

Make document management user-friendly

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Rogério Rabelo
MD, PhD, MBA
Clinical Chemistry/Automation
/POCT Senior Consultant
Product Manager – High-volume,
Automated Testing and POCT
Former Management Representative
– ISO 9001:2000 and 14001:1996

In 1998, Fleury Diagnostics, Brazil's most comprehensive center for diagnostic medicine and pathology with 1,600 employees and 2,500 patients a day, implemented its own system for managing documents necessary for certification and point-of-care testing (POCT) programs. The system was entirely developed in-house in the space of three months. Based on a Microsoft platform, the system is simple, effective and easy to use.

Dr Rogério Rabelo, Fleury's senior consultant and product manager for POCT and high-volume automated testing, spoke to acutecaretesting.org about developing the system and why it is a success.

acutecaretesting.org: The electronic system for managing ISO certification and POCT documents has been in place at Fleury Diagnostics since 1998. What are its main features?

Dr Rogério Rabelo: The system is very simple and user-friendly. Because we have developed it ourselves, it

is fully customized to our needs. And it is cost-effective as well. All the programs we have used to develop the system are standard Microsoft Office programs. Anyone who has a license to them could in theory develop a similar system.

acutecaretesting.org: How does it work?

Dr Rogério Rabelo: The system has three components: document creation and modification, access and management. With the system, users can easily create and modify documents by using customized Microsoft Word templates. The entire document workflow, including the review and approval of documents, occurs online.

Once a document is created, an e-mail message is sent via Outlook to at least two reviewers chosen by the author. Once reviewers submit their comments, the document is sent back to the author, who then finalizes the document – accepting or rejecting the comments – and sends it for approval. Once approved, the document

is made available online. All of this is done through Word and Outlook, while Office Assistant messages guide users in completing the necessary steps.

The second component is accessibility: all employees have access to these documents on our Intranet through Internet Explorer. This is very important, because if users cannot access documents, they tend to keep printed copies that are not updated. In our system we cannot print documents: the official version is online, and that version is always the latest one. We only use document prints for training purposes. Afterwards, these copies are destroyed.

The third element is the actual management of documents, which is restricted to administrators. The system is very robust and effective: administrators know at all times which documents are being created and when, who is currently reviewing them and when documents have been approved. They can also easily trace back all previous versions of an updated document, which are kept in a separate database for auditing purposes.

acutecaretesting.org: Why did you decide to create such a system?

Dr Rogério Rabelo: Fleury Diagnostics has always been very quality conscious. Since it was founded in 1926, it has been providing humanized and personalized services, always striving to improve the quality of its tests.

In the mid-1990s we decided to formalize all the quality processes we had in place through an ISO certification. We chose ISO 9001, because we wanted to focus not only on technical or POCT aspects, but also on our entire organization. We developed a quality management system to oversee the entire institution and, since a document management system is an essential part of any certification, we decided to create our current system.

Today, we are both ISO 9001:2000 and ISO 14001:1996 certified, and all documents and SOPs of our Quality and Environmental Integrated Management structure are administered through this online, electronic system.

acutecaretesting.org: What was the main success criterion of the system?

Dr Rogério Rabelo: To develop it based on an interface that everybody knew, so people would use the system and not be intimidated by it.

acutecaretesting.org: Were there certain specifications common to certification and accreditation programs that the system needed to meet?

Dr Rogério Rabelo: At Fleury, we are ISO certified. We also have the Brazilian and CAP external quality control programs that we follow, as well as several Clinical Trial audits, each with their own set of requirements. But interestingly enough, most certification and accreditation programs have the same requirements for document registration and management. Some documents may need template adjustments, but that can be easily achieved in our system by using customized Microsoft Word macros.

acutecaretesting.org: How did inspectors react to this paperless system?

Dr Rogério Rabelo: In the beginning there was some resistance on the part of some external inspectors. Particularly American inspectors were a little skeptical as to whether a paperless system could deliver all the information they needed.

But we have proven to them that the system is so comprehensive in terms of the information it provides that there was no need for paper binders. The system offers full document traceability and safety. All document versions are recorded in a separate SQL database and can easily be retrieved during an inspection.

acutecaretesting.org: One of the principles guiding Fleury's Integrated Management Policy is to reduce the environmental impact of its practices. Did this influence your decision of creating a paperless system?

Dr Rogério Rabelo: When we went for the ISO 9001:1994 certification in 1999, we knew that a new version would be coming out soon that would be closely integrated with the ISO 14001:1996 for



Quality and Environmental Department team and Dr. Rogério Rabelo

environmental management. So we decided to include the environmental aspects of our work as part of our efforts to become certified.

Some may question how much environmental damage labs cause, since we do not deal with large amounts of reagents and chemicals as manufacturing and chemical companies do. But once we began mapping our processes, we detected around 200 ways in which our practices can affect the environment. Generating paper trash was one of them, so by having a paperless system, this impact has been minimized.

However, the document management system is just one element of our overall effort to minimize our impact on the environment. Our entire 140,000 square-feet facility in São Paulo was built in 2000 according to strict environmental principles. Eventually, Fleury became ISO 14001 certified in 2002, as one of the first labs in the world.

acutecaretesting.org: Why develop your own system instead of buying it from a vendor?

Dr Rogério Rabelo: It was a combination of two things. First, at that time, the market did not offer a system that fully met our needs. Second, Fleury has a very good IT team and a tradition of developing its own IT systems. This goes back to the 1980s, when the Brazilian economy was completely closed and access to information technology developed abroad was restricted.

