

Time and cost savings in bioprocess operations through efficient data management



Discover how biotech company Bota Bio has implemented unified and reliable data management and analytics through the implementation of PAS-X Savvy at its sites Hangzhou (China) and Lafayette (USA), enabling high-performance bioprocesses and ensuring significant added value in drug development and manufacturing.

The ICH (International Council for Harmonization) Q10 requires the implementation of a pharmaceutical quality system throughout the product life cycle to promote innovation and continuous improvement and to strengthen the connections between pharmaceutical development and manufacturing. To achieve this, knowledge management is essential. A major aspect of knowledge management is managing data in a contextualized form.

According to ICH Q10, “Product and process knowledge should be managed from development through the commercial life of the product up to and including product discontinuation. For example, development activities using scientific approaches provide knowledge for product and process understanding.” Thus, it can be seen that uniform and reliable data management and analysis play a critical role in successful drug development and production.

In the field of bioprocess development, process scale-up validation, or manufacturing excellence, the main challenges typically revolve around these questions:

Where and how to obtain the necessary data, how to integrate the data and make it available for analysis, how to effectively utilize the data for analysis, and how to export the results of the analysis as a report in a specific format or template.

There are multiple reasons for the difficulties of data preparation and processing: “One is the vast diversity of data and data applications in the pharmaceutical industry – material supply information, data on the history of the used strains, experimental design data, process raw data, analytical data, derived process data, associated metadata, statistical models, mechanistic models, hybrid models, single-unit operation models, holistic models (e.g., integrated process models and digital twins), analysis workflows, validation workflows, and batch records, to name just a few”¹.

¹ Herwig, C. et al. (2021, March). Data Science for Pharma 4.0TM, Drug Development, & Production—Part 1. ISPE | International Society for Pharmaceutical Engineering. <https://ispe.org/pharmaceutical-engineering/march-april-2021/data-science-pharma-40tm-drug-development-production>



Why is process data of critical manufacturing steps so challenging to manage?

In the case of fermentation processes, for example, up to 210,000 data points can be generated in a single batch, and their repeatability is very low². The challenge for organizations in this situation is evident:

Challenge of data collection

Pharmaceutical companies conduct numerous experiments during process development, involving long experimental cycles and massive devices and measuring instruments, which generate a substantial amount of data. Managing such large-scale data can give rise to performance issues and challenges in data analysis.

The data may be stored in different systems, departments, or plants, leading to the issue of data fragmentation. This fragmentation can result in data that is difficult to access, search, and integrate. It may also lead to missing data and incomplete data analysis, further complicating the process of data retrieval and utilization.

Additionally, data could be manually extracted from different sources, introducing inconsistencies, errors, and time delays. Manual data entry can also increase labor and costs, as laboratory staff must invest time in repetitive, low-yield tasks, leaving analytical work to fall by the wayside. In most cases, the person conducting the experiment and the data analyst are not the same person. The data analyst usually faces challenges with data transfer. This means that significantly more time must be spent on communication between the two parties in this process, which could be allocated to other purposes.

Challenge of data processing

The data generated by a batch of processes often originates from various devices and storage systems. These sources differ in data formats and collection frequency, making the process of collecting, integrating, and aligning them time-consuming. Moreover, data collection is often carried out manually, increasing the likelihood of errors.

Dealing with a large volume of data in different formats poses challenges in organizing and extracting key information, as well as in comparing and analyzing it. This difficulty becomes particularly pronounced when performing statistical tasks throughout the product lifecycle. Additionally, transferring data between departments or plants hampers real-time access and exacerbates the error rate.

Challenge of data use

Excel's interface is not inherently intuitive, leading to data that is challenging to work with effectively. Engineers invest significant time in standardizing Excel worksheets using formulas and macros, yet inconsistencies often persist. Over time, the practice of copying and pasting between spreadsheets consumes valuable time.

Alternative methods such as capturing photos or screenshots result in weak presentations of information, complicating subsequent data mining and analysis efforts.



² Source: Bota Bio

More efficient use of resources: Time and cost savings in the process



Managing product development through to commercial production in an agile, secure, and robust way is crucial – especially during the transition from Research and Development (R&D) to scale-up. With PAS-X Savvy, the collaborative data analytics platform from Körber, you can quickly, comprehensively, and in real time manage, visualize, and analyze bioprocess data.

