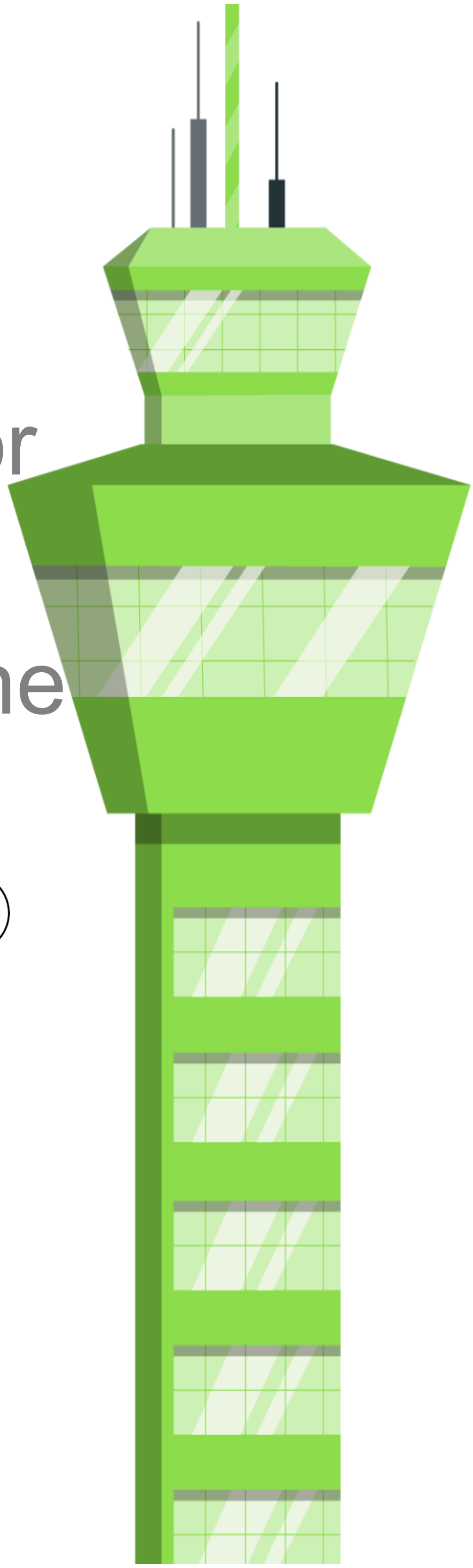
Business Case for QC and QA Departments in the Pharmaceutical Industry by q_alizer



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1. Executive Summary

The q-alizer platform is a new, cloud-based tool designed to help pharmaceutical companies improve their Quality Control (QC) and Quality Assurance (QA) departments. It tackles inefficiencies and ensures compliance with strict regulations by offering real-time data analysis, automated workflows, and easy integration with existing systems.

Key Benefits:

- Cuts documentation time by 10–15%.
- Boosts productivity by 10–15%.
- Speeds up batch release by 2 days (up to 20% faster).
- Increases batch releases by 2–4% (e.g., 60–120 more batches out of 3,000 per year).
- Pays for itself in 3–6 months, saving €813,977 per year (e.g., €221,591 from QC analysts).

With q-alizer, companies can get products to market faster, lower costs, and stay competitive in a highly regulated industry.

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2. Challenges in the Pharmaceutical Industry

QA and QC teams in pharma face growing problems:

- **Too Much Paperwork:** Up to 30% of work time is spent on documentation. q-alizer reduces this by 10–15%. Studies (e.g., FHNW, 2017) say 20–40%, and McKinsey estimates up to 60% in less automated labs.
- **Disconnected Systems:** Separate tools like LIMS, ERP, and Excel slow down decisions and cause errors.
- **Batch Delays:** Long approval times can cost millions of euros per day for critical drugs.
- **Strict Rules (GxP):** Regulations demand detailed records, and mistakes can lead to big risks.
- **Complex Products:** Biologics and personalized medicines put extra pressure on QA/QC teams.

These issues depend on a company's automation level, processes, and product types, but they show why digital tools are so important.

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3. Solution: q-alizer

q-alizer is a cloud-based platform that improves QA/QC processes. Here's how it works:

Main Features:

- **Understand:** Real-time dashboards show throughput, bottlenecks, and work in progress (WIP).
- **Improve:** AI compares performance and suggests improvements.
- **Run:** Automates planning and simulations (e.g., saves 8 hours per batch for QC planners), includes digital whiteboards.
- **Connect:** Links with LIMS, Excel, and other systems, offers a chat feature, and needs minimal setup data.

