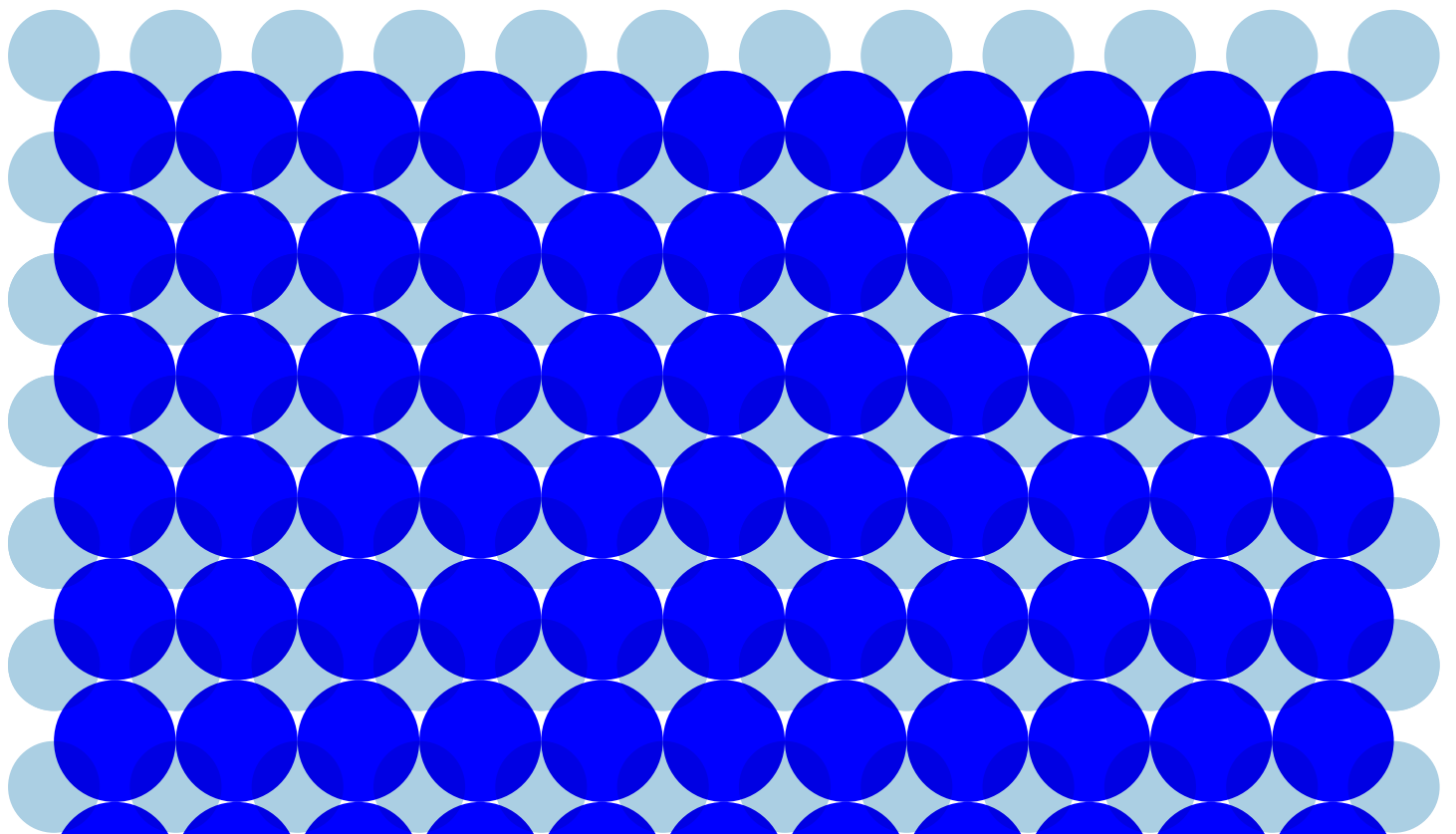


# Engineering excellence: Organic part of seamless biotechnology process transfer

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In the dynamic field of industrial biotechnology, challenged by product diversification and economic pressure, there is a need for fast, economical, and efficient process transfers to production scale. Particularly in the contract manufacturing environment, which is constantly exposed to various processes moving from one scale and/or facility to another, the ability to tailor processes and equipment to meet specific customer demands is critical. Robust engineering is the cornerstone of such a journey. Arxada's engineering team supports process transfers from laboratory to commercial manufacturing by customizing production lines, adjusting processes to different production scales, and integrating new technologies. Moreover, the team is capable of handling complex engineering projects focused on building new assets, broadening plant efficiency, and expanding the portfolio of services for customers. Let us delve deeper into more than two decades of engineering expertise.

