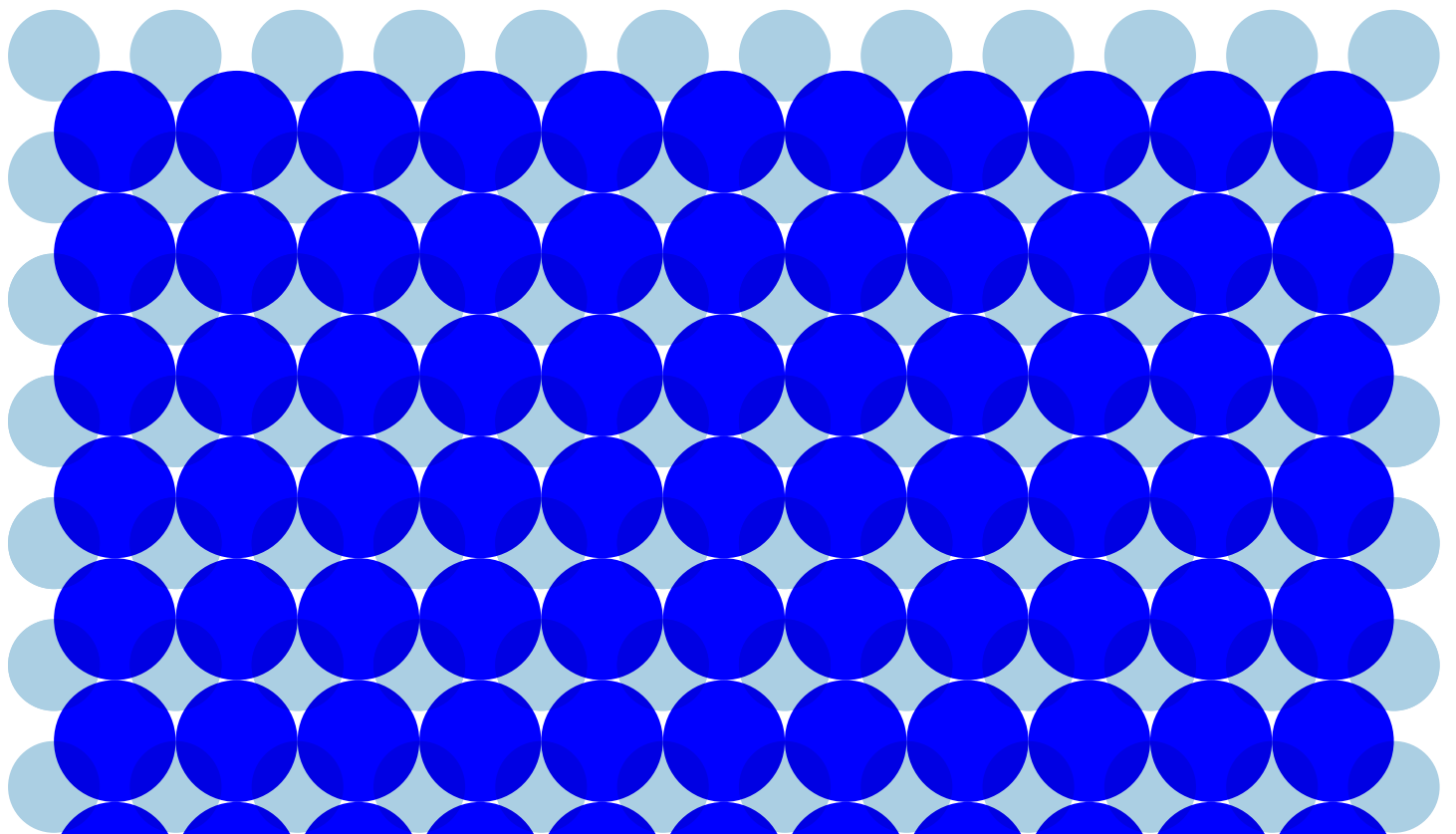


Navigating diverse projects in industrial biotechnology: The critical role of project management in contract development and manufacturing organizations

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Curious about the pivotal role of project management in the industrial biotechnology sector? Delve with us into the complexities faced by Contract Development and Manufacturing Organizations (CDMOs) in industrial biotechnology, tackling diverse technologies, regulatory demands, and tight budgets. Discover how Arxada handles complex projects with strong focus on quality, speed and delivery, aligned with customer needs, budget and commercial success.



