

ATREUS WHITEPAPER ON THE PHARMACEUTICAL INDUSTRY

SUCCESSFULLY DELIVERING MAJOR CAPEX PROJECTS IN PHARMA AND LIFE SCIENCES

**Driving projects to successful completion
through leadership, governance, and trust**

How to deliver major CapEx projects in pharma and life sciences successfully despite complexity, regulatory requirements, and time pressure – with a clear business case, strong leadership, and a culture of learning from mistakes.



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MAJOR CAPEX PROJECTS AS A STRESS TEST FOR LEADERSHIP

Pharma and life sciences companies invest billions in production facilities, infrastructure, and advanced technologies. Major CapEx projects determine supply capability, regulatory approvals, and competitive position – and therefore become a stress test for the executive team and senior management.

At the same time, the environment is becoming increasingly challenging, with stricter regulatory expectations, volatile markets, shortages of skilled labor, and ongoing internal transformation initiatives putting organizations under significant pressure. Delays and budget overruns can rarely be passed on to customers or payers; instead, they hit margins and the balance sheet directly, as well as the company’s reputation and competitiveness.

Experience shows that projects rarely fail due to technology alone. What matters most is clarity around the business case, the quality of the project organization, and a lived culture of leadership and learning from mistakes.

*“According to a study by the Hertie School of Governance, major projects are generally far more expensive and take considerably longer than originally planned: The private university analyzed 170 projects dating back to 1960. The findings revealed that the average gap between planned costs and actual expenditures amounts to **73 percent.**”*
(Source: ingenieur.de)

*“A total of **119 out of the 170 major projects** examined recorded cost overruns amounting to EUR 59 billion. Instead of the originally planned EUR 141 billion, total costs exceeded EUR 200 billion.”*
(Source: Handelsblatt)



“‘Change by Design’ instead of ‘Change by Disaster’ – many companies know what they should do, but fail to act amid day-to-day pressures. An external CapEx Health Check combined with experienced interim leadership creates transparency, sets priorities, and builds a resilient project culture within just a few weeks.”

NAMTRUNG NGUYEN
Atreus Director,
Pharma and Life Sciences



THE TRIPLE CONSTRAINT FROM A C-LEVEL PERSPECTIVE: COST, QUALITY, TIME.

Every successful major CapEx project begins with a clearly defined business case: Why are we investing? What value do we expect it to create? Under what conditions can the project still be considered successful? Without this clarity, the project scope remains ambiguous, and subsequent decisions quickly turn into political or budget-driven conflicts rather than sound business decisions.

On that basis, the triple constraint of quality, time, and cost comes into play:

- In GxP-regulated environments, quality is non-negotiable.
- Time-to-market expectations and commissioning deadlines are typically tight and clearly defined.
- Flexibility primarily remains on the cost side – provided it is deliberately addressed and managed.

For senior management, this means:

- **Set clear priorities:** Which of the three dimensions has absolute priority in this project?
- **Stay consistent:** Priorities must remain stable over time; otherwise, reliable planning is impossible.
- **Allow realistic targets:** Purely cosmetic target-setting, such as across-the-board budget cuts of 20 percent, destroys trust and sends damaging signals to the organization.



PROJECT ORGANIZATION AS A TEMPORARY STRUCTURE

A major CapEx project is not merely an extension of day-to-day operations. It is an independent organization with its own rules, roles, and rituals.

1 Clear separation between line functions and the project

- Key personnel must be released from their operational responsibilities to focus on project execution, at least partially, and often fully.
- Projects that are treated as “side activities” frequently fail. Employees are torn between operational duties and project demands, decisions are delayed, and responsibilities become increasingly blurred.

2 Clear separation between line functions and the project

Early clarification of roles and responsibilities is a critical factor for success:

- Operations and functional departments: define requirements and are responsible for acceptance and later operations.
- Engineering and project teams are responsible for implementation, coordination, and the management of internal and external partners.
- Quality/compliance/regulatory affairs: ensure regulatory compliance and distinguish between direct-impact and indirect-impact systems.
- External planners and implementation partners contribute specialized expertise and additional capacity, but must be fully integrated into the project’s governance structure and cultural framework.