Thanks to PAS-X Savvy, you can swiftly gain deeper insights, holistically screen processes, and pinpoint critical parameters. As a result, you accelerate the development of biopharmaceuticals, ensure the consistent quality of existing products, and optimize your processes.

PAS-X Savvy supports the digital transformation of your pharmaceutical or biotech company. Utilize real-time visualization and processing of biotech process data, back up your decisions with robust statistical analysis, and connect information across all unit operations.

At a glance



Challenges	Solution	Customer benefits
<ul style="list-style-type: none"> • Heterogeneous data that is hard to contextualize, visualize and analyse • Inefficient scale up and tech transfer due to missing data accessibility and transparency • Time-consuming manual data management • Complex cross-departmental collaboration • High production costs and insufficient product quality 	<ul style="list-style-type: none"> • Körber’s software solution PAS-X Savvy 	<ul style="list-style-type: none"> • Data contextualization (batch genealogy) • Finding process data quickly • Automates repetitive tasks • Ensures high quality standards • Enables digital transformation • Considers processes holistically & user-friendly • Comprehensive and fast implementation strategy



Would you like to find out more about PAS-X Savvy and accelerating process data analytics?

[Learn more here](#)



Reference case: How Körber's data analysis and management platform PAS-X Savvy creates major value for biotech company Bota Bio

The Bota Biosciences, Ltd. (Bota Bio) is a global industrial biotechnology company focused on programming biological systems for the clean and efficient bio manufacturing of common household and industrial products. Bota Bio is led by an experienced, multidisciplinary team of industry veterans combining data and automation to translate biotechnologies into business value and consumer welfare. Since 2021, Bota Bio has implemented PAS-X Savvy at the sites of Hangzhou in China and Lafayette in the USA.

lected from lab, pilot, and industrial scales seamlessly. This integration of data allows for efficient analysis and decision-making across different projects, operations, and scales. With PAS-X Savvy, Bota Bio has successfully identified critical process parameters and scaled up from 2L tanks to 200,000L fermenters. Furthermore, introducing the new software solution has enabled Bota Bio's partners to increase their annual revenue by more than 100 million RMB (approx. 12.8 million €).



PAS-X Savvy enables Bota Bio to effectively utilize its data to track carbon and total mass balances in the bioreactors. Bota Bio has achieved a 100 percent mass balance and a 95 percent carbon balance, providing a solid data foundation and credibility for its Design-Build-Test-Learn iteration.

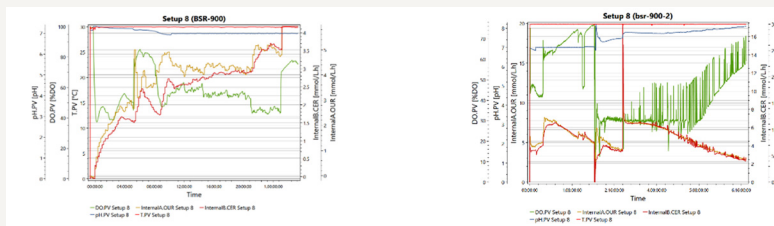
This means that Bota Bio can accurately monitor and analyze the flow of materials and energy throughout the operations, enabling it to optimize efficiency and understand where efforts for improvement are best spent.

PAS-X Savvy provides a single software suite that can effortlessly pull and compare any run from any project without the need for data reformatting. Additionally, it enables Bota Bio to compare fermentation data col-

Moreover, Bota Bio no longer needs to allocate specialist staff to manually copy and move data into different formats for online and offline data synchronization. This automation saves Bota Bio valuable time and resources, allowing the team to focus on more critical tasks. The exchange of fermentation data between Bota Bio project managers, customers, and internal departments is also simplified by PAS-X Savvy's standardized data format. This consistency ensures clear communication and facilitates collaboration, significantly increasing Bota Bio's overall productivity and customer satisfaction.

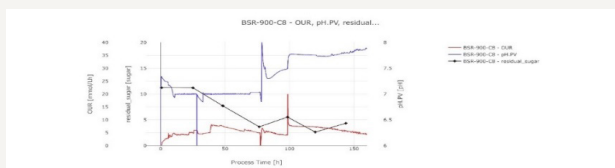


Without PAS-X Savvy



Time hour	Residual sugar g/L	Ammonia mM	Phosphate mg/L
0.00	11.24	44.158	1376.93
24.00	11.21	35.731	1272.47
48.00	7.716	10.633	1157.6
72.00	3.64	5.56	1117.46
96.00	5.54	5.56	973.11
120.00	2.63	5.56	1159.24
144.00	4.34	7.185	1301.94
168.00	2.72	33.496	1474.98

With PAS-X Savvy



The figures above show that before the introduction of PAS-X Savvy, multiple screenshots and tables were required because the data could not be visualized in one plot. Now, as shown in the figure below, the data can be visualized in PAS-X Savvy, with OUR, pH and offline residual sugar data, among others, displayed in one plot.