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Biomanufacturing involves intricate processes and large-scale operations. Effective project management is crucial for coordinating all activities essential for successful project execution. While much has been discussed about the role of project management in the pharmaceutical industry, this paper focuses on the complexity and specific challenges in the industrial biotechnology space. Here, technical teams handle projects with a wide range of quality grades, varying levels of regulatory requirements, fast time to market, all under often tight budgets. We highlight the key functions of project teams, the necessary skills for project managers, with an emphasis on communication and stakeholder management, and the challenges faced in the volatile CDMO environment.

Contract Development and Manufacturing Organizations (CDMOs) are often the preferred choice for customers looking to industrialize new and innovative processes, bridge heavy investment phases, and/or reduce unit costs. Experienced CDMOs offer rapid engineering and technical solutions, regulatory expertise, and ready analytical toolboxes. Arxada CDMO stands out with its unique capabilities in developing early-stage biotechnology processes, using various scales for technology transfer, piloting, registration campaigns, and commercial manufacturing. Our in-house engineering capabilities enable us to design the most effective project plans to meet customers' timelines for market launch. Before we dive deeper into the specifics of biotechnology CDMO project management, let us stress out an important organization prerequisite: company culture. Years of fostering an environment of open and transparent internal communication, both vertically and peer-to-peer, create an essential part of our operational and commercial success. Project managers are team leaders and should be supported by line management, not the other way around. Team members must feel encouraged to identify risks early and should never be pushed back. A strong focus on pragmatic technical solutions, backed by creativity and acceptance of frequent changes are natural elements of our business. In such a culture, people can quickly develop a robust sense of project risks. During complicated technology transfers and early commercial phases, transparency is appreciated by all stakeholders, especially customers.

The role of project management in the CDMO environment

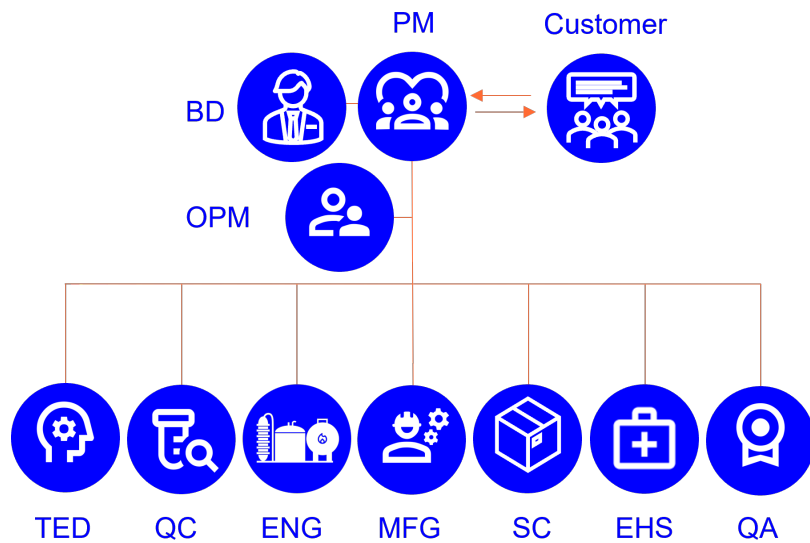
Mature project management is essential for successful project completion in any discipline. In complex environments, seamless project organization becomes even more critical. Before the project team assembles and begins the execution phase, the evaluation team conducts a feasibility study based on mass balances and process flows. This study results in a commercial proposal that outlines the project stages, corresponding manufacturing assets, and economic performance. The proposal identifies process potentials, bottlenecks, and projected cost structures, along with timelines. This marks the beginning of the project, with a detailed project plan and clear definition of project team responsibilities (Figure 1).

