arxada

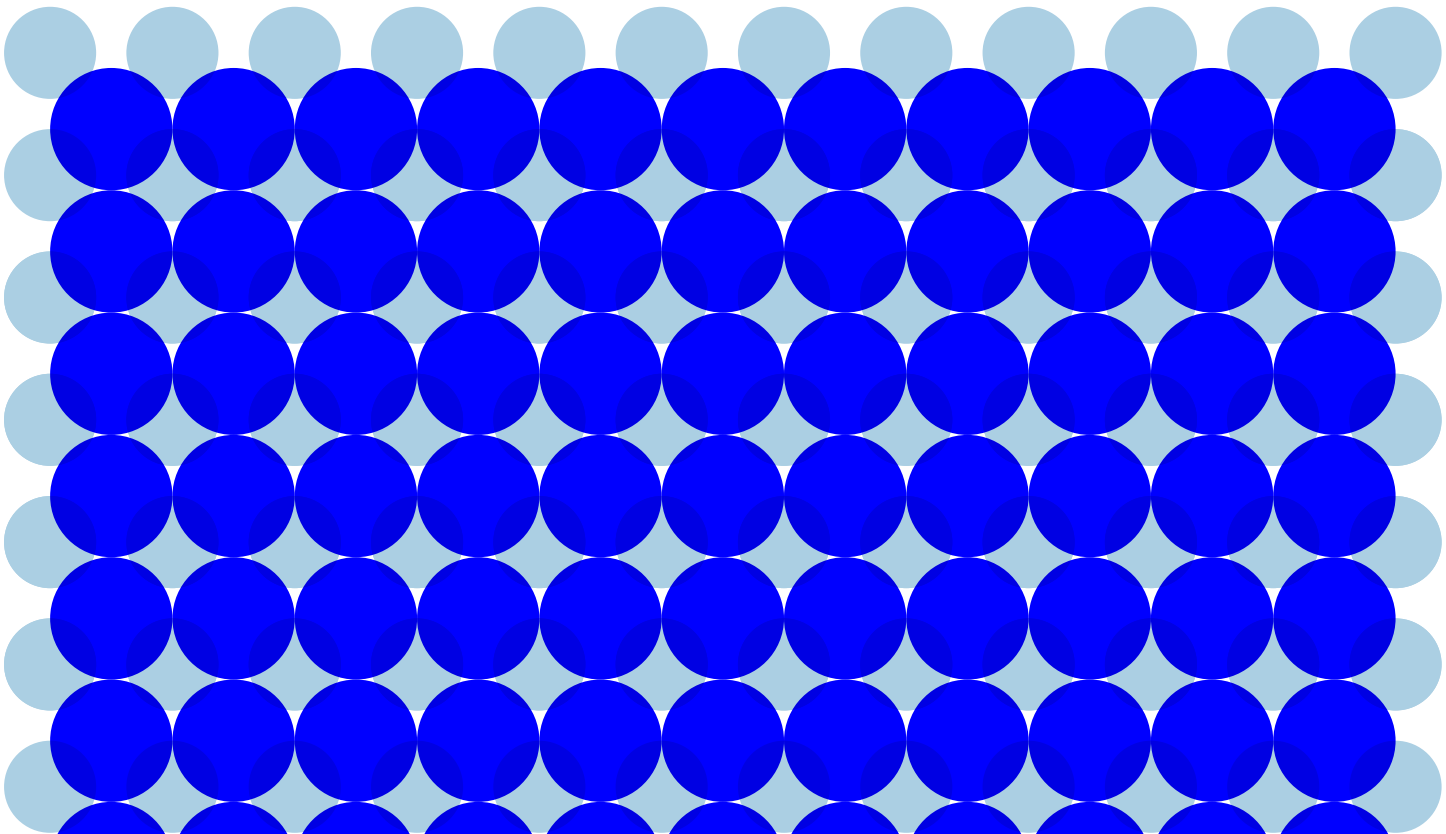
White paper December 2024

Custom Development & Manufacturing Organization (CDMO)

Holiday highlights: A year-end review of industrial biotechnology with Arxada

Vratislav Stovicek

As the festive season approaches, we take this moment to reflect on the year coming to an end. In this year-end review, we summarize the key insights of our white papers published throughout the year, highlighting the impact of biomanufacturing operational excellence. Additionally, we are excited to present a new video tour of our state-of-the-art manufacturing facility, offering a behind-the-scenes look at the cutting-edge technology and processes that help drive biotechnology innovations. Whether you seek a guide for your journey to market, an overview of Arxada's capabilities and expertise, or simply a read for long winter nights, join us in exploring the magical world of microorganisms and biomanufacturing.



Holiday highlights: A year-end review of industrial biotechnology with Arxada

Starting the journey in the beginning of the year, we have published seven white papers describing in detail the aspects of the world of microbial fermentation, bioprocess development and contract manufacturing. Eleven experts, specializing in areas such as upstream and downstream process technology, techno-economic analysis, quality control, engineering, operations management, and business, shared their views on biomanufacturing with a broader audience.

Simple click on the title of each white paper allows for direct download. If you prefer watching over reading check out the video tour (Figure 1).

Figure 1: Snapshot of the facility video tour. Click on the image to open a website with the video file.

