

Buffer Management Simplified: MOTIV Keeps You Moving

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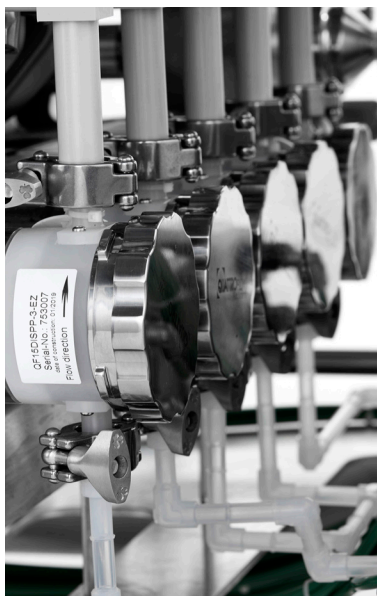
Generating a consistent, optimized buffer solution for a drug product is crucial to ensuring its efficacy and establishing a reliable supply chain for market scale-up. Because of their varying applications and formulations, finding the right solution to guarantee a buffer that meets a project's needs at every phase is crucial.

Many pharmaceutical companies arrive at the buffer formulation stage and immediately begin the process of partnering with an outside organization to produce their buffers. While this represents a perfectly valid choice in many instances, there are a number of scenarios in which opting for in-house buffer production affords companies greater flexibility, tighter turnaround, and more freedom than most contract organizations can offer.

MOTIV™, the award-winning Inline Buffer Formulation (IBF) fluid management systems from Asahi Kasei Bioprocess America (AKBA), represents some of the most advanced equipment for buffer formulation available. By providing technologies that offer customers greater productivity, heightened control, and tighter timelines, AKBA helps companies increase their downstream production efficiency and manage risk more effectively than ever before.

IN-HOUSE BUFFER FORMULATION MADE EASY

For many pharmaceutical companies, the idea of bringing their buffer formulation in-house is a daunting prospect: concerns regarding the space needed, as well as the labor involved, keep many from pursuing it. These misconceptions – that inline buffer equipment requires a large space footprint or is labor intensive – discount the recent advancements in these technologies, which have enabled more modular, highly automated systems capable of producing niche buffers and adjusting their parameters on the fly to meet specifications.



Many companies are familiar with the traditional approach to buffer formulation: combining the requisite water and chemicals into a large tank, mixing it, taking samples for laboratory analysis, and adjusting it until they are able to achieve the appropriate formulation. This type of batch processing differs from continuous or on-demand manufacturing, in which a system takes the established parameters for a buffer and, thanks to very precise and autonomous controls, is able to replicate the buffer repeatedly without the need for the extraneous testing and recalibrating inherent to traditional methods.

To achieve this, AKBA works closely with customers to determine their project needs, their resources, the facility's capacity to accommodate various types of equipment, and the customization required to optimize the equipment. This evaluation can be very granular; AKBA will evaluate every aspect of a system's transport, including whether it will need to navigate tight spaces

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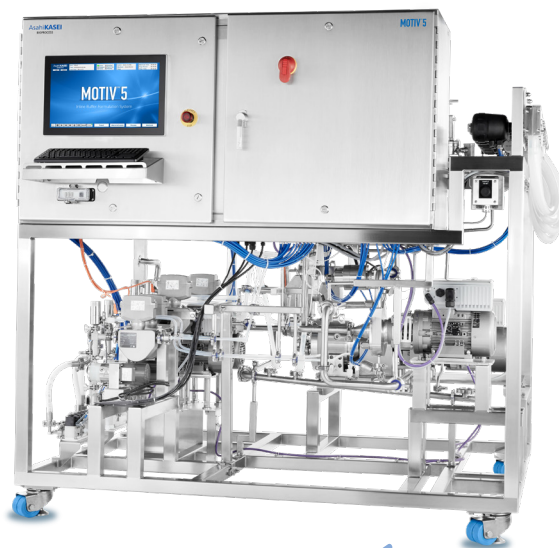
or elevators prior to installation, as well as where and how it will connect to the facility's utilities and other location-specific factors. Once installed, AKBA works to integrate the new system with the facility's existing systems in order to allow it to "communicate" with those systems, enabling remote and autonomous operation, even between locations. Having this sort of flexible production brings a new meaning to "just-in-time" delivery – through producing buffers as needed, operators can circumvent the issues inherent to storing buffers produced externally, including the freezing conditions that plague certain facility setups.