Figure 1. Illustrative flow of CDMO projects from customer request over evaluation, commercial proposal and agreement, to project execution. The project execution is handled by the technical team communicating with the customer, in tight collaboration with the commercial function, and supported by operations management.



Over the decades, Arxada's project teams have evolved into efficient small units capable of working directly with customer counterparts. Depending on the project scope, the team comprises of experienced specialists representing key areas essential for project execution. These individuals serve as focal points and frontline contacts for customers, fully responsible for coordinating work within their respective departments. Each team member is accountable for timely delivery of agreed tasks and promptly reports any technical issues to the project manager. This approach ensures that mitigation scenarios can be implemented swiftly and the potential impact on project timelines and budgets is quickly understood. Our extensive experience with technology transfers and commercialization of novel processes has led to the definition of the following key team functions (Figure 2):

Figure 2: Illustration of key functions within the project team. TED – technology, evaluation and development, QC – quality control, ENG – engineering, MFG – manufacturing, SC – supply chain, EHS – environment, health and safety, QA – quality assurance. PM – project manager, BD – business development, OPM – operations management.



- **Technology transfer specialist** – Upstream/downstream/ formulation process technologist. This role is critical, often filled by individuals who have participated in the initial evaluation process and feasibility study. Process technologists are responsible for a detailed review of the customer’s technical package, precise mass balances, and process flow diagrams. They design experimental work for the familiarization, scale-up, and piloting phases. The same people oversee process implementation at the commercial scale, prepare manufacturing documentation (e.g. batch records), and propose cleaning schemes for review by a manufacturing specialist. Later in the project life cycle, the process technologist drives continuous improvement, collaborating with the manufacturing crew to identify opportunities to reduce cycle time, optimize raw material consumption, and improve yields.
- **CAPEX (Capital expenditure) specialist** – An experienced process engineer. While not all projects require heavy and complex investments, nearly all necessitate a certain level of instrumentation and software adaptation. Arxada’s environment is highly automated, with processes secured by robust batch recipes that ensure standardized, reliable, and controlled manufacturing. When new unit operations need to be implemented, the process engineer oversees all stages from design to construction, coordinating with vendors and our internal engineering workforce. Complex CAPEX implementations often function as projects within projects, making a thorough understanding of milestones crucial from a CAPEX perspective to avoid delays and budget overruns.
- **Manufacturing specialist** – Typically a manufacturing line coordinator. This person ensures that all equipment is fit for purpose and cleaned according to the required quality standards. Manufacturing coordinators review batch records, secure changeovers, and ensure adherence to regulatory requirements. Additionally, they work with the manufacturing team to prepare a robust training plan for production personnel. Operational excellence is prioritized as soon as the first engineering batch is produced.
- **Quality control specialist** – Analytical or microbiology expert. These specialists cover the full scope of the relevant analytical toolbox, including in-process control, release methods, and stability testing during scale-up and regular manufacturing. Their responsibilities include methods verification and validation plans, as well as communication with external laboratories if any qualified partners are part of the analytical scheme. Additionally, cell banking, microbial methods implementation, and routine plant processes like environmental monitoring and bioburden control are managed by our microbiologists.
- **Supply chain specialist** – A purchaser. This person compiles the Bill of Materials (BOM), understands the local supplier landscape to drive the raw material cost down. The supply chain negotiates lead times with suppliers and vendors (e.g. particularly filtration membranes are customized and not always ready off the shelf). For highly regulated products in food ingredient market, the number of required certificates may be challenging and, in combination with technical specification, create a single supplier situation. Constant market screening throughout the project life cycle is part of a cost improvement effort.
- **Quality assurance specialist** – This person works closely with the customer to understand all regulatory requirements and reflects them in the scope of Quality Agreement. Quality assurance takes a lead to prepare HACCP plan and makes sure raw materials, consumables, and processes comply with required quality standard. The site is always ready to accommodate customer audits, and our quality assurance unit represents Arxada’s full compliance to industry standards and regulatory requirements.
- **EHS specialist** – This role serves as our connection to safe labor practices on site. The EHS representative on the team ensures that we uphold our commitment to comply with environmental regulations and our responsibility to reduce all types of waste.