Who Benefits and How:

- **QC Manager:** Tracks WIP and status, creates reports faster (saves 3.5 hours per batch).
- **QC Planner:** Plans tests more efficiently, less coordination (saves 8 hours per batch).
- **QC Analyst:** Tracks costs better (saves 0.5 hours per batch).
- **QA Manager:** Gets an overview without manual lists (saves 1 hour per batch).

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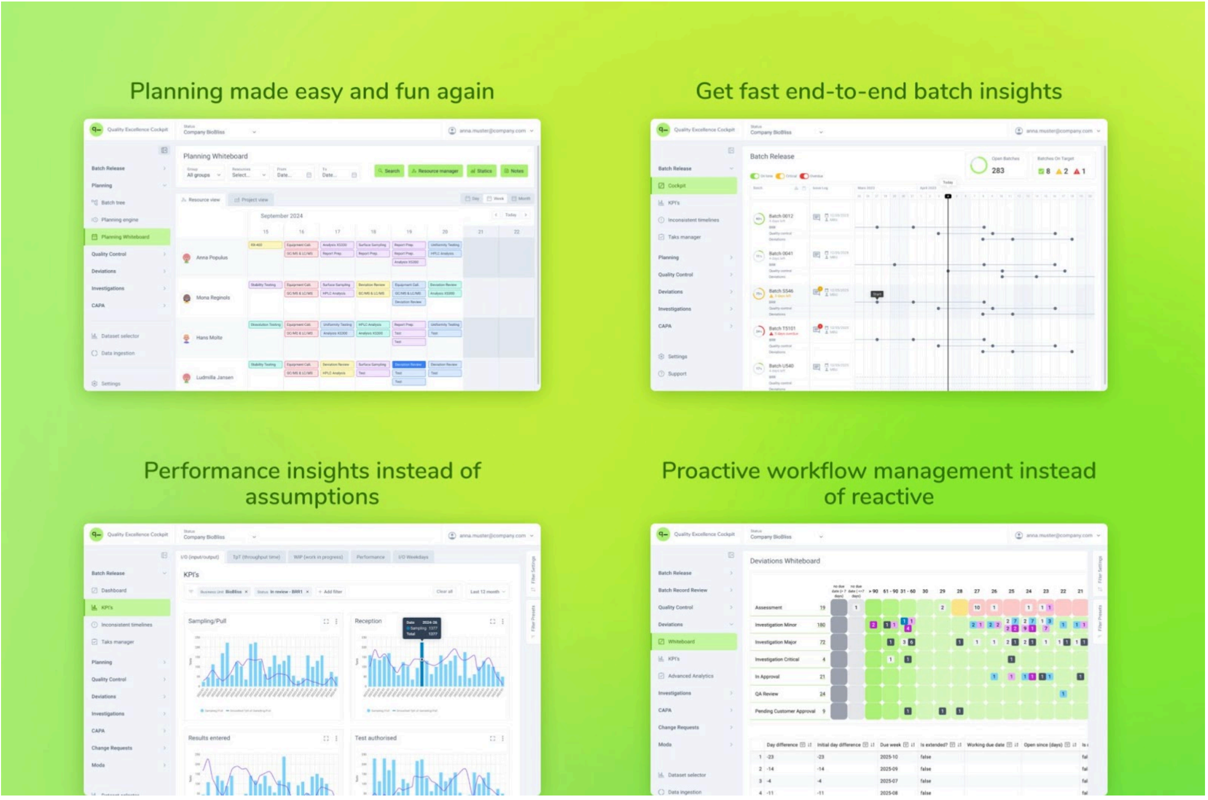
Advantages:



- Cuts batch approval time by 2 days (10–20%) with 16 hours saved per batch.
- Improves data accuracy and meets GxP rules.
- Boosts efficiency by 10–15% using LeanLab ideas (e.g., less manual paperwork).

