MasterControl[®]



Company Overview

Focus: Pharmaceutical compounding

Countries: 20

Locations: 66

Employees: 2994

Quality Professionals: 357

How do you get quality experts around the world on the same page?

With 66 global locations — from Kansas to Krakow — Fagron needed a way to ensure each facility could consistently produce pharmaceuticals that meet the company's lofty quality standards.

Fagron's worldwide footprint comes with a few challenges. The trickiest one might be staying in compliance with the regulations of every market they serve. The FDA in the United States has slightly different rules than ANVISA in Brazil. And those differ from the European Commission in the European Union. In fact, for the EU member states in which Fagron operates, 17 different regulators need to be accounted for and validated.

All that variability led to inconsistent processes. The teams at each Fagron location had their own standard operating procedures. Even common processes had issues. Teams would use Word documents to update work instructions, often leading to confusion about which document was the most recent – and the most accurate. Required training used a cumbersome manual process as well. Quality management teams would print up to 300 pages of training materials every week. It would take nearly nine hours to print, bind, and place the large binders in an autoclave to sterilise them so they were able to be used in the laboratory and manufacturing clean rooms.



Training Metrics

We have specialised teams that focus on the various regulatory and quality requirements required by either the local state, country, or region."

– Jason Maguire, Global Quality Director, Fagron



Improved Communication. Simplified Consistency.

The Fagron team began by rolling out MasterControl in several U.S. sites. The positive results were seen quickly.

Quality documentation that was once siloed could now be easily shared between the offices in Nevada, Florida, Minnesota, Texas, and Kansas, and seven European sites are leveraging the powerful functionality of MasterControl's documents and training modules. There's no longer any need to email documents, which increases the risk of employees using outdated documentation. Now every piece of important quality documentation is in the one source of truth: MasterControl.

When an update needs to be made to a document, the changes can be made directly within MasterControl by any of the team members at any location by filling out a document change request. And the quality team can rest assured that the most up-to-date document is the only one people are using.

Since rolling out MasterControl in seven European sites, the advantages have continued to grow.

"We're all working from one source of truth on one platform. So, everybody around the world is together. Now I can see the documents that Poland is working on and vice versa. We haven't had that flexibility until now," said Matt Seitz-Paquette, Fagron's North America Quality Specialist.

Less Paper. More Efficiency. Better Quality.

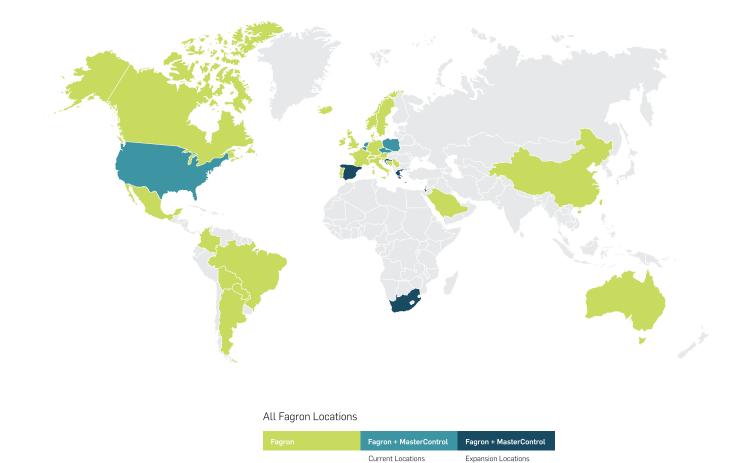
Today those binders full of training materials have been replaced by tablets. This saves the Fagron team hundreds of hours a year in training prep, not to mention over 500 sheets of paper every week at each site. Those savings are important given their company-wide emphasis on sustainability, including their goal to reduce greenhouse emissions by 30% by 2026, compared to 2019 emissions.

The changes also align with their right-first-time quality goals. Even in the early stages of rolling out this streamlined quality system, they've improved right-first-time metrics by 100%. The North American team is already nearing their goal of 95% right-first-time output.

As Fagron continues to use MasterControl and collects more data, the team is broadening the use of the system's trending and tracking features to get real insights into where problems might exist. And this is allowing them to be more proactive with quality processes.

I would say MasterControl has made our life so much easier. Now we can put our focus on making our products and bringing them to people."

-Matt Seitz-Paquette, North America Quality Specialist



Expanded Scale. Greater Harmonisation.

Achieving global quality standardisation by expanding the use of MasterControl has always been the cornerstone of Fagron's long-term vision, according to Seitz-Paquette.

"From the beginning it's been part of the plan to get all sites on the same standard," he said. "Obviously, we can't do it all at once all around the world, so we're doing it in chunks. We're just always adding. And as we're adding sites and modules, they're all following the same standard processes."

Fagron is currently live and thriving with MasterControl quality solutions in 11 global sites — four the U.S. and seven in Europe. One of every three Fagron employees — nearly 1,000 people — are now MasterControl users. Extending the use of MasterControl has dramatically streamlined the way Fagron manages correction action / preventive action (CAPA), deviation, training, and other essential quality processes.

"We now have more data to analyse events and understand trends, so we know exactly when to launch a CAPA instead of launching a CAPA for everything," said Seitz-Paquette.

He credits the expansion with empowering every user in the global company to directly participate in quality activities.

"We're giving people access to quality, really," he said. "We're putting it in their own hands, so they can report anything and then it can be escalated as appropriate."

The wider use of MasterControl has enabled Fagron take efficiency to a new level and achieve staggering quality performance metrics such as:

Reduction in deviation times.

Revisions or new

documents made

50% /

Average training tasks distributed at each site per month.

1,000 🗒

Approximate views of documents in the system by users worldwide every month.



effective every month.



We're always adding sites. And as we are, all the sites are following the same processes."

-Matt Seitz-Paquette, North America Quality Specialist The favourable results have underscored the team's goal to continue implementing as many MasterControl solutions as possible in as many sites as they feasibly can, according to Seitz-Paquette.

"We have a whole road map and we're just at the beginning," he said. "And quality is at the middle of everything because it's the core of everything we do. We move fast and we're just going to keep going!"

Summary				
The Challenge	Getting 66 sites around the world to follow the same quality processes and procedures.			
The Solutions	Dx	Qx		ţĴ
	Development	Quality	Cloud	VxT
The Results	The team has reduced over 450 hours per year spent on preparing paper-based training materials, saving more than 500 sheets of paper per week at the sites that have implemented MasterControl. The manufacturing facilities have seen a 100% improvement in right-first-time metrics and a 50% reduction in deviation times.			

About MasterControl

MasterControl Inc. is a leading provider of cloud-based quality, compliance and production management software for life sciences and other regulated industries. Our mission is the same as that of our customers – to bring life-changing products to more people sooner. The MasterControl Platform helps organisations digitise, automate and connect critical processes across the regulated product development life cycle.

Learn more at mastercontrol.com



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