



HEALTHCARE & LIFE SCIENCES

INTERIM LEADERSHIP: TRANSFORMING A CRUCIAL INTERNAL DEPARTMENT INTO AN EFFICIENT AND EFFECTIVE ORGANISATION

A Case Study: How A&M Can Help Healthcare Companies Overcome Crisis Situations

Situation

Fragmented Data and Analysis Capabilities Within the QRA Department

A private equity backed medical device company needed an interim vice president to fill a vacant leadership role in the organisation's Quality and Regulatory Affairs (QRA) department, a critical function within the business to remain compliant in a highly regulated sector. The client operated with 10-plus different SAP systems that were not integrated and multiple quality management systems, one of which required 30 people to manage manual processes.

The company also faced multiple legal proceedings over its products with authorities having concerns over safety and reporting. The department had to oversee 30,000 SKUs for 8,000 products, and each SKU required regulatory documentation that needed to be updated annually.

The whole QRA department needed organisational restructuring to improve management succession and to implement a performance tracking system. The department needed better data, analysis tools and better systems to ensure timely resolution of product and safety complaints.

Finally, the company needed to implement some cost cutting measures across the organisation and to hire a full-time vice president to lead the department.

What we did

The A&M interim QRA vice president stepped in to redesign the department of 400 people and initiated process improvement projects. The goal was to simplify the processes to allow the department to address complaints, remediation cases and recalls in a more efficient manner.



Scientific and technical experience combined with a predisposition toward action enabled the restructuring of a dysfunctional organisation within the company into a more efficient, effective department that was vital for the company's operations and reputation in the industry.

Significant Resources and Time Saved

- Simplified various systems into a single hybrid structure to ensure business continuity and process efficiency
- Developed a tailored KPI dashboard to inform key decision makers on QRA performance and pinpoint critical areas
- Implemented QRA best practices into the organisation, ensuring quick identification of key QRA issues and contributed a high-performing QRA team for the client



To undertake the transformation, A&M assessed the current organisation structure and implemented a new one based on local site reporting and global centres of excellence, aiming to drive efficiencies and remove the legacy organisation from acquisitions. A&M also created a tailored KPI dashboard to assist in executive level decision-making.

The work included setting up a cross-functional transformation team headed by the A&M interim QRA vice president and launching seven initiatives to improve the performance of the global QRA team. Among the objectives were implementing best practices for Field Service Corrective Actions (recalls) and Corrective Action, Preventative Actions (CAPAs) creating remediation plans, leading the company's preparation for dealing with the new Medical Device Regulation (MDR) in Europe and engraining a new culture of quality across the organisation.

In addition, new products coming out of the company's research and development department needed to be approved by QRA before entering the next design phase.

A&M's interim QRA vice president was also part of a cross-functional team to drive the resolution of legal proceedings against the company regarding certain products.

A&M's Expertise Leads to Results

Healthcare Companies Facing a Crisis Management Situation Can Rely on A&M Operational Help

Clients who face daunting and unexpected challenges, including the loss of key roles or dysfunction in a crucial area of their business turn to A&M for operational, interim experience. A&M provides day-to-day, hands-on technical knowledge and a bias to action to ensure gaps in functionality get filled and that the organisation operates with better efficiency.

In this case study, A&M worked with the COO and multiple company stakeholders to achieve for the client:

- A new organisational structure with better functionality across geographic regions
- Sustained success in ensuring products complied with new medical device regulations
- A successful collaboration with a European institute to act as a strategic partner with data and research needs
- An improved service quality across the organisation and a leaner structure through cost cutting
- The hiring of a new management team with the right leaders in preparation for the incoming full-time vice president
- A more efficient company as a result of A&M's turnaround expertise
- The benefits of applying scientific and technical expertise to the company's unique problems





A&M: Leadership. Action. Results.SM

A&M has worked with some of the largest European and global organisations to transform operations and accelerate growth through decisive action. A&M's teams across Health and Life Sciences, Private Equity Performance Improvement and Corporate Transformation bring decades of experience and fact-based, action-oriented leadership to create value and drive rapid results for healthcare businesses. To learn more, reach out to our key contacts listed below.

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ABOUT ALVAREZ & MARSAL

Companies, investors and government entities around the world turn to Alvarez & Marsal (A&M) for leadership, action and results. Privately held since its founding in 1983, A&M is a leading global professional services firm that provides advisory, business performance improvement and turnaround management services. When conventional approaches are not enough to create transformation and drive change, clients seek our deep expertise and ability to deliver practical solutions to their unique problems.

With over 6,000 people across five continents, we deliver tangible results for corporates, boards, private equity firms, law firms and government agencies facing complex challenges. Our senior leaders, and their teams, leverage A&M's restructuring heritage to help companies act decisively, catapult growth and accelerate results. We are experienced operators, world-class consultants, former regulators and industry authorities with a shared commitment to telling clients what's really needed for turning change into a strategic business asset, managing risk and unlocking value at every stage of growth.

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