OLYMPUS KEYMED IMPROVES QUALITY ASSURANCE WITH IFS APPLICATIONS™

The range of legislation governing the interrelated fields of quality assurance (QA) and corporate social responsibility (CSR) is continually growing and spans virtually all markets and industries. Increasing demands are placed on companies to report, track, and control their supply chains and manufacturing processes.

As one of Europe's leading manufacturers of healthcare devices, UK-based Olympus KeyMed operates under stringent regulations on a daily basis. The company is certified in accordance with ISO 9001, EN ISO 13485 for medical products, ISO 17025 for its calibration facilities, as well as ISO 14001 for Environment and ISO50001 for Energy Management. This means that QA/RA (quality assurance/ regulatory affairs) is one of Olympus KeyMed's most crucial business processes and that its quality management system must be constantly monitored.

ABOUT OLYMPUS KEYMED

Olympus KeyMed, part of the Olympus Group, is based in Southend-on-Sea, UK. The company is a leading European healthcare and consumer electronics company. Since Olympus was founded in Japan in 1919, it has become a leading manufacturer of innovative optical and digital equipment for the healthcare and consumer electronics sectors. For over 90 years we have lead the way in designing endoscopy and microscopy products, medical and industrial equipment, cameras and voice recorders.

Olympus KeyMed acts as the Olympus Group's business center for the UK, Ireland, the Middle East, and Africa. An IFS customer since 2003, the company focuses on offering superior product quality and service excellence throughout the post-sale product lifecycle.

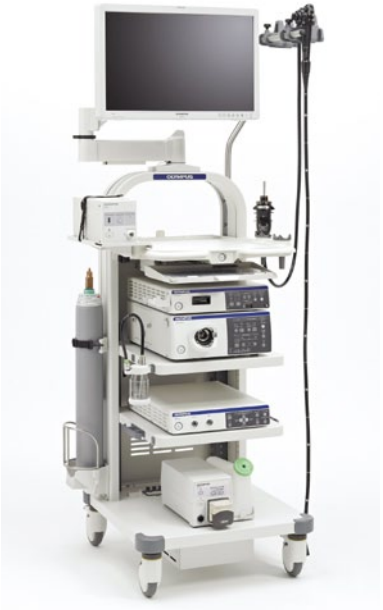
COMPLYING WITH QUALITY STANDARDS

Over the past two years, there has been a dramatically increased focus on quality assurance within the medical device industry. For a global company such as Olympus KeyMed, this means ensuring compliance with a number of regulatory bodies. "Not only are we obliged to meet European medical device regulations, but also those of the U.S. Food and Drug Administration. In fact, the FDA recently stepped up its focus on overseas manufacturers, placing increasingly stringent requirements on our products," Richard Cherry, Director of Corporate Services, Olympus KeyMed said.

INTEGRATED QUALITY ASSURANCE

The increased regulatory focus among governmental organizations around the world raised the question of quality assurance throughout the Olympus group. The decision to update the QA systems used by the group's various subsidiaries was made by the Olympus corporate office in Tokyo.

This gave Olympus KeyMed the opportunity to examine and specify the company's requirements in terms of system support. "This process revealed that the existing QA solutions did not cover all of our requirements. But most



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importantly, they were not integrated with any other part of the business. The existing systems supported the QA/RA team, but in isolation. We decided to implement the IFS Quality Assurance solution to ensure full process support as a natural part of the overall business," said Cherry.

Olympus KeyMed will also use IFS Document Management as its QA document control system in addition to the IFS Case Management solution, which will become the company's customer concern management tool. The company will utilize parts of the core IFS solution in its quality management processes, for example material review board (MRB) for handling quarantined material.

ENSURING QUALITY THROUGHOUT THE SUPPLY CHAIN

Supply chain management and export control are crucial business processes for Olympus KeyMed, whose products are sold all over the world. "When we quote prices and delivery dates, we must be 100 percent sure that we can deliver. The nature of our products make them critically important for our customers and therefore very time-sensitive," Cherry, said.

Olympus KeyMed recently implemented a warehouse RFID scanning solution using IFS, registering serial and lot numbers. The aim was not only to increase productivity, but also to guarantee traceability, which is an absolute requirement among manufacturers of medical devices.

"We are required by European law to be able to provide full traceability of any medical device. We have to trace it from the point we receive it to the point that we ship it to the customer. If there is a problem, or a product recall, we have to be able to contact all customers that have purchased the device. In this industry, it is not enough to issue a general statement; we need to pinpoint every single customer using the product in question," said Richard Cherry.

LEVERAGING BUSINESS BENEFITS

Business integration is one of the main benefits that Olympus KeyMed is looking to leverage with the IFS solution. "By implementing this system, we are effectively moving QA/RA out of the QA/RA team and making the entire organization responsible for keeping this information up to date. In practice, this means that a customer concern, for example, will be entered only once into IFS Case Management and directly assigned to the person responsible—without involving the QA/RA team for manual administration," said Cherry.

The system will also lead to improved management visibility as well as cost reductions. "The system will give senior management real-time visibility of all registered concerns and how they are processed. For us, the return on investment is foremost the business improvements which we gain from the system, rather than the pure cost savings—even though going from four different QA packages to a single solution will mean a reduction in software maintenance costs," Cherry said.

BENEFITS

- Integrated QA support throughout the organization means less time spent manually entering data
- Increased control of global supply chain
- Improved visibility of customer concerns

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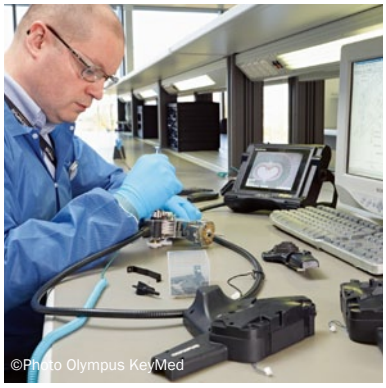

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