming a strategic requirement, not a nice-to-have.

Pharma has a long history of learning the hard way that complexity is a quality risk. Every additional component you introduce into a changeover, every extra chute, bowl, guide, track, gate, insert, or format kit, creates more opportunities for:

- residue carryover
- parts mix-ups
- undetected damage / wear
- incomplete cleaning verification
- documentation gaps
- line-clearance failures

The industry often treats “change parts” as an operational detail. Regulators don’t. They treat them as product-contact surfaces and potential contamination vectors, and they expect you to control them with the same discipline you apply to the machine itself.

That’s why the idea of a weight sorter that can handle almost all tablet and capsule formats with no dedicated format parts isn’t a “nice usability feature”. It’s a way to design out risk and it aligns directly with the direction GMP has been moving for the last decade.

Regulators are explicit: parts and shared equipment are a cross-contamination hazard

EU / UK / PIC/S frameworks make a consistent point: if you share equipment across products, you must manage cross-contamination risk using Quality Risk Management (QRM)—and that includes parts.

- ***EU GMP Chapter 5 (Production)*** states that QRM should determine the extent of dedication needed and that this may include dedicating specific product-contact parts (not only entire equipment/facilities).

- ***PIC/S PI 043-1 (Cross-contamination in shared facilities)*** explicitly lists hazards originating from movement and mix-up of equipment or parts.

- ***EU GMP Chapter 3 (Premises & Equipment)*** pushes design that minimises errors and enables effective cleaning to avoid cross-contamination build-up.

- ***ICH Q9(R1) (now central to GMP thinking)*** formalises the expectation that manufacturers use risk tools to reduce patient risk, and it specifically highlights reducing subjectivity and improving decision-making, meaning: if you can eliminate a failure mode, do it.

And when products share equipment, regulators increasingly anchor the discussion on health-based exposure limits (HBELs):

- ***EMA HBEL*** guideline frames cross-contamination as a patient risk and provides a scientific basis for determining threshold levels used in risk identification and risk reduction.

- ***PIC/S PI 046-1*** transposes that expectation into the PIC/S context for shared facilities.

Translation into plain English: if your process forces you to swap lots of product-contact parts, you've created a bigger contamination/mix-up surface area, so your control strategy must get heavier (more cleaning validation effort, more verification, more training, more admin, more deviation exposure).

A "universal" sorter changes the equation by removing a chunk of the hazard.

Inspection reality: "change parts" are a repeatable failure mode

This isn't theoretical. Regulators repeatedly cite change parts in inspection findings.

Case evidence (FDA Form 483): "cleaned" change parts found dirty, no verification, and checks signed off incorrectly

In a publicly posted FDA Form 483 for Baxter Pharmaceuticals India (Jan 2023 inspection), the investigator documents (paraphrased):

- procedures lacked detailed instructions for cleaning change parts of different sizes/shapes/materials
- lack of cleaning verification
- "cleaned" change parts were observed with unknown residues/materials
- line clearance checklist required checking parts for correct size and damage, yet operators still marked "not damaged" despite damaged parts being found

That's the real-world risk stack created by large change-part ecosystems:

cleaning complexity + verification gaps + human factors + weak line clearance = inspection exposure.

Case evidence (FDA Warning Letter): independent assessment of "equipment including change parts"
The subsequent FDA Warning Letter to Baxter (Jul 2023) explicitly calls for an assessment of the condition of equipment including change parts, and the procedures and practices associated with equipment maintenance.

Case evidence (FDA Form 483): capsule size change parts referenced in residue observations
Even in smaller-scale compounding contexts, FDA observations explicitly mention equipment used with capsule size change parts, alongside observed visible residue in "clean" storage areas.

None of these are "weight sorting" per se. That's the point: change parts fail the same way everywhere… presses, fillers, packaging lines, inspection equipment. Product-contact part proliferation consistently expands the failure surface.

The operational math: fewer parts means fewer failure opportunities

Risk management people will tell you: if you want robust control, reduce the number of steps and interfaces.

A simple approximation illustrates why. If a changeover requires n discrete, error-prone actions (swap part A, fit part B, confirm orientation, confirm revision, confirm cleanliness status, etc.), and the chance of an error per action is p, then the probability of "at least one error" is:

$$1 - (1 - p)^n$$

As n increases, risk rises fast.

Competitor systems that require unique format kits for each tablet/capsule size and type drive n up:

- more part picks from storage
- more cleaning and drying steps
- more "clean/dirty hold" management
- more inspection points
- more documentation and QA release checks
- more opportunities for the wrong kit or wrong revision to be used

A near-universal sorter pushes *n* down dramatically, because you're not repeatedly introducing a new set of product-contact surfaces into the process.

That matters in R&D and CDMO environments where high-mix, low-volume and frequent changeovers are commonplace.

"But isn't this just about speed?" No. It's about GMP resilience.

There is an efficiency benefit, sometimes large, but the strategic value is resilience: fewer deviations, fewer investigations, fewer "unexplained" rejects, fewer schedule shocks.

