

iGrafx[®]

Case Study

iGrafx Helps Medical Device Company Achieve Sustainability Certifications

Complying with EMAS and ISO 14001

About the Company

The company is a global leader in sports medicine and less-invasive surgery. Their mission is to help surgeons treat their patients better. Whether it's an elbow injury in golf, a shoulder injury in rugby, or a foot injury in running, they supply the assets and education to make less-invasive surgery simpler, safer, and more reproducible.

Headquartered in Naples, Florida with close to 30 subsidiaries, they have a worldwide impact in making the world a better place. They serve both the public and private healthcare sectors, providing products, state-of-the-art surgical techniques, and training to clinics and hospitals so that they can support their patients.

The Challenge

With sustainability growing as a board-level topic and customers demanding more environmental accountability from vendors, organizations like this company employ eco-friendly policies and procedures to drive their operations. In more progressive regions such as EMEA, the pressure on vendors to act sustainably is immense. In fact, it's an evaluation requirement for many companies selecting vendors. In this case, clinics and hospitals require that their medical device suppliers like the company comply with certain environmental standards such as Eco-Management and Audit Scheme (EMAS) and ISO 14001.

ISO 14001 uses a matrix certification, meaning that it applies to all of the company's certified EMEA subsidiaries, but if even one subsidiary fails an audit, all affiliated companies lose certification until the non-conformity is resolved. The stakes are massive. To remain competitive in the market to meet the demands of their customers, the company needed a solution to be able to document and manage the environmental impact of relevant processes at every subsidiary. Even though some processes were standardized across all subsidiaries, many subsidiaries also had their own unique processes owing to specific jurisdictional requirements.

To become EMAS and ISO 14001 certified, each process at a minimum needed to have a process owner and associated Standard Operating Procedure (SOP) documented. To make the process easier and take a more holistic approach, the company also created process diagrams and associated work instructions to understand the environmental impact at as granular a level as each activity within a given process. Originally, the company was creating process diagrams in Visio, but this did not provide sufficient flexibility to capture the full range of required SOPs as well as their ongoing management and periodic updates.

This is an ongoing effort for the medical device company. In order to maintain these certifications, documentation must be kept current. This means creating a governance cycle to ensure that the information is accurate, reviewed, approved, and ultimately acknowledged by the employees that execute a given process.

The Solution

The company's Head of the Executive Office EMEA is responsible for strategic governance, project management, and sustainability topics. Together, with the Head of the Environmental Certifications EMEA, these employees share almost 20 years of experience with the company and have been driving success with iGrafx since 2017.

The company had considered other solutions to meet their process management needs. But these solutions fell short in terms of ease of use, documentation, and governance. One team member said "With Process360 Live, it's easy. With the user interface, you immediately understand what you have to do as a user." Because of the global nature of the business, the stakeholders also appreciate the ability to easily switch between different languages when reviewing the SOPs.



For processes that apply to the entire organization and are relevant to their EMAS certification, The Head of Executive Office EMEA's team diagrams the processes and creates the SOPs. For processes specific to a subsidiary, a process owner is elected for each process and is in charge of creating the documentation. It's a team sport to scale the documentation effort throughout the company.

Regardless of whether it's Executive Office team or a process owner, the process governance capabilities of iGrafx are crucial to the company's success in creating, distributing, and monitoring audit-relevant documentation. When the team creates process documentation, it is sent to the process owners to review for accuracy and ultimately approve. After it is approved, each employee that is responsible for executing the process then reviews and acknowledges that they are aware of this information.



With Process360 Live, it's easy. With the user interface, you immediately understand what you have to do as a user, said Head of the Executive Office EMEA.

Process360 Live stores the documentation, orchestrates the review cycles through notifications, and keeps an audit record of every approval, review, and endorsement related to the process. This is incredibly important when undergoing an internal or external audit, so that the auditor can verify that what they observe the employees doing in their day-to-day matches the approved documentation.

These review and acknowledgement cycles happen every time the process changes, or at a minimum every year automatically. Process360 Live process version control is also critical for the auditors because they can see when a document was changed, related process version information, and the record of the employees endorsing the process.

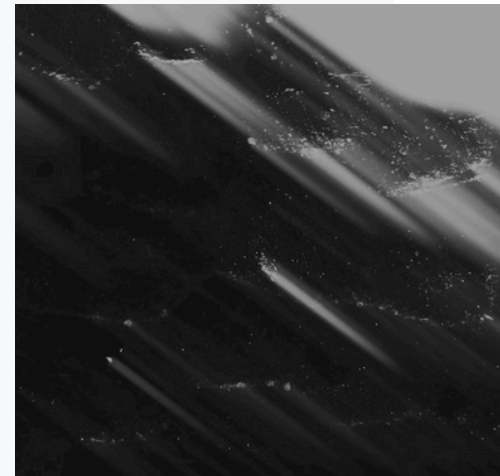
Documenting the entire documentation and governance process is required for the company to successfully receive their EMAS and ISO 14001 certification. Looking at an example, their customer service process, the SOP includes objectives related to environmental considerations. It also includes performance objectives such as making sure that their customers receive timely delivery and service, and ensuring that their issues are resolved.

The Result

Ongoing Certification

The Head of the Executive Office EMEA said “We couldn’t be more successful. We have no subsidiary that is certified under ISO that has failed any audit”, referring to the fact that they have never failed an ISO 14001 audit or had a lapse in certification as a result of the documentation process governed within Process360 Live. This means delivering on their company’s objectives and driving more business, by being a good partner to their customers and a good partner to the planet.

As the company matures their program and looks to the future, their ambition is to take the next step from documenting and governing the processes, to improving them in terms of productivity and cost. To do so, they look to process mining to gain visibility into process execution, identifying areas for efficiency gains and other improvements.



Summary

To remain competitive amongst their customers, many of the company's subsidiaries needed to become EMAS and/or ISO 14001 certified. Through a team effort between the central Sustainability Team and process owners at their subsidiaries, they continue to pass audits and remain certified across the entire organization.

They used Process360 Live to document their processes, including diagramming processes, defining Standard Operating Procedures (SOPs), and creating work instructions. All of this documentation is governed through built-in review, approval, and endorsement cycles, and a record of any changes and the governance activities is automatically created to assist with their audits.

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