From cell bank to market: How Arxada helps pave the way in white biotechnology

Vratislav Stovicek, Marek Jiricek, Zdena Cermakova, Leonardo Kleebauer

This white paper delves into Arxada's Contract Development and Manufacturing Organization (CDMO) services in industrial biotechnology. It addresses the challenges of transforming innovative biotechnology concepts into market-ready products, underscoring the need for effective collaboration between early-stage entrepreneurial ideas and industry. The paper highlights Arxada's expertise in microbial fermentation and downstream processing, showcasing the state-of-the-art facilities and technical proficiency. Achieving commercial success hinges on choosing the right manufacturing partner with full focus on speed, cost reduction, and delivery of high product quality. The authors also outline the critical stages of bioprocess development, from laboratory scale to commercial manufacturing, stressing out the importance of addressing scale-up challenges early enough to reach cost-efficient and economically viable processes.

Technology transfer documentation – What is essential and why?

Pavel Havelka, Marek Jiricek, Vratislav Stovicek, Leonardo Kleebauer

This white paper emphasizes the importance of comprehensive technology transfer documentation in the contract manufacturing environment. It outlines the initial step of crafting technology narratives and assessing the completeness of the technology transfer package (TTP) to enable accurate price estimates and timely responses to customer requests. The document provides guidelines for customers to understand which basic set of information needs to be included in the technical package. Obtaining detailed process data, information on process robustness, and quality requirements is desirable for quick and successful process transfers. Thorough communication and documentation allow for proper identification of critical technology points, understanding of process readiness, and addressing potential bottlenecks and scale-up challenges.

Scale-up of microbial fermentation processes: Smooth and economical path to large-scale commercial manufacturing

Denis Smirnov, Vratislav Stovicek, Marek Jiricek

This white paper discusses the critical aspects of scaling up microbial fermentation processes. It highlights the importance of manufacturing experience in foreseeing and mitigating of common scale-up pitfalls. The paper details all the stages of microbial fermentation, from working cell banks to main fermenters, and underscores the significance of accurate propagation steps and comprehensive process documentation. Key challenges discussed include nutrient medium preparation, process parameter control, and production strain stability. The authors further stress the importance of using appropriate raw materials and the impact of scale-up on process economics. The paper highlights best practices for mitigating risks and ensuring cost-effective, efficient, and reliable large-scale production.

Scale-up of biotechnology downstream processes: How to deliver required bioproduct quality at commercial manufacturing scale

Michal Norek, Marek Jiricek, Vratislav Stovicek

This white paper addresses the complexities of scaling up downstream processes (DSP) in industrial biotechnology. It emphasizes the importance of thorough process design and equipment selection to ensure successful scale-up. The paper outlines the main stages of DSP, including primary recovery, purification/concentration, and product polishing/formulation, and discusses the challenges and best practices for each stage. Arxada's extensive experience and advanced capabilities in DSP are showcased, emphasizing the ability to optimize processes, reduce costs, and deliver high-quality bioproducts at a commercial scale.

Bridging laboratory scale and commercial biomanufacturing: Arxada's pilot line in spotlight

Denis Smirnov, Martin Janosek, Vratislav Stovicek

This white paper explores the role of Arxada's pilot line in bridging the gap between laboratory-scale bioprocess development and commercial-scale manufacturing. The pilot line, with a main fermenter volume of 1.5 m^3, offers a versatile and modular setup for process demonstration, parameter fine-tuning, and small-scale production. It supports various purposes, including process validation, regulatory testing, or manufacturing of initial product quantities. The paper emphasizes the importance of piloting in optimizing processes, ensuring scalability, and reducing risks before full-scale production. The pilot line provides a controlled environment to test and refine processes, generate valuable data, and demonstrate process robustness, ultimately facilitating a smooth transition to large-scale manufacturing.

Analytical and microbiological methods in industrial biotechnology: Indispensable attributes of bioprocess development and commercial biomanufacturing

Lubomir Kriz and Vratislav Stovicek

This white paper discusses the critical role of robust analytical and microbiological methods in the development and manufacturing of biotechnological products. It highlights the importance of these methods in ensuring process efficiency, yield, and product quality across various stages, from microbial strain development to downstream processing. The paper emphasizes the necessity of state-of-the-art analytical capabilities and certified quality control laboratories for manufacturing organizations to maintain product integrity and regulatory compliance. Key challenges and best practices in method transfer are also explored, underscoring the need for thorough planning, standardization, and effective communication to achieve successful and reliable biomanufacturing outcomes.

Engineering excellence: An organic part of seamless process transfer in industrial biotechnology

Jan Novak, Jiri Riha, Vratislav Stovicek

This white paper discusses the crucial role of a strong engineering team in the seamless integration and optimal performance of biotechnology processes. It emphasizes Arxada's in-house expertise that spans from minor line modifications to the complete design and construction of new production lines, including buildings and utilities. The authors showcase the engineering team's end-to-end support, guiding projects from initial feasibility studies through detailed engineering to final commissioning. This comprehensive approach ensures meticulous planning and execution, minimizing risks and maximizing efficiency. The paper further emphasizes how robust engineering helps broaden the manufacturing efficiency and expand the portfolio of services for customers.

Summary

The season is ending, and with it comes the promise of a new year filled with new customers, processes, and challenges. Our passion for biotechnology innovations, operational excellency, and relentless drive for continuous improvement remain unwavering. As we look forward to the opportunities ahead, we invite you to join us on this journey. Leverage our expertise, and let us create a brighter, more sustainable future together!

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Our offer

- **One-stop-shop CDMO services in the field of industrial biotechnology**
- **Engagement at any stage of product/process development**
- **Dedicated team throughout the whole project**
- **Facility registered as food manufacturing site at FDA. Holding additional certification such as cosmetic manufacturing (EFfCI cGMP), ISO 9001:2015, FSSC 22000/HACCP, FAMI QS, Halal and Kosher**
- **Long lasting experience with high quality, speed, and strong focus on continuous process improvement**
- ***Focus on what matters to you***

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