

Zambon Successfully Manages CAPAs with TrackWise®



Zambon is a leading Italian pharmaceutical and fine-chemical multinational company, who has earned a strong reputation over the years for high-quality products and services. Zambon is headquartered in Milan and was established in 1906 in Vicenza, where Italian fine-chemical and pharma plants are based. The other manufacturing units are in Switzerland, France, China and Brazil. Zambon is present in 15 countries with more than 2,600 employees.

Zambon Company S.p.A. is the industrial holding group, which incorporates Zach (Zambon Chemicals) which is a preferred partner for API, Custom synthesis and generics products for big pharma companies; Zambon S.p.A., the pharma business, which mainly operates in respiratory, pain and women healthcare; Z-Cube, the corporate research venture, scouting new technologies and drug delivery system opportunities. Thanks to privileged relations with the scientific international community, Zambon has also created "Open Zone", a research and innovation Scientific Campus in Bresso (Milan).



COMPANY OVERVIEW

NAME: Zambon

INDUSTRY:

Pharmaceuticals

DISTRIBUTION: Global

EMPLOYEES: 2,600+

SOLUTION: TrackWise

Today, TrackWise is used across all Zambon sites. The Zambon team quickly benefited from the technology with an increase in compliance, state of control, efficiency and visibility into issues and potentially risky trends.

THE OPPORTUNITY: Automating the Corrective and Preventive Action Process

As a company focused on quality and innovation in the pharmaceutical and chemical industries, Zambon understands the importance of efficiency and compliance, and believes the successful implementation and documentation of corrective and preventive actions (CAPAs) is critical to its daily operations. CAPA documentation had traditionally been handled by a paper-based system and office automation tools. However, the need for a more robust quality management system (QMS) had been discussed during Zambon's international quality meetings, to address the following areas:

- · An increase in the number of quality records in manufacturing plants
- The complexity of record management (compliance, cost, time)
- The need for monitoring quality-related key performance indicators
- An increase in the number of CAPAs relating to new projects or improvement projects
- An increased focus on CAPA management by inspection

THE SOLUTION: A Standardized Solution with TrackWise

Once Zambon realized that a QMS solution was needed, the Company went through a detailed selection phase and evaluated several international vendors with QMS software products. After receiving a demonstration of Sparta Systems' TrackWise Enterprise Quality Management Software (EQMS) through its local consulting company, LifeBee, the Zambon team agreed that the Company stood out from the competition for the following reasons:

- Expertise in the pharmaceutical industry and respect from pharmaceutical auditors and regulatory inspectors
- Best practices implied by TrackWise's structure and templates
- High configuration capability, native with the product, with no need for customizations
- Ease of standardization to deploy the same processes for all Zambon sites
- Presence of a local and highly qualified Consulting company, LifeBee, for implementation and post-go-live support

The implementation of the CAPA tracking system went live initially in 2 sites: Bresso Headquarters, Cadempino and then the Vicenza site. The entire deployment took nine months including key user/ system administrator training and system validation.

The solution implemented was also easily delivered to the Zach plant of Avrillé (France). This roll out project was performed in only 3 months. The next step was to roll out the system to other Zambon affiliates.

THE RESULTS: Increased Compliance, Efficiency and Visibility

Today, TrackWise is used across all Zambon sites. The Zambon team quickly benefited from the technology with an increase in compliance, state of control, efficiency and visibility into issues and potentially risky trends. TrackWise also proved its worth by reducing open issues, quality process closure time, time spent on non-value added activities and missing records, data or approval.

"We are proud to announce this important success together with Sparta Systems and Zambon" said Teresa Minero, Chief Executive Officer and founder of LifeBee, the Consulting partner of Sparta Systems in Italian speaking territories. "The Zambon Quality Management System represents the first significant and successful project developed in full synergy between Sparta and LifeBee. We especially thank Zambon for the proactive and open-minded approach in managing the change and we are looking forward to expanding the benefits of TrackWise in Zambon, as well as in other Italian Life Science companies"



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REV1:210716