A pharma-sector case study on packaging line changeovers (SMED + lean integration) reported objectives including up to 50% reduction in changeover/batch change time and ~25% improvement in OEE.

That's for improving procedures around changeover. If you can remove large parts of the changeover content altogether (because the equipment doesn't need dedicated format parts), you're starting from a structurally better position than "training and standard work" alone can usually achieve.

Why this matters specifically to weight sorting (manufacturing + R&D)

Weight sorting is often deployed at points where organisations are most sensitive to quality and data decisions:

- incoming R&D batches and formulation screening
- blend/press optimisation and process development
- stability studies and investigation samples
- batch recovery and salvage decisions
- containment-controlled environments (potent compounds, shared facilities)

In these contexts, the "hidden cost" of change parts isn't just the time to swap them.

It's the additional GMP system load you must build and maintain:

The compliance overhead created by format-part ecosystems

If a competitor's sorter requires format kits per product shape/size, you inherit requirements such as:

- unique part identification, status labelling, revision control
- defined cleaning procedures per part type/material
- verification of cleaning effectiveness (as appropriate)
- controlled storage and segregation of clean/dirty parts
- line clearance checks that include correct format size verification

- investigation readiness when rejects spike post-changeover

FDA cGMP requirements reinforce that equipment and utensils must be cleaned and maintained to prevent contamination affecting product quality.

And packaging/label operations explicitly require procedures incorporating prevention of mix-ups and cross-contamination. The same control logic applies to any product-contact parts moving between campaigns.

Again: “universal” format capability reduces the number of moving pieces the GMP system must control.

The strategic angle: it supports modern manufacturing strategy (not just today’s operations)

Pharma is trending toward:

- more SKUs and dose strengths
- smaller campaigns
- faster tech transfer
- CDMO models with shared assets
- more potent compounds and stricter cross-contamination expectations
- tighter supply continuity expectations (where deviations cause availability problems)

ICH Q9(R1) also pushes the industry to treat quality risk management as part of preventing wider impacts like supply disruption from quality failures.

In that environment, a piece of equipment that needs fewer change parts is aligned with the strategic direction: reduce complexity, improve control, shorten release cycles, and stay inspection-ready.

A practical “numbers” illustrations

Scenario: high-mix CDMO sorting 12 products/week

Assumptions:

- 12 product changeovers/week on a sorter
- competitor requires 1 dedicated kit per format (average 6 parts per kit)
- each part adds handling steps (retrieve, verify status, fit, clean/store, document)
- changeover labour fully loaded: £60/hour
- post-changeover verification/first-article/QA checks: 20 minutes

Competitor approach (format kits):

- 12 changeovers × (45 min changeover + 20 min checks) = 13 hours/week
- labour cost ≈ £780/week (~£40k/year)
- plus deviation exposure (rare, but expensive when it hits)

Near-universal approach (minimal dedicated parts):

- 12 changeovers × (15 min changeover + 10 min checks) = 5 hours/week
- labour cost ≈ £300/week (~£15k/year)
- Indicative delta: ~8 hours/week and ~£25k/year in direct labour alone, before you count:
- scrap/reject swings after changeover
- time lost to investigations
- extra inventory of spare kits
- cleaning verification effort for multiple part types

Even if your numbers differ, the logic is stable: every eliminated part eliminates a cleaning surface, an ID check, a storage decision, and a potential mix-up.

Conclusion

If your operating model involves frequent changeovers, shared equipment, and high product mix, then format-part complexity is not a minor inconvenience.... it's a structural GMP risk.

Modern guidance expects risk to be controlled proportionately, and inspection evidence shows change parts are a recurring weak point. Designing a sorter that needs almost no dedicated change parts is one of the cleanest ways to reduce both contamination/mix-up exposure and the operational burden that comes with controlling them.

How many dedicated change parts are you managing per product family today, and how many changeover-related deviations did that create last year?
Share your number (even a range). I'll reply with a practical risk-reduction checklist you can use in your next QRM review.

References:

- EU GMP Guide, Chapter 5 Production (dedicating specific product-contact parts as a mitigation option).
- EU GMP Guide, Chapter 3 Premises and Equipment (design to minimise error and enable effective cleaning).
- PIC/S PI 043-1 Aide Memoire: Cross-contamination in shared facilities (hazards incl. mix-up of equipment/parts).

- EMA: HBEL guideline for shared facilities (scientific approach to cross-contamination thresholds).
- PIC/S PI 046-1 HBEL guideline (PIC/S transpose).
- ICH Q9(R1) Quality Risk Management (risk-based decision expectations).
- FDA Form 483: Baxter Pharmaceuticals India (Jan 2023) (change parts cleaning/verification failures).
- FDA Warning Letter: Baxter Healthcare Corporation (Jul 2023) (assessment including change parts).
- Bevilacqua et al., “Changeover Time Reduction… pharmaceutical sector” (SMED/lean case study; changeover reduction up to 50%, OEE +25%).

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1.1 Amendments

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