

Beckman Coulter, Inc., implemented ISO 13485 to meet a new medical device regulation requiring registration to the standard. However, although "registration was a goal", says the company, "we recognize that the pursuit of quality provides benefits well in excess of passing a registration audit," adding, "Robust, quality-imbued processes add immense value to development, manufacture, distribution and customer support."



HEALTH CARE AND MEDICAL DEVICES

**ISO 13485
certification
helps
Beckman
Coulter meet
regulatory
deadline
for medical
devices**

BY DIANA MERRYMAN

When you have your blood tested, you expect the result to be correct and rapid, especially in an emergency situation. By providing laboratories with high technology automated diagnostic systems, Beckman Coulter plays a vital role in fulfilling those expectations.

Quality is paramount in a health care setting, and diagnostics manufacturers like Beckman Coulter must meet strict quality standards in an increasing number of countries. In response, we see our quality management system (QMS) as a perpetual work-in-progress. Before seeking certification to ISO 13485:1996, *Quality systems – Medical devices – Particular requirements for the application of ISO 9001*, the company already had more than 30 facilities around the world certified to ISO 9000 – a mix of the 1994 versions and ISO 9001:2000 versions. We were also compliant with the quality system regulations in the countries in which our products are sold.

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Why ISO 13485?

Our aggressive goal involving ISO 13485:1996 was to achieve 15 certifications in just 15 months, driven by a critical deadline for a new medical device regulation in Canada. Beginning in 2003, companies that design/develop, assign intended use, produce, install and service medical devices for use in Canada must be ISO 13485-certified before they can sell products in the country. Achieving this objective was not without its challenges, but by following a clearly defined plan we managed to secure certifications in time to meet the deadline.

Worldwide, there is a growing trend to improve the quality of medical devices through medical device regulations. ISO 13485 is used as the basis for quality system compliance for two European Union (EU) regulations: the Medical Device Directive (MDD), currently in force, and the In Vitro



Diagnostics Directive (IVDD), effective December 2003. Medical device manufacturers who sell IVD's in the EU must by then fulfil conformity assessment requirements that include compliant quality systems (i.e., ISO 13485 certification).

Work is also underway in Australia, China, and in countries seeking entry into the EU, to create national medical device regulations – and these countries are eyeing ISO 13485 as a basis for their own regulations. We hope that the new version, ISO 13485:2003 (see below), will help pave the way for a common set of global quality requirements for our industry.

Most importantly, we want ISO 13485 certification to give our customers another reason to buy our products by demonstrating that we have adequate, compliant quality processes – particularly to those customers that do not have the opportunity to conduct personal, on-site inspections at our facilities.

Mapping the journey

By early 2002, our plan to achieve ISO 13485 certification was in full swing. The scope of the project was huge – with more than 10 000 employees, Beckman Coulter is a large player in the medical device field.

To prepare, we worked with our existing quality system registrar, the National Standards Authority of Ireland (NSAI)¹. NSAI is authorized to conduct ISO 13485 compliance audits on behalf of the Canadian federal health department, Health Canada, and is a Notified Body within the EU.

Since our quality processes were already well established under ISO 9001, we were able to accomplish the transition led by our Global Quality Systems team without the help of external consultants.

We focused first on the Brea and Fullerton facilities in Southern California – the most complex and diverse ISO 9000 certification in the company – to learn valuable lessons we could then apply to the rest of our locations.



A medical technologist at ISO 13485-certified Beckman Coulter operates a power processor for chemistry, immunoassay and hematology testing.



The author, Diana Merryman, is Group Manager of Beckman Coulter Global Quality Systems

Key planning steps:

1. The Global Quality Systems (GQS) team reviewed Beckman Coulter's internal Quality Management System Policy to determine if updates would be required, and identified sections where further explanation might be needed to ensure understanding in the context of ISO 13485.

2. The team held a series of kick-off meetings, initially in Brea and Fullerton, to explain ISO 13485 objectives and the medical device regulations. Most attendees were members

of the Quality Systems Committee, a 100-person team linking GQS and the other functional organizations in the implementation programme. Elsewhere, these meetings were attended by site man-

agement teams leading the local effort.