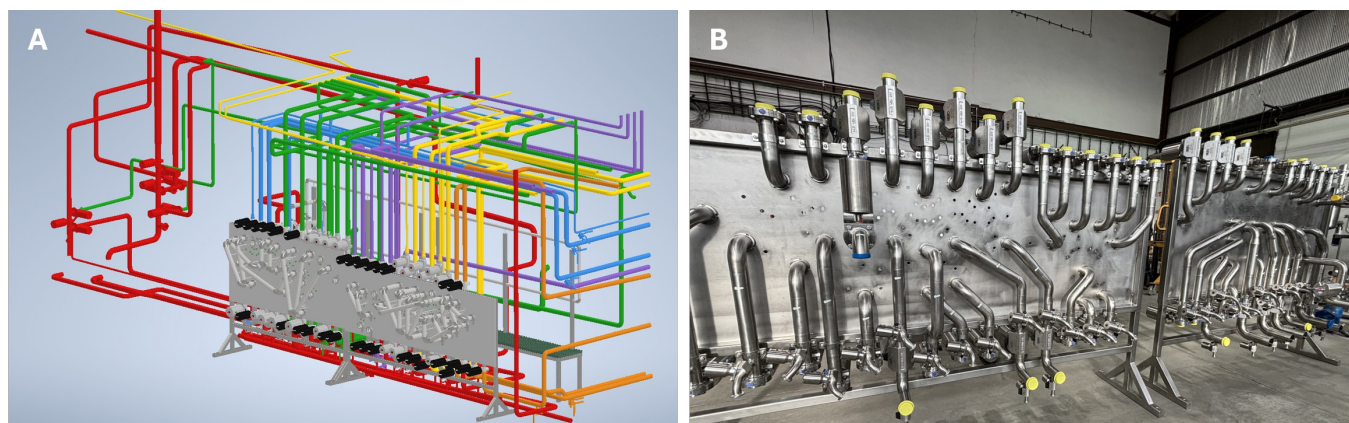


## Engineering excellence: Organic part of seamless biotechnology process transfer

Strong engineering, capable of comprehensive project management from feasibility studies to detailed engineering and commissioning, ensures seamless integration and optimal performance of biotechnology processes. Arxada possesses in-house expertise in managing investment projects, ranging from minor modifications, such as the implementation of additional regulation loops, to the comprehensive design and realization of new production lines, including buildings and utilities. The end-to-end support of the engineering team, from initial assessment to final implementation, ensures that projects are completed within pre-established timelines and budget.

Process engineers must have a comprehensive understanding of both the technical and practical aspects of process scale-up and transfer as well as in-depth knowledge of production lines, state-of-the-art equipment, and the latest technological advancements. Arxada's engineering team enables the design and provision of customized skid-mounted technology units that can be seamlessly integrated into existing production lines. These designs are visualized and finalized in 3D models (Figure 1), with customer collaboration when needed. In addition to mechanical engineering, dedicated EI&C (Electrical, Instrumentation, and Control) and software experts handle process automation, from specifying requirements to final programming and solution testing.

Figure 1: A) 3D visualization of a transfer panel, B) Assembly of the transfer panel in the workshop.



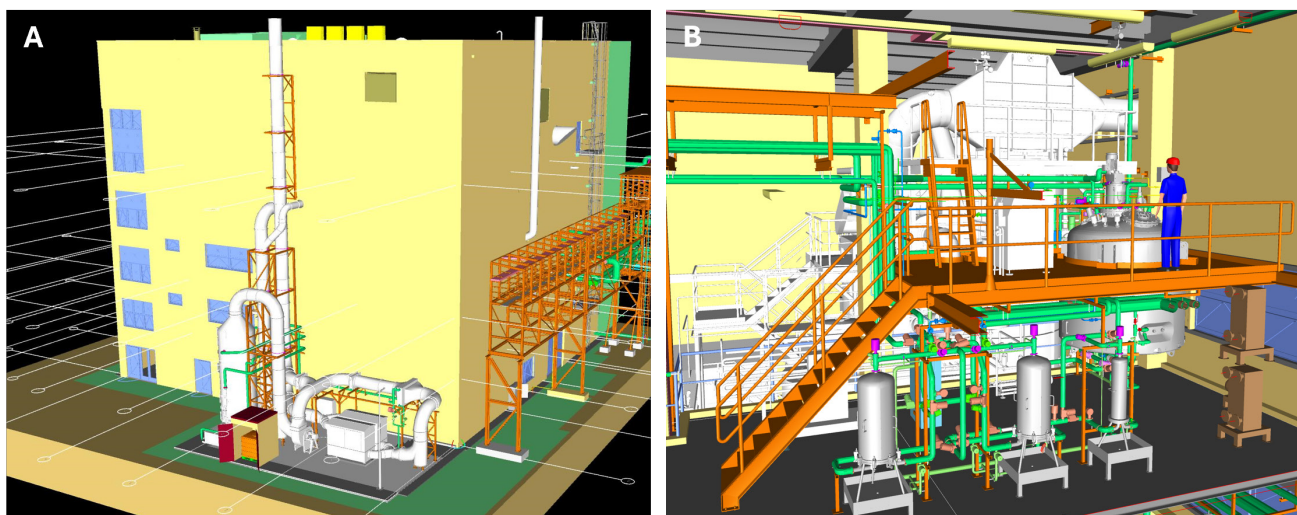
The engineering mission consists of several stages:

- **Assessment of the technical package:** The team participates on evaluation how the new process fits into the current manufacturing set up. Process schemes and mass balances are created and magnitude of investment is identified with certain level of accuracy, which varies depending on the investment complexity and timelines in which the project is planned to be executed. Cost estimation is calculated based on both internal historical price standards and suppliers' trustworthy relations, and potential price development, using the CEPCI (The Chemical Engineering Plant Cost Index) methodology.
- **Feasibility and engineering studies:** The studies are carried out using the Basis of Design (BOD), while more accurate plans and budgets are being formulated. Early analysis considers available production assets, their operating ranges and technical limits. Safety aspects, production and/or storage conditions and availability of media and utilities are assessed as well. By evaluating pros and cons of possible options for line modifications, the process engineers provide an optimal solution considering the production efficiency and necessary capital expenditures. The outcome of the initial analysis together with provided technical details help the customer to better understand production scale issues and financially justify the project execution. Here, the engineering expertise eliminates hidden pitfalls in the project execution and allows the customer to create a successful business case.

- **Detailed engineering phase:** A concept design is elaborated down to the level of individual elements. At this stage, precise calculations are made with a clear definition of technical parameters such as pipeline and fitting dimensions, selection of proper pumps, profiling of control valves, or selection of proper materials, considering the dynamic characteristics of the handled material. The E&C specialists suggest the most suitable control points and respective sensors for each of the monitored parameters and/or control loops, evaluating the behavior of the material at the operating range, bridging the mechanical concept through instrumentation to the control domain. Software engineers create specifications upon which the existing control system is either modified or supplemented by new control routines and/or product-specific data sets. A substantial part of the work, mainly mechanical and electrical installations, is carried out by external companies under the project managers' supervision. A bidding evaluation process is always managed diligently, considering bidders' professional competence to deliver both on quality and the best value for money. During the rich history of successful project implementations, strong partnerships with reliable engineering companies have been established. This ensures high-quality standards for every task that is subcontracted.
- **Execution phase:** All necessary installations and modifications are orchestrated together with multiple participants until successful commissioning, focusing on personal safety, asset security, and environmental protection. Good documentation practice applied throughout the entire process of project preparation and execution is an integral component of the company's quality assurance records.

More than 20 large-scale capital expenditure projects have been executed at Arxada in the past 5 years, many driven by the demand for various customer processes and the adaptation of production lines. However, the engineering excellence at Arxada goes far beyond the scope of production setup adjustments. Complex projects such as the construction of the 1.5 m<sup>3</sup> pilot line, a spray dryer facility (Figure 2), or a drinking water treatment plant have recently been successfully executed as well. This expands the plant's capabilities and improves hygiene, quality, safety, and security standards. Furthermore, the team's efforts lead to increased energy efficiency and sustainability of production, and a reduction of the carbon footprint.

Figure 2: A) 3D visualization of the spray dryer building, B) Visualization of the facility interior, where an operator checks the dryer infeed operation.



## Summary

The combination of flexibility, speed, and strong engineering is essential for the successful scale-up and transfer of biotechnological processes. Arxada's engineering team excels in managing even the most complex projects, guiding them from initial feasibility studies through detailed engineering to final commissioning. This comprehensive approach ensures that every aspect of the process is meticulously planned and executed, minimizing risks and maximizing efficiency. The engineering excellence plays a pivotal role in meeting business needs, ensuring that customers can bring their innovations to market quickly, efficiently, and in the most economical way.

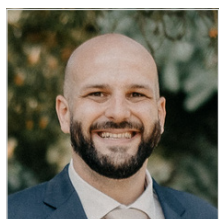
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