

Improving Operational Efficiency: Streamlining Large-Scale Buffer Production with Direct Dispense Raw Materials

A global CMO specializing in monoclonal antibody production gains significant advantages in productivity, operator safety and GMP compliance.

STREAMLINING A LABOR-INTENSIVE BUFFER PREPARATION PROCESS

A global contract manufacturing organization (CMO) specializing in monoclonal antibody and biologics production sought to streamline its buffer preparation process. At one of its manufacturing sites, approximately eight tons of sodium chloride (NaCl) were used each month across various downstream buffer preparation and formulation steps.

Handling raw materials such as NaCl is typically complex and labor-intensive, requiring more than 50 steps, including handling, storage, wiping, sampling, testing, weighing, dispensing and solution preparation.

The CMO evaluated two options for handling the NaCl: 12 kg packs and pre-weighed J.T.Baker® 100 kg direct dispense bags.

- 12 kg NaCl packs require manual handling and weighing before buffer preparation. Under GMP conditions, each pack must be opened, weighed, verified, labeled and documented individually, a process necessitating ~102 operator hours per month. This translates to two full-time employees, an option that cannot be implemented quickly under GMP training and qualification requirements.
- J.T.Baker 100 kg Direct Dispense NaCl bags eliminate the need for internal weighing or verification and the need for additional operators. The bags can be connected directly to the buffer preparation tank and discharged using a mechanical lifting device such as a crane or hoist arm.

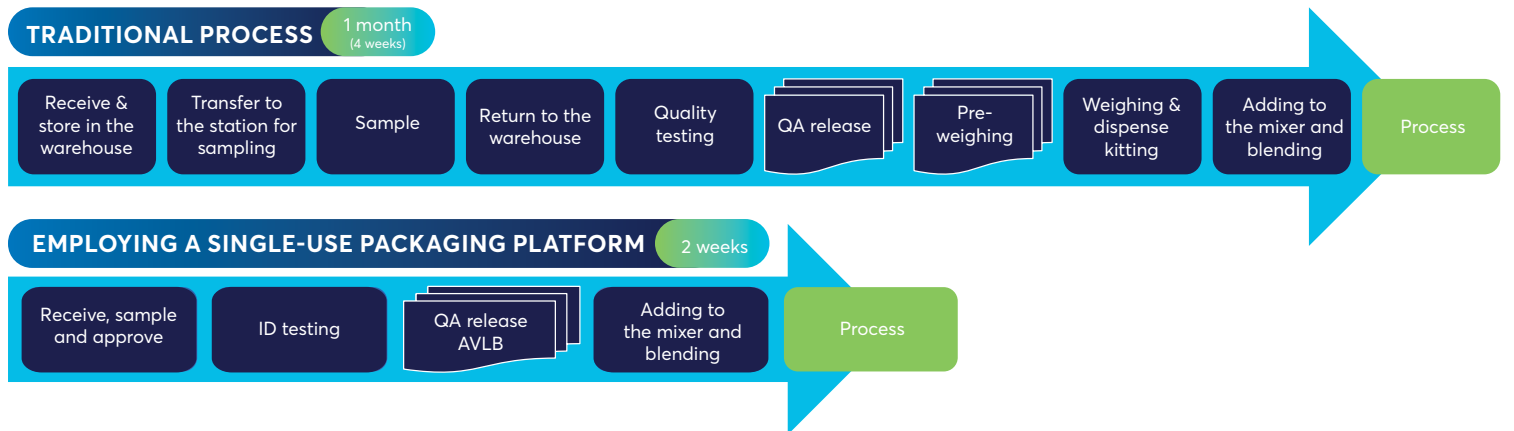


IMPROVED OPERATIONAL EFFICIENCY AND FLEXIBILITY

Adoption of J.T.Baker® Direct Dispense bags reduces operational expenses and risk, while improving production efficiency and flexibility.

Single-use bags	→	Space savings, labor savings, reduced cleaning, reduced downtime, lower CapEx
Pre-weighed raw materials	→	Labor savings, reduced non-conformance, reduced wastage of materials, including reduced sick leave.
Direct material delivery	→	Reduced batch time, enhanced operator safety, including reduced sick leave, decrease safety/ergonomic concerns during processing
Rapid Raman ID & Satellite Samples	→	Reduced QC testing, labor savings, robust database to track chemical inventory
Quality support for rapid release and investigation (electronic weight data /E&L)	→	Reduced regulatory risk, lower non-conformities, easy information sharing, electronic redundancy of raw material data

For this CMO, the use of J.T.Baker 100 kg Direct Dispense NaCl bags in the manufacturing workflow resulted in impressive efficiency gains by eliminating multiple steps compared to traditional processes.



CONCLUSION

By transitioning from manually handled 12 kg packs to J.T.Baker 100 kg Direct Dispense NaCl bags, this global CMO significantly simplified a traditionally labor-intensive buffer preparation process. Eliminating internal weighing, verification and additional operator requirements reduced operational complexity while freeing valuable GMP-trained resources.

The ability to connect pre-weighed raw materials directly to buffer preparation tanks not only accelerated production timelines but also reduced handling steps, documentation burden and associated operational risk. As a result, the CMO achieved meaningful gains in efficiency, flexibility and GMP robustness, demonstrating how Direct Dispense raw materials can streamline large-scale buffer production while supporting reliable, compliant biologics manufacturing.