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Wahab received his Bachelor of Applied Science (BASc) in Biology/Biological Sciences from Northeastern Illinois University and Lean Six Sigma from Northern Illinois University. He has worked in field service engineering at AKB for over seven years.

Many organizations have embraced routine maintenance as part of their overarching manufacturing strategy.

Implementing Predictive Maintenance Practices For Better, Faster Manufacturing

The speed at which most drug manufacturers operate leaves little room for error, with highly specialized equipment and instruments often scheduled to operate continuously or near-continuously, switch between products and processes as quickly as possible, and scale seamlessly. This model has created increasing pressure to reduce downtime, which has, in turn, led to greater focus on the maintenance practices that typify these increasingly complex, costly production schemes.

While reactive maintenance was the status quo for decades, the pitfalls inherent to this approach have only increased as pharmaceuticals have become more complex. Many organizations may fall into the trap of trying to postpone scheduled maintenance, hoping to continue operating well beyond the prescribed timelines for a particular system or component. This can result in catastrophic delays and cost overruns in the current landscape, as procuring replacement equipment can take weeks or months. Many drug manufacturers are contract development and manufacturing organizations (CDMOs) working on several client programs simultaneously. Losing one piece of equipment can create cascading impacts for the timelines of not just the involved project, but of other projects waiting for the same equipment or diverted in order to meet deadlines for other projects.

In order to mitigate the issues that attend reactive maintenance, many organizations have embraced routine maintenance as part of their overarching manufacturing strategy. While this approach offers numerous advantages over reactive maintenance, manufacturers can realize even greater productivity and uptime by incorporating predictive maintenance practices in their processes.



AVOIDING THE PITFALLS OF REACTIVE MAINTENANCE

Many of the highly specialized instruments and equipment that comprise a pharmaceutical manufacturing paradigm represent a large capital expenditure. That expense, coupled with the costs associated with producing certain drugs such as advanced therapeutics, has made avoiding lengthy downtime or complex repairs paramount. Having an established maintenance plan that helps maximize the usable life and utility of a piece of equipment or system can greatly minimize this risk, ensuring that operators are getting maximum utility from these systems and increasing overall productivity.

In the current market landscape, much of the work producing drugs is performed by CDMOs or CMOs, introducing added complexity to manufacturing, as these organizations work to balance multiple clients and applications across their sites. One lengthy delay can serve to disrupt a CDMO's entire manufacturing ecosystem, forcing them to reprioritize applications and potentially creating compounding delays for multiple customers. In this respect, a single inoperable piece of equipment can create a scenario in which a CDMO loses millions of dollars of revenue and materially harms their relationship to clients.



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Implementing Predictive Maintenance Practices For Better, Faster Manufacturing

Avoiding the pitfalls of subpar maintenance requires identifying the best maintenance schedule and practices for a given system. Finding a flexible, accessible equipment supplier that can offer customized solutions and preventative maintenance strategies is critical to maximizing and extending the utility of these technologies. At Asahi Kasei Bioprocess America (AKBA), customers' equipment is produced to spec and serviced according to an individual application's needs, with trained field technicians available on demand to address emergent issues. Because AKBA develops equipment for customers on a case-by-case basis, it is well-positioned to advise on the most appropriate maintenance plan for a given system. This process and component understanding is crucial to developing a holistic maintenance plan that accounts for the interplay between discrete components, as well as the systemic burden of a given process over time.



COMBINING ROUTINE AND PREDICTIVE MAINTENANCE STRATEGIES TO MINIMIZE RISK

Having a maintenance plan in place is the foundational step in establishing practices that go beyond the reactive and toward more predictive methods. In order to foment a strategy that accounts for emergent issues that may not be fully mitigated by routine maintenance, operators must consider more comprehensive plans that enable swift, responsive repairs for a number of scenarios. This often means having spare components on hand in the event of failures that fall outside scheduled maintenance; a plan that follows predictive maintenance principles will account for this, with the most appropriate components kept on hand and replenished as needed. This is particularly important with the current supply chain issues impacting the industry, which can create long lead times and stymie even those with scheduled maintenance in place.

While any robust maintenance strategy requires significant up-front cost to implement, this pales in comparison to the potential losses a prolonged manufacturing delay can cause. That is why combining a routine maintenance plan with predictive maintenance practices is key – by regularly maintaining a system while simultaneously monitoring it for performance losses, operators can avoid both catastrophic losses and incremental ones. As part of its customer service contract, AKBA offers emergency visits to assist customers with urgent problems. This, combined with a service plan that includes predictive monitoring and spare parts, means that a customer can limit a system's downtime to days rather than weeks, regardless of the scenario.



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Another issue many operators experience relates to unseen performance loss – a system that is capable of producing up to 30 liters per minute, when operated using a method that produces 10 liters per minute, may slowly lose maximum capacity over time without impacting the current method. Without predictive monitoring, this performance decline may not become apparent until operators attempt to switch to a more demanding method, only to realize that the system can no longer run at its full capacity and requires maintenance. This often necessitates diagnostics to pinpoint the source of the performance loss, with the potential for more delay if the operator or supplier does not have a replacement component on hand.



PARTNERING WITH A SUPPLIER THAT PRIORITIZES CUSTOMER CARE

With the right maintenance plan and spare components in place, the last tenet of a comprehensive maintenance strategy is expertise. Maintaining and repairing complex pharmaceutical manufacturing equipment can create both safety issues and damage to interconnected components, as improper handling or repair attempts can cause issues with other linked components. With decades of experience and dedicated teams worldwide, AKBA has positioned itself as a premier partner for both equipment procurement and maintenance. Its 847 Continuum Program™ offers customers everything necessary to keep their systems running, from services to parts to training. Its reliable technical support network is available throughout North and South America, Europe, and Asia, and offers both remote and in-person diagnostics, onsite system and column repairs, and emergency services.

Ultimately, AKBA has established a robust, accessible model for predictive maintenance that meets the demands of a complex segment of the pharmaceutical industry. With technology platforms for virus filtration, inline buffer formulation, chromatography, and oligonucleotide synthesis, AKBA's bioprocessing systems, columns, and automation solutions advance GMP manufacturing of critical drug substances around the world. Its 847 Continuum Program is based on AKBA's eight company values – sincerity, challenge, creativity, wisdom, curiosity, growth, passion, and responsibility – its four core services of support, parts and consumables, training, and maintenance, and its commitment to making its international teams available to customers seven days a week.

Questions?

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