A common mistake is promoting outstanding subject-matter experts into project management roles – projects involving budgets in the high nine-figure range require, above all else, strong leadership and communication skills, as well as effective stakeholder management, not merely in-depth knowledge of the technical details.



“A major CapEx project rarely fails for technical reasons alone. If the business case and the triple constraint of quality, time, and cost are not clearly defined, every steering committee meeting becomes a crisis meeting.”

DR. MICHAEL ATZOR
Former Senior Vice President
Global Project Management
and Engineering, Bayer AG;
Board of Management Member,
ISPE DACH

GOVERNANCE, STAGE GATES, AND STEERING COMMITTEES

Professional governance determines whether risks are identified early or allowed to escalate too far. Three key elements are essential in this context:

1 Stage-gate process as a safety net

A rigorously applied stage-gate process forces deliberate decisions at defined milestones:

- Alternatives (left/right) are systematically evaluated with pros and cons.
- Detailed planning is completed before irreversible commitments are made.
- Lessons learned are fed into the next phase between gates – not just captured at the end of the project.

Those who “just keep going” without robust gate decisions risk late-stage course corrections – with significant consequences for the timeline and budget.

2 Steering committee as an enabler rather than a control body

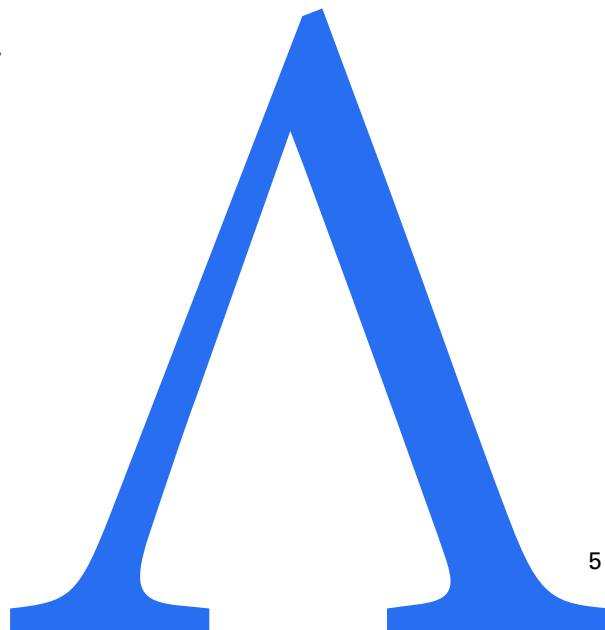
The steering committee should not function merely as a reporting platform, but as the primary mechanism for enabling fast and reliable decision-making:

- It must be staffed with experienced decision-makers who understand project logic and risks.
- Projects must be given sufficient attention and priority, not merely brief slots on the agenda slipped between other unrelated topics.
- The focus should be on support rather than micromanagement: The committee’s role is to remove barriers rather than interfere in the operational details.

3 External perspectives during critical phases

Between gates, external reviews can help reveal blind spots and identify misalignments at an early stage – before they become irreversible.

Neutrality keeps the focus on objective project success rather than individual agendas or stakeholder self-protection.





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CULTURE, TRUST, AND A CULTURE OF LEARNING FROM MISTAKES AS KEY LEVERS

Major projects often fail quietly — not because of one major event, but because many small warning signs are addressed too late. Key cultural levers:

1 An open culture of learning from mistakes instead of a culture of fear

Employees must be able to address risks and adverse developments at an early stage without fear of personal consequences.

2 Trust in estimates and expertise

When management consistently “adjusts” or “smooths” budgets, estimates become politicized, and planning baselines lose their reliability.

3 Shared understanding of project objectives

Everyone involved, from operations and engineering teams to the steering committee, must share a common understanding of success and of which compromises are acceptable.

For the C-level, this means: Culture is not a “soft factor,” but a critical project variable with a direct impact on risk, adherence to schedules, and motivation.



“Leading large-scale projects means creating clarity – regarding objectives, scope, and the rules of engagement. Only when all stakeholders share a common understanding of success can speed, trust, and the willingness to address issues at an early stage truly emerge.”

