

Myconostica: achieving certification to ISO 13485 with Q-Pulse

Executive Summary

Myconostica, a developer and supplier of molecular diagnostic products, needed to be able to manage their Quality System efficiently and effectively, in order to ensure regulatory compliance for all aspects of their operations, including compliance with ISO 13485.

Using Q-Pulse, Myconostica have developed and implemented a process whereby draft documents can be distributed and reviewed prior to approval and publication entirely within Q-Pulse. The company are now also managing corrective and preventive actions (CA/PA) entirely through the system.

At Myconostica, the whole Quality System is now embedded much more effectively within the company. Q-Pulse has made the Quality System more accessible to all of their users across the company, which has resulted in significantly greater buy-in to the whole process.

The Background

Established in Manchester in 2006 as a spin-out company of the University of Manchester, Myconostica is a new company which develops and supplies molecular diagnostic products to assist the rapid and accurate diagnosis of life-threatening invasive fungal infections.

Chances of surviving such infections are significantly improved by early diagnosis, and Myconostica's products aim to allow healthcare professionals to rapidly identify those infected, enabling clinicians to prescribe appropriate drug treatment.

The Challenge

As Director of Quality, Regulatory & Clinical Affairs at the company, Martin Hughes is responsible for ensuring regulatory compliance for all aspects of Myconostica's operations, including ISO 13485 compliance and all other applicable regulatory bodies:

'From the outset we understood the importance of implementing a Quality System, but, as a small company, the resources that we had available to manage it on a full-time basis were limited. As we developed, we had a rapidly increasing number of documents in need of updating, as more and more documents were being produced.'

In addition, staff throughout the company needed access to documents, including SOPs and FDA guidance documents, but maintaining both control and accessibility of documents was proving to be a challenge with the paper-based system that they had in place.

'We therefore needed a more efficient method of managing our Quality System, and as we wanted to register for ISO 13485 certification, we had begun to look for a solution when we heard about Q-Pulse.'



The Solution

In looking for an appropriate system to help manage their Quality System, management at Myconostica needed a system that would be as user-friendly as possible, and to which all staff could have direct access.

'Any system we selected also needed to be flexible', says Hughes, 'in order to cope with the demands of PhD-level staff carrying out research tasks, as well as the requirements of production and the maintenance of Regulatory Guidance and standards documentation.'

The system also needed to be manageable by a small staff group, and, as a small company, Myconostica did not have a dedicated IT department, so access to technical support when and where they needed it was a must in choosing the right system.

Following a one-to-one online demonstration from Gael, management at Myconostica chose Q-Pulse, having seen its potential to give staff throughout the company point-of-need access to accurate, up-to-date documents.

“ It's undoubtedly the case that Q-Pulse has made our Quality System more accessible to all of our users across the company, and this has resulted in significantly greater levels of buy-in to the whole process. ”

Martin Hughes
Director of Quality,
Regulatory & Clinical Affairs
Myconostica

'In an organisation such as ours,' explains Hughes, 'users are responsible for areas of work which might, in larger organisations, be managed by dedicated departments. Q-Pulse's concurrent licensing meant that there was no need for us to implement a larger and potentially costlier system.'

'Q-Pulse has become an integral part of our Quality System, and as such it's had an impact throughout the company, in some areas more than others. R&D and Operations use the system the most, but we've also integrated it into Marketing, Customer Service and our financial group, as well as general administration.'

The Benefits

Within Myconostica, the chief benefit of using Q-Pulse is that the whole Quality System is now embedded much more effectively within the company. *'There's more of a feeling of "ownership" of the system,'* explains Hughes, *'and without a doubt, more of the documents are being accessed and used.'*

'Additionally, being able to store and provide access to regulatory standards has given us a much better understanding of some of the factors involved in experimental plan design, which is contributing to how we can continue to improve product safety and quality.'

'The only difficulties we had were in the beginning with the IT side of things. As a small organisation, we don't have a dedicated IT department, and installing the software had proven a bit more challenging than we had expected.'

'However, we were able to resolve our problems and get everything running smoothly with the help of the Technical Support at Gael. They have always been there for us, and in my experience of customer service are second-to-none.'

In August 2009, Myconostica successfully achieved certification to ISO 13485, with Q-Pulse lending considerable support to their efforts throughout the audit.

'During our preparation phase we were able to review all the top-level documentation with ease,' explains Hughes. *'In the few instances where there were some discrepancies between related documents, we were easily able to edit and have the documents re-authorised in a very timely manner through Q-Pulse.'*

'During the audit of the manufacturing facilities, our staff were able to easily reference the necessary documents, which demonstrated compliance to SOPs, as well as the competence to readily obtain the documentation they needed.'

'And with two auditors on-site, in reviewing paperwork we were able to have full access to all documents without having to be constantly swapping files and folders between rooms – a huge advantage which meant we were able to complete the audit on schedule.'

Hughes concludes: *'It's undoubtedly the case that Q-Pulse has made our Quality System more accessible to all of our users across the company, and this has resulted in significantly greater levels of buy-in to the whole process.'*