Data contextualization enables trend processing and deviation studies

PAS-X Savvy offers visualization techniques for all bioprocess relevant data types and allows you to easily plot and align your data, so you can check, compare, analyze, and create reports. For example, the software offers multi-axis overlay diagrams for analyzing processing trends and boxplots/histograms for displaying quality and product characteristics, which are ideal for viewing data.

“PAS-X Savvy provides intuitive interface and powerful features, which simplify insights, visualization, and informed decisions. From basic stats to advanced machine learning, it meets diverse user needs. Highly recommended for accuracy, speed, and user-friendly analysis. With streamlined interface and batch comparison, it’s effortless to extract valuable insights”



Yishu Tai
VP of Process, Bota Bio

PAS-X Savvy’s unique data model allows the visualization of the batch genealogy and ontology. An effective end-to-end data integration from various source systems into a fully contextualized data foundation with a clear semantic structure (ontology) is the key for successful data analytics. PAS-X Savvy’s visualization of complex process flows enables process engineers to find relevant process data quickly, facilitates cross unit operation data analytics and gather insights across multiple unit operations at all stages of the product life cycle. Through this, users can consistently uphold a comprehensive overview of the processes at all times, manage their projects, set-up pre-defined analysis workflows and create meaningful diagrams in seconds.

This “central database” approach automates repetitive and monotonous work steps and uses customizable templates for mapping, reporting and review. It is particularly suitable for cross-project and cross-organizational mapping, presentations and debriefings, facilitating the next step of in-depth analysis.

Main Fermentation																		
BSR-3592-B1	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	884.4	2179	SD550 42-005	5.562	✓
BSR-3592-B2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	818.8	1720	SD561 72-002	4.565	✓
BSR-3592-B3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	965.2	1305	SD561 76-003	4.104	✓
BSR-3592-B4	⊗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	361.8	2314	SD589 28-004	4.945	✓
BSR-3592-B5	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	709.9	3056	SD601 45-001	6.998	✓
BSR-3592-B6	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	20.6	61.61	SD610 78-011	0.2299	✓
BSR-3592-B7	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	57.65	102.1	SD611 23-006	0.4583	✓
	LCP_mg/L [mg/L]	b-car_mg/L [mg/L]	ZEA_mg/L [mg/L]	carotenoids [mM]	OUR [mmol/L/h]	RQ [-]	DO_PV [%DO]	DO_Out [%]	pH_PV [pH]	VB_PV [mL]	VC_PV [mL]	tank_mass [g]	ZEA/b-car ratio [mol/mol]	ZEA_mg/L_max [mg/L]	b-car_mg/L_max [mg/L]	strain_name	carotenoids_max [mM]	carotenoids_norm [%]

Bota Bio can easily manage 24h automatic fermentation sampling with PAS-X Savvy.



All-in-one platform significantly saves time in data collection

PAS-X Savvy supports automatic collection of available data across departmental boundaries and defines personalized access rights. With its unique data model, it aligns and contextualizes all data from MES, ELN, LIMS, DCS, Historian, Data lakes, and other standalone devices, making them available on a single platform. Database filter settings can be customized to quickly identify relevant batches, unit operations, and data types, enabling users to create personalized data sets.

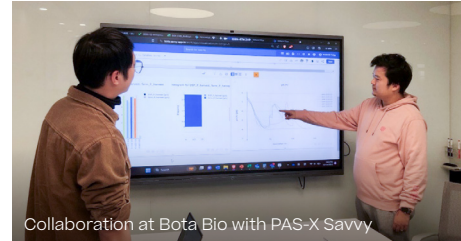
“Sharing screenshots of control software to communicate results is a thing of the past. Now, we swiftly contextualize offline data to the online process timeline, significantly enhancing our efficiency. Additionally, comparing data across recent and historical batches has become effortless.”