NAM TRUNG NGUYEN
Atreus Director,
Pharma and Life Sciences

THREE MANAGEMENT PRIORITIES FOR SUCCESSFUL MAJOR CAPEX PROJECTS

Based on experience gained from complex pharma and infrastructure projects, three key priorities for decision-makers can be derived:

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| <p>1 Clarify the business case and scope without compromise</p> <ul style="list-style-type: none"> → The investment rationale, expected value contribution, and overall framework conditions must be clearly defined before the project begins. → Allow changes to the project scope only through deliberate change processes and with due consideration of the triple constraint of quality, time, and cost. | <p>2 The right people in the right project organization</p> <ul style="list-style-type: none"> → Project leaders with strong leadership skills and a clear mandate – not just technically strong specialists. → Free the core team from day-to-day business responsibilities and establish clearly defined, binding roles and responsibilities. | <p>2 Actively shape governance and culture</p> <ul style="list-style-type: none"> → Consistently establish the stage-gate process, steering committee, and external reviews. → Reward a culture of learning from mistakes, early transparency, and swift countermeasures – instead of penalizing them. |
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INTERIM EXCELLENCE DURING CRITICAL PROJECT PHASES

Atreus brings experienced Interim managers into your organization who take responsibility, establish structure, and ensure effectiveness within weeks rather than months.

Typical roles in the context of major CapEx programs:

- Interim Head of Engineering/CapEx Program Director
- Interim Site Project Director for major capital investments
- Interim PMO Lead to stabilize governance and reporting
- Interim Change and Culture Lead to strengthen a culture of learning from mistakes and collaboration
- Interim Steering Committee Coach to professionalize steering committee operations

From consulting document to effective implementation

- Unlike traditional consulting, Atreus focuses on operational implementation:
- Accountability for results instead of just making recommendations
 - Interim responsibility for line management and leadership
 - Rapidly visible changes in governance, culture, and project performance

These roles work in close integration with executive management, business functions, and external partners, with a clear mandate to deliver projects successfully.

CONCLUSION AND RECOMMENDATIONS FOR DECISION-MAKERS

Major CapEx projects in pharma and life sciences are too important to be viewed primarily as technical initiatives. They are leadership and culture initiatives with major financial implications.

1 Those who act now gain four key advantages while accelerating execution:

- Predictable time-to-market despite regulatory complexity
- Greater investment confidence through realistic targets and disciplined governance
- Greater motivation and retention of key project talent
- A learning organization that continuously improves with every project

2 Next steps for C-level decision-makers:

- Check whether your current major CapEx projects have a clearly defined business case and scope.
- Assess governance, roles, and the culture of learning from mistakes – especially within the steering committee.
- Decide where experienced interim expertise can strengthen your organization in the short term.
- Talk to Atreus about a focused “CapEx Health Check and Governance Assessment.”



“With Atreus, you gain implementation expertise, industry insight, and robust networks – so your major CapEx projects become a lever for sustainable competitiveness rather than a risk to returns and reputation.”



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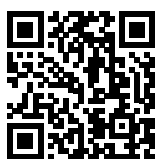
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ATREUS – EXPERTS IN PHARMA

Complex challenges are familiar territory to us because our director team operates at the C-suite level. Atreus quickly identifies the right, proven resources for your project – people who tackle your challenge with speed and determination. Throughout the engagement, Atreus directors remain closely involved as trusted advisors. Our network also enables us to quickly mobilize additional high performers, from subject-matter experts to CEOs. We support you in overcoming challenges across the pharmaceutical industry.

ATREUS HAS RECEIVED MULTIPLE AWARDS

For years, our customers and competitors have consistently ranked us among the leaders in interim management and across numerous industry and competency domains. This demonstrates that our consulting and implementation expertise in all these fields is clearly recognized in the market. We thank everyone who has recognized us with these awards.



Click here for an overview of our current awards:

Hidden Champion, Best Consultant, German Brand Award Winner, Atreus Top Interim Service Provider Europe, Handelsblatt, and many more.



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