Each MOTIV system AKBA provides is custom-built to a customer's specifications. These systems can be outfitted to produce up to 5,000 liters of buffer solution per hour, and can be fully customized to meet the entire range of end-user requirements. For larger requirements, AKBA can construct an entire ecosystem able to operate simultaneously with the required flow rates; for smaller ones, a more modular system that requires relatively little space to operate can be outfitted to produce a variety of formulations with unique specifications. In either scenario, AKBA works closely with operators to ensure each system is primed to execute on schedule and according to specifications with every run.

FLEXIBLE, CUSTOMIZABLE EQUIPMENT TO SUIT EVERY NEED

For pharmaceutical companies considering inline buffer equipment, concerns surrounding producing more complex buffers can win out in their decision on whether to proceed. A recent case study from one of AKBA's customers demonstrates why this issue can be easily mitigated with the right partner: the customer, based in Asia, approached AKBA with a buffer formulation, which AKBA was able to reproduce in an engineering run using its MOTIV system. AKBA quickly turned around 200 liters of sample solution, along with the necessary batch records, and was met with astonishment on the part of the customer – because certain components of the buffer were required in such small, discrete amounts, their incorporation in the final formulation was difficult or impossible to achieve using more common approaches. As a consequence, every prior competitor had been unable to replicate it at the level required for commercialization.

This ability to tailor systems to meet unique specifications is just part of what makes MOTIV unique. Part of the system's value proposition to customers is the software which accompanies it – OCELOT™, a universally compatible software solution capable of interfacing with plant-wide control systems to achieve intuitive integration within the larger process. By leveraging both automated control and data collection and analysis, OCELOT affords operators unparalleled flexibility, allowing them to remotely initiate production, tweak process parameters, and implement additional



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SYSTEM CONTROL



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features that help them track and maintain records. The software can even be translated into primary languages other than English, as requested by a customer, to ensure ease of use. Installing OCELOT as MOTIV's operating software is not a requirement; AKBA can provide customers a bare-bones skid they can integrate with their own software.

Because it is directly supplying buffer to the user, MOTIV does not require the holding tanks of traditional buffer formulation systems. In addition, its relatively small footprint – approximately two meters by two meters – allows it to fit into a customer's existing facility with relatively little workaround. The remaining tanks and solutions can often be stored outside a facility and supplied via pipeline, virtually eliminating the system's footprint. Cleaning is commenced by process analytical tools, and the next run is initiated. Together, the design of MOTIV, its accompanying software OCELOT, and the customization provided by AKBA all serve to simplify the supply chain from start to finish.

SIMPLIFYING WORKFLOWS TO SOLVE COMPLEX PROBLEMS

Because most manufacturing processes require buffers consistently and in large quantities, ensuring that their production is as timely and cost effective as possible can go a long way in optimizing scale-up and commercialization. Through its automated production and data generation, MOTIV offers customers the ability to reallocate their human resources to more intensive parts of the process. And since the buffer formulation can be adjusted on the fly from anywhere, users also stand to gain time back that would otherwise be spent reformulating and testing solutions produced more traditionally or communicating their needs to an outside partner and waiting for that implementation to occur.

Once installed, the process for employing MOTIV is a simple one: the operator is able to upload the specs of a given buffer formulation, connect the required solutions and chemicals to the system, and press the start button. The volume of buffer produced, as well as the formulation, can be changed without revalidating the system, which is able to retain multiple buffer formulations in OCELOT. The process, once initiated, is fully autonomous, and in instances where the supply of water or another necessary chemical is nearly depleted, the system will cease operating and alert operators of the issue.

All of these features are complemented by AKBA's commitment to supporting its customers through a product's lifetime. While its hardware components have a relatively long lifespan, MOTIV's software, OCELOT, will require regular updates to conform to newer operating systems. With the right upkeep, these systems can last more than 15 years – many of the first inline buffer systems sold by AKBA are still in operation today, with continued support from the company to ensure they meet regulatory standards and customer expectations.

Through its innovative, flexible design, MOTIV provides customers with equipment capable of meeting their buffer formulation needs for years to come. That flexibility, coupled with AKBA's commitment to supporting customers from installation through end-of-life, make MOTIV the ideal choice for bringing a company's inline buffer formulation in-house, generating cost savings, improving timelines, and minimizing waste in the process.

Questions?

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