Frederick Twigg
Scientist, Bota Bio

This unified data platform acts as a standard specification, streamlining the R&D and manufacturing process and ensuring each step follows a standardized methodology. This enhances productivity, product quality, and reduces the risk of errors and human intervention. Standardized data analysis tools and processes provided by data processing platforms enable researchers to repeat analyses and ensure result consistency, crucial for validating findings and replicating experiments.

Moreover, it helps organizations establish compliance verification and reporting processes to ensure compliance with regulations and industry standards, effectively mitigating compliance risk.



Collaboration at Bota Bio with PAS-X Savvy

In essence, PAS-X Savvy assists biomanufacturing companies in succeeding in a competitive marketplace and adapting to new challenges in an ever-changing environment.

Reference case: A summary

Challenges

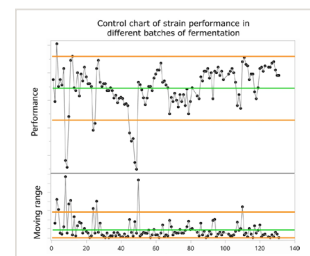
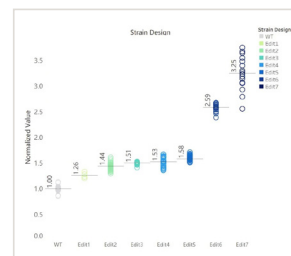
Over the past two decades, the production capacity of the target product remained stagnant due to strain modification challenges. The slow growth, the complexity of genetic modification, and unidentified bottlenecks in the metabolic pathway posed significant obstacles for strain improvement.

Solutions

Bota Bio developed a high throughput genetic modification method tailored for this industrial strain, established an efficient screening platform for semi-rational and random mutagenesis, and thoroughly assessed strain performance using a high-precision parallel fermentation system. With help of PAS-X Savvy, Bota has optimized the fermentation process, achieved remarkable performance reproducibility, exceeding 80 percent.

Impact

The modified strain, combined with optimized fermentation process, significantly increased the strain's fermentation performance; under the same facilities, this led to increased annual production, reduced production costs, substantial growth in net profit and benefited the up- and downstream.



About Bota Bio

Bota Biosciences (Bota Bio) is a global industrial biotechnology company connecting biological design to scale-up manufacturing to accelerate shifts to sustainable living. Bota has built an integrative bioengineering platform, to develop and implement efficient, eco-friendly, and cost-effective biomanufacturing technologies.

Committed to its mission, Bota established its own pilot plant and manufacturing facility, affirming its dedication to offering scalable industrial solutions and market-ready products. This infrastructure strengthens support for customers and partners across industries such as nutrition, food, personal care, and animal health.

Powered by a dynamic, multidisciplinary team, Bota Bio channels biotech innovations to create a global impact. The company's Series B financing has surpassed \$100 million, bringing its aggregate funding to \$145 million, with investment from notable strategic and financial investors, including Hong Shan Capital, Matrix Partners, and BASF Ventures.

www.bota.bio

About Körber

We are Körber – an international technology group with more than 12,000 employees at over 100 locations worldwide and a common goal: We turn entrepreneurial thinking into customer success and shape the technological change. In the Business Areas Digital, Pharma, Supply Chain, and Technologies, we offer products, solutions and services that inspire. We act fast to customer needs, we execute ideas seamlessly, and with our innovations we create added value for our customers. In doing so, we are increasingly building on ecosystems that solve the challenges of today and tomorrow. Körber AG is the holding company of the Körber Group.

At Business Area Pharma, we deliver the difference along the entire pharmaceutical value chain by offering a unique portfolio of integrated solutions. Based on in-depth experience spanning consulting, inspection, transport systems, packaging machines and materials, track and trace and software, we understand the challenges in pharmaceutical processes and regulation that our customers face day to day, from the beginning to the end of their production. For them, we deliver the difference to unlock the potential of global pharmaceutical and biotech manufacturing.

Delivering the difference in pharma

As your personal partner and expert for the pharmaceutical and biopharmaceutical industry, we support you with industry-leading software solutions – our PAS-X Suites have everything you need for a successful digital transformation:

- Körber's specialists uniquely integrate data management and analysis with a 100% focus on the biotech domain to ideally support your company's digital transformation journey
- Accelerate your bioprocesses from bioprocess R&D to commercial production through a transparent and holistic data science tool
- Save time and money by automating redundant tasks, leaving your experts more time for their core business

Industry sector
Biotech

Production site
China, USA



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