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Stefan received his Master of Science (M.S.) in Mechanical Engineering with a field of study on controls and an Engineering Management Minor from Northwestern University.

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A user-friendly platform that simplifies implementation and operation

OCELOT System Control: Painless Precision for Process Automation

New and innovative treatments and changing market dynamics have led to a dramatic shift in how drugs are developed and manufactured. For example, a focus on smaller patient populations means drugs must be produced in lower volumes, resulting in an increased focus on process intensification in upstream manufacturing. As antibody titers go up, though, the strain on downstream processing creates significant bottlenecks in the production of novel therapies.

Automation can help overcome these challenges by improving process control, which ultimately results in better productivity and consistency. However, many of the current automation software platforms are not designed for both the needs of industry as well as the people who will be using it. OCELOT System Control, a new automation software platform from Asahi Kasei Bioprocess America (AKBA), offers all the capabilities of its competitors but with a user-friendly platform that simplifies implementation and operation.

SEAMLESS INTEGRATION ACROSS YOUR FACILITY

While there are many benefits to using automation in the pharmaceutical industry, custom installation of these types of solutions by a third-party system integrator can be expensive and complicated. Through its new user-friendly, innovative software platform, AKBA reduces the need for automation integrators by providing a fixed architecture that offers you a direct connection to equipment throughout your facility. This allows access to information about your batch process and its critical values and setpoints without additional customization, all made possible by the reliability of Rockwell Automation tools. Through the application of Rockwell's CompactLogix programmable logic controllers (PLCs) with a dedicated OPC-Ready ethernet port, OCELOT can also reduce the time and cost of installation by easily integrating with plantwide programs, allowing your downstream experts to monitor and record vital information, such as trends on each system during processing.



In addition, OCELOT uses Rockwell's modern HMI, FactoryTalk View, which is an interface that includes a library of preconfigured options and AKBA-built global objects that are well tested, modular, and readily available for use, reducing the need for custom scripting. Equipped with FT View and Windows group-based security, AKBA can configure specific users within OCELOT using your IT infrastructure and domain. As a result, users are able to log in on any piece of equipment using the same username and credentials, and each login can be traced back to them. If necessary, you can create

and manipulate tiered and group-based user privileges across different types of equipment to control access as needed. Once a user is logged in, they can take advantage of seamless integration and operation through a highly specialized system that offers strong repeatability with enough flexibility to be as valuable as possible for each customer that uses it.



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SIMPLE OPERATION THROUGH BROWSER-BASED, REMOTE METHOD EDITING

Recipe creation and editing during drug development and manufacturing is one of the most labor-intensive activities for process engineers. While they are not often the ones executing the recipes they create, they are responsible for monitoring the recipes and making changes as needed. Requiring them to be present at the equipment every time they want to check in can be a cumbersome and time-consuming task. That is why OCELOT includes a browser-based, remote editing tool through a centralized data server that allows subject matter experts to log into the system from any computer connected to the company intranet. This includes access via a VPN, should a process engineer need or want to work from outside the office — even at home. They are able to create new recipes, make and save changes, and even access old batch reports from the comfort of their own desk.

This functionality can be used simultaneously with other system operations, so users can execute product runs while engineers are preparing the batch for the next set of operations. The user-friendly interface simplifies recipe creation using pre-populated fields and default critical parameters that drive efficiency while minimizing errors and delays. OCELOT's recipe-editing tool also facilitates scale-up by allowing users to easily validate parameterized recipes and update those parameters at point of use.



REGULATORY COMPLIANCE IN A DATA-DRIVEN INDUSTRY

Current pharmaceutical pipelines contain thousands of emerging drug candidates that hold the potential to completely transform patient care. One of the most important tools manufacturers and regulatory authorities use to ensure these products are safe and effective is process and product data. Therefore, the ability to view and share data throughout a drug's journey to market is crucial. Yet, as these products continue to increase in complexity, so too does the information they collect during the drug development and manufacturing life cycle, leading to a data fire hose that is becoming more and more difficult to maintain.