3. Team members provided training, gap analysis questionnaires, and interpretation of the requirements, and coached the QS Committee

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About Beckman Coulter

Beckman Coulter, Inc., of Fullerton, California, USA, is a leading manufacturer of instrument systems, chemistries and supplies that simplify and automate laboratory processes. The company has more than 10 000 employees and conducts business in over 130 countries. To date it has installed some 200 000 systems around the world that provide essential biomedical intelligence to enhance health care. Annual sales in 2002 totalled USD 2,06 billion, 62 % of which was generated by recurring revenue from supplies, test kits and services.

members and quality management teams at other locations, enabling them to be effective agents in the departments and/or functions they supported.

4. Committee members conducted detailed gap analyses in all medical device-related areas of the business to identify any differences between Beckman Coulter's current work practices and ISO 13485 requirements. From this, we developed "to do" lists of corrective and preventive actions.
5. We conducted internal audits and spot checks, focusing on areas where new requirements needed to be met. Many groups throughout the company volunteered to audit themselves as confirmation of their own readiness for the official NSAI audit.
6. NSAI then conducted on-site audits.
7. The team disseminated information and "lessons learned". The learn-share-learn-share cycle was repeated following each audit, allowing us to leverage our experience for the benefit of later certifications. Meanwhile, corrective actions were underway where necessary.

Challenges

Our implementation plan was effective, with the greatest challenges being education and communication.

To boost communication, the team worked with QS Committee members and management representatives to drive information throughout the clinical diagnostic businesses of the company. Because of company travel limitations since 11 September 2001, we relied on technologies such as WebEx and NetMeeting when connecting people at distant sites.

Our goal was to raise company-wide awareness about ISO 13485 and our overall quality systems. Employees understood that if we did not meet ISO 13485 requirements, we would not be able to sell certain Beckman Coulter products in Canada.

Keys to success

Our focus on education and communication paid off. Employees understood not only the importance of securing ISO 13485 certification, but the benefits the company would derive from quality system improvements. We had a very high level of interest and participation, which enabled us to achieve our goal. An NSAI lead auditor noted that most corrective actions were completed while the audit was still in process.

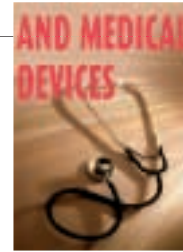
In addition to good communication, sharing lessons learned was a critical element of our success. By addressing the most complex sites first, we were able to share our knowledge so other sites could prepare better for the inspections.

During the entire process, our executive management demonstrated commitment to obtaining ISO 13485 registration. It was discussed at company communication meetings, in company literature, and at quality system management reviews. Management's visibility on the subject of quality helped us gain the necessary support throughout Beckman Coulter.

More than registration

Registration was a goal, however we recognize that the pursuit of quality provides benefits well in excess of passing a registration audit. Robust, quality-imbued processes add immense value to development, manufacture, distribution and customer support activities, and help reduce costs

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and improve efficiency. This is one of the biggest benefits for our customers, shareholders and employees.

During implementation, many employees were reminded of the unbreakable bond between quality and good business. The more they became involved in the preparation activities, so the connection between Beckman Coulter's QMS and their own work took on real meaning – it was a tangible, critical foundation for a successful organization.

Now, with ISO 13485 certification, we are ready for Canada, and well positioned to meet the emerging requirements of other countries. As a global company, we see enormous benefit in having a single, globally harmonized set of medical device requirements – and ISO 13485 goes a long way in that direction.

Like ISO 9001:2000, the latest version ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes* (see “Quality management systems for the medical device industry,” p. 16), takes a process-based approach, which is better aligned with the way businesses operate. As a result, ISO

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By the end of 2002 we had met our aggressive goal to secure 15 certifications in 15 months. Two of our other sites are expected to achieve their ISO 13485:2003 registration by the end of this

year. The original 15 will be migrating to the new version during 2004.

There is no end point to quality; instead, we are on a journey of continual improvement. Quality is a way of life at Beckman Coulter – and we know the bar will continue to rise. ■



In the search for greater quality, accuracy and safety in medical devices, robotics speed the processing of patient samples for faster delivery of results to physicians, while reducing both costs and errors. The elimination of manual processing can also increase lab safety.



Ohio State University Medical Centre in Columbus, Ohio, USA, one of the most modern clinical laboratories in the world, features an automation system from Beckman Coulter that enabled the laboratory to eliminate 23 out of 42 steps in the pre- and post-analytical testing processes, reduce the opportunity for human error by 71 % and for biohazard exposure by 88 %. Average test turnaround time was reduced by nearly half.