4. Benefits and ROI

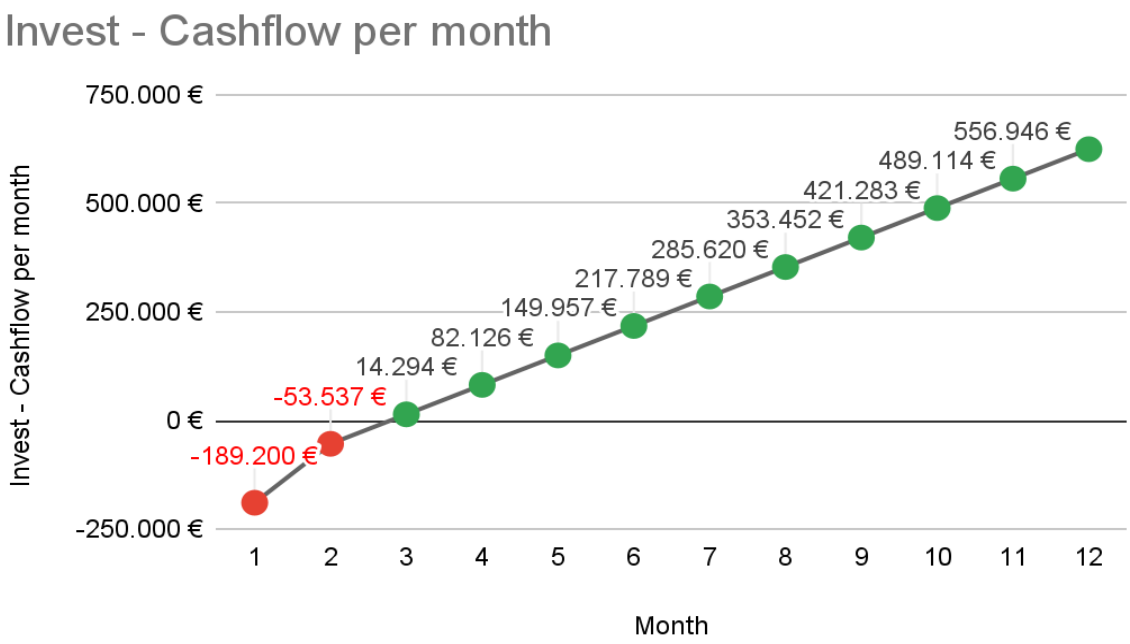
Savings Potential:

- Productivity increases by 10–15% with less documentation.
- Batch approval speeds up by 2 days (10–20%).
- Releases 2–4% more batches (e.g., 60–120 extra out of 3,000 per year).

Example Calculation: For 3,000 batches per year, q-alizer saves:

- €813,977 in costs (e.g., €221,591 from QC analysts, €186,136 from QC managers).
- Extra capacity for 60–120 batches (e.g., €1 million revenue potential for high-value products).

ROI Timeline: With 16 hours saved per batch (e.g., 8 hours for QC planners), savings reach €813,977 per year for 3,000 batches. The tool pays off in 3–6 months, depending on implementation risks.



5. Indicators of Success

- **Efficiency:** Manual work drops by 10–15% (16 hours per batch).
- **Data Quality:** q-alizer becomes the single reliable data source, reducing Excel errors.
- **Cost Savings:** €813,977 per year (e.g., €221,591 for QC analysts), plus potential from 2–4% more releases.
- **Daily Use:** Faster decisions for QC managers and planners.
- **Integration:** Real-time data connects QA/QC to supply chain and production.
- **Scalability:** Handles growth (e.g., from 3,000 to 10,000 batches) and new uses.

6. Typical Challenges and Risks

- **Resistance to Change:** Teams used to Excel might not like new tools.
- **Lack of Expertise:** Generic tools may not fit pharma-specific needs.
- **Integration Issues:** Without good connections to ERP/MES systems, data problems stay.
- **Ease of Use:** Complex or slow features could lower acceptance.

- **Proving ROI:** Long sales cycles and unclear benefits might delay adoption.

q-alizer solves these with an easy interface, flexible integration, and clear savings (e.g., €813,977 per year).

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7. Investment and Cost Structure

Initial Costs:

- Setup, training, and internal effort: €69,200.
- Dashboard customization: €10,000–€25,000.

Ongoing Costs:

- SaaS license: €120,000 per year (8 users at €15,000 each).
- Optional coaching: €30,000 per year.

ROI Projection:

- Pays off in 3–6 months.
- Saves €813,977 per year.

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8. Maximizing Success

- **Industry Expertise:** Work with experts for tailored improvements.
- **Change Management:** Roll out in phases with training and support.
- **Smooth Integration:** APIs and ERP links for easy use.
- **Flexible Options:** Cloud, on-site, or hybrid setups based on customer needs.
- **User-Friendly:** Simple design focused on key features.
- **Clear Results:** Trackable goals (e.g., €813,977 savings, 2 days faster release).

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9. Next Steps

- **Proof of Concept (PoC):** Test q-alizer in the customer's environment.
- **Customization:** Adjust dashboards to customer needs.
- **Optional Study:** Detailed ROI analysis and more potential savings.

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Let’s shape the future of your QA/QC department together!