Key skills and competencies of project managers in CDMOs

An experienced project manager (PM) can quickly transform a group of individual contributors into a well-organized team. While there are some general rules to follow, it all begins with the PM's expertise and personality. The ideal project manager profile in biotechnology CDMO does not necessarily include a long professional PM career or proficiency in using project management tools. Our best project leaders are those who are closely connected to the manufacturing process, technology transfers, investments, or have served as experienced line managers in various operational positions throughout their careers. These leaders excel in their fields and demonstrate the ability to overlap into other areas, identify and address any risks, and naturally assume responsibilities with automatic leadership.

A good project manager understands, anticipates, and communicates critical paths without delay. There must be a high level of trust between the project manager and operations management that should step in only to support in difficult situations, expedite lead times with vendors, and continuously prioritize resources. Since Arxada serves customers from various biotechnology industries, including start-ups and key market players, and adopts processes of different maturity, setting expectations is not a routine. A close connection between the project manager and the commercial lead (business development or key account manager) is essential. The technical team, under the leadership of the project manager, must fully understand the service or manufacturing contract and the quality agreement with equal importance. Asking for feedback is a good practice at Arxada. It is part of our ability to manage multidisciplinary teams and communicate effectively with both internal teams and customers.

Challenges faced by project managers

Time planning and budgeting are primary tasks for project managers, but they come with numerous challenges. Issues can arise not only from external parties but also from the technical team. Utilizing milestones or project gates is helpful, as it allows for tracking progress and preparing detailed summaries on lab scale-up experiments, investment progress, and other activities for customers.

The complexity of biotechnology projects is among other reasons given by the basic element of biotechnology – living organisms at the core of the technology. Therefore, a detailed scale-up approach is fundamental to eliminate discrepancies from scale-down models.

Robust change management is crucial. It encompasses monitoring and justifying modifications throughout the entire project, whether these changes relate to quality, regulatory standards, shifting customer demands, new laboratory findings, unforeseen raw material variations, or regulatory updates. Such dynamics are common in the biotechnology industry.

During the COVID-19 pandemic, many industries faced supply chain disruptions. Industrial biotechnology experienced delays due to the prioritization of vaccine manufacturing, prompting companies to find alternative suppliers. Fortunately, Arxada can rely on strong local sourcing.

Summary

Effective project management is crucial for CDMOs in industrial biotechnology. CDMOs frequently onboard novel and diverse technologies with varying regulatory requirements. Aligning with customer business plans, maintaining flexible business models, and fostering open communication and proactive risk management are the key elements of success. Arxada's project teams consist of experienced specialists in key areas essential for project execution, ensuring high-quality and timely delivery. We invest into ongoing development of project managers and their teams and cultivate the culture of trust and transparency. Partner with us if you are ready to elevate your bioprocess to next level. Our team of experts is keen on moving your project smoothly to commercial success.

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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 and experienced team throughout the whole project**
- **Compliant to multiple manufacturing standards. Holding certification such as cosmetic manufacturing (EFfCI-GMP), ISO 9001:2015, FSSC 22000/HACCP, FAMI-QS, Halal and Kosher**
- **Eleven years without Loss Time Injury**
- **Excellent on time in full delivery performance with over 60 processes transferred to commercial scale in the past decade**
- **Strong focus on continuous process improvement and on what matters to you**

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For further information and/or if you would like Arxada to support your project(s), get in touch with:
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