Developing our own laboratory information system (LIS) and being pioneers in Internet reporting of patient results since 1997, gave us the experience and a head advantage in developing technology applied to the clinical lab and lab testing. So for us, at that time, it was much easier, quicker and cheaper to build our own system. We estimate that building the system ourselves was 50 % cheaper than buying a standard system and having it customized to our needs.

acutecaretesting.org: Who was involved in developing the system?

Dr Rogério Rabelo: We had two teams working on this project: IT and the team working towards the ISO certification, who now make up our Quality and Environmental Department. The IT team consisted of two programmers who were very good at Visual Basic programming and knew Microsoft Office inside out.

While the IT team had to deliver the system, it was up to the certification team to determine its scope and main prerequisites, which in our case were ease of use, a high level of customization and a Word-Outlook-browser-based platform to allow paperless, online management of documents.

acutecaretesting.org: How long did it take from defining the system to implementing it?

Dr Rogério Rabelo: Only three months. In August 1998, the system was implemented in its first version and



Fleury Diagnostics

validated by users during the following months. By May 1999, it was ready for the ISO inspection.

acutecaretesting.org: What were the milestones of this process?

Dr Rogério Rabelo: The starting point was our own philosophy of always wanting to do an excellent job and being fully committed to quality. The next step was having a Quality Management system in place, giving us a framework to map processes and optimize them. Then came the specification phase of this particular project, where we determined the scope of the system and its main characteristics.

Only when the specifications had been made did the IT team begin developing the system and testing it. Once the system had been implemented, different employee groups began testing it: from nurses, physicians and lab professionals to call center employees, management and technicians. After the system had been validated, we began training users and putting the documents necessary for certification in the system.

acutecaretesting.org: Were there any problems in the implementation phase?

Dr Rogério Rabelo: The system was so effective that it ended up being ahead of its time! One interesting problem was that, back in 1998, not all of our users

had computers and Intranet connections fast enough to download and edit complex documents online. Thus, the system could be a little slow when working with heavy documents.

Authors soon became more aware that adding fewer attachments and graphics to their documents would increase the speed of the system. Nowadays, even though older computers have been replaced and the system speed has continuously improved with high-speed Intranet connections, we continuously remind our users that heavy documents are a disadvantage.

acutecaretesting.org: How many documents does the system manage?

Dr Rogério Rabelo: Currently, there are about 1,100 documents in the system, which are constantly being revised and updated. Interestingly enough, we have now fewer documents than when we were first certified. That is partially because ISO 9001:2000 requires fewer documents than ISO 9001:1994. I also believe that we became better at making fewer documents and making them more concise.

acutecaretesting.org: How many users and administrators does the system currently have?

Dr Rogério Rabelo: All of Fleury's 1,600 employers have access to these documents – from top management

to housekeeping. Every employee can create and review documents. Document approval is done by a smaller group of people and document management is restricted to three administrators.

acutecaretesting.org: How are users trained in using the system?

Dr Rogério Rabelo: Training is very straightforward due to the nature of the system. Because it is based on tools and programs that are widely known and used on a daily basis, training can take as little as a half-hour. In addition to training, Outlook and Office Assistant messages provide those creating, reviewing and approving documents with the necessary information to complete the task they have at hand.

acutecaretesting.org: Has the system been updated in any way since it was first installed?

Dr Rogério Rabelo: Yes. Today, users can create documents in portrait or landscape format, which allows authors to include bigger tables. We have also added an advanced search function to the system and the possibility of recategorizing documents as a group instead of having to do it individually.

acutecaretesting.org: After having the system in place since 1998, would you say that it has contributed to a better workflow at Fleury?

Dr Rogério Rabelo: The system is one of our many Quality and Environmental Management projects and it is the sum of these efforts that has created a more efficient organization. Nevertheless, the system has undeniably played an important role in helping us manage the huge amount of documents deriving from POCT programs and

certification, in a way that is easy, efficient, cost-effective and with minimal impact on the environment.

acutecaretesting.org: What are your main recommendations to other institutions considering a document management system?

Dr Rogério Rabelo: Planning is essential. Before you go to the IT department, have a clear idea of what you want, so they can make a realistic estimate of the resources – time, people and money – that the project will require and whether the system can be built inhouse or with the help of an outside vendor. Never go to the IT department and say "give me this solution" without carefully considering what you want, why you want it and what you need it for.

It is also important to determine the exact scope of the system. Ours is extremely comprehensive, but many hospitals and labs can certainly do with less, with a system that only manages POCT documents, for example. But the most important thing is to have a system that is easy to use. There is no use in having a system that looks nice on paper, but that nobody uses. So making it user-friendly is the key to success.

The main principle behind our Quality and Environmental Management System is not to have systems that are neat for auditors to look at, but systems that are easy for our employees to use. It is when people use a system, when it becomes a natural part of their everyday work, that the system becomes really effective and a success.



Testing at Fleury

Interviewee

Rogério Rabelo, MD, PhD, MBA

Clinical Chemistry/Automation/POCT Senior Consultant
Product Manager – High-volume,
Automated Testing and POCT
Former Management Representative
– ISO 9001:2000 and 14001:1996
Fleury Diagnostics
Av. General Waldomiro de Lima, 508
São Paulo, SP 04344-070
Brazil

Interviewer

Ana Cristina Magalhães

Radiometer Medical Aps Åkandevej 21 2700 Brønshøj Denmark