Automation serves as a key component in managing data, improving not only its integrity but also compliance. Yet, this is possible only if the system is able to communicate and collect information from other equipment across your facility. Along with OCELOT's simplified facility integration, the system also complies with **21 CFR Part 11** by maintaining an audit trail of all actions that occur during or outside of a batch, which can be easily generated into a full report. This report includes any instances of operator intervention, automatic system actions, and even charts and graphs of the recipe and process values.





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Questions?

Email me at stefan.hyde@ak-bio.com



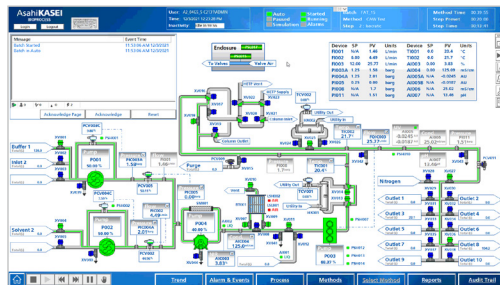
OCELOT System Control: Painless Precision for Process Automation

A BUILT-FOR-PURPOSE SYSTEM FOR THE FUTURE OF PHARMA

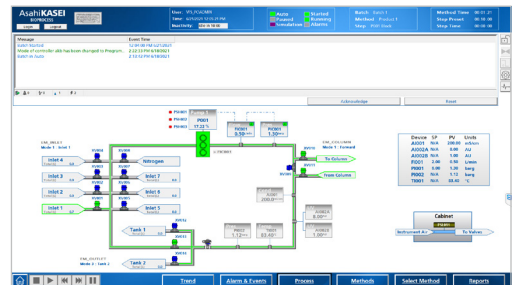
When it comes to automation software, there are many options available. However, the launch of OCELOT gives you the option to take advantage of a system that is built with not only your needs in mind but also with careful examination of the areas where our competitors' systems lack. While other solutions rely on the same user interface for a wide range of applications, OCELOT is configurable, so you can request exactly how you want your system to function and look at the time of factory acceptance. This means our experienced and knowledgeable team is able to create a tool that fits your exact process needs and mode of operation. We can then walk you through how to use the system while you are onsite as well as provide you with a detailed user manual and ongoing remote support.

As the industry evolves, it is AKBA's goal to continue to provide you with reliable, future-ready tools that can increase efficiency and mitigate the inherent risks associated with drug development and manufacturing. We understand data integrity plays an essential role in assuring consistent and repeatable results throughout the life cycle of your product, which is why OCELOT is designed for easy integration and continued flexibility, so you can maintain system control even as your needs change. Therefore, by implementing a solid automation software platform like OCELOT while utilizing AKBA's decades of experience, you can be confident you are maintaining the safety and efficacy of your current products as you explore new opportunities in today's changing market.

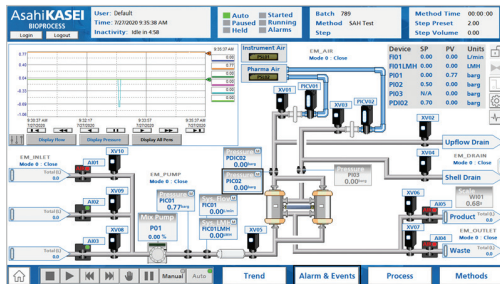
A CLOSER LOOK AT OCELOT SYSTEM CONTROL



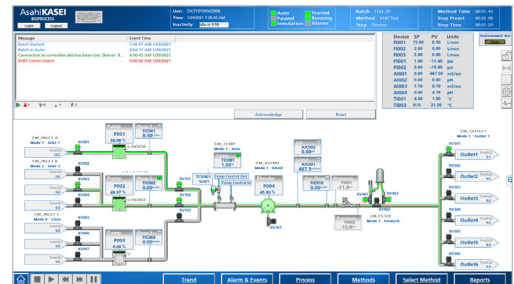
Chromatography



Oligonucleotide Synthesis



Virus Filtration



Inline Buffer Formulation