



## **Smith & Nephew boosts BIRMINGHAM HIP Resurfacing Quality Management with Proquis**

### **ABSTRACT**

Smith & Nephew's BIRMINGHAM HIP Resurfacing (S&N BHR) product is a world leader in innovative orthopedic treatment. The BHR provides an alternative to total hip replacement for patients suffering from abnormalities of the hip, including osteoarthritis, and has found critical acclaim worldwide. The BHR product is approved by the FDA for use in the United States of America and is recognized as the leading hip resurfacing product globally. With a forecasted 100 per cent year-on-year growth, S&N UK needed to revise its legacy Quality Management System (QMS) to cope with its success. Following a review of available QMS products, S&N UK chose an automated solution from Proquis that has delivered a return on investment in 12 months.

### **FULL CASE STUDY**

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Pioneered by UK orthopedic surgeons, Mr. Derek McMinn and Mr. Ronan Treacy, hip resurfacing replaces the surfaces of the hip joint, leaving the femoral head substantially preserved. This is a less invasive bone sparing approach to treating arthritis in younger or more active patients. The system utilizes proven low wear metal-on-metal bearing surface technology and the broad hip head design offers a high range of motion and excellent stability. There have been over 80,000 surgeries performed since 1997 when BHR was introduced.

#### **Evolution of a cutting-edge business**

S&N UK's Metal-On-Metal Group evolved from the acquisition of Midland Medical Technologies in 2004. With an initial staff of 18, two of whom were in manufacturing, the majority of the BHR workforce focused on sales and marketing. The challenge ahead for the organization was to grow its manufacturing capability in line with the projected growth for hip resurfacing. In addition, this would severely test the existing QMS system, which although adequate for small businesses, would not support the 100 per cent growth S&N UK was looking for.

Dave Telling is Senior Manager Quality Assurance and Regulatory Compliance for S&N UK Orthopedics Limited. He recounts the journey taken by the organization since he joined S&N UK in December 2004. This entailed migrating from a proven and ISO 13485 approved paper-based system to the fully automated Proquis Enterprise solution that supports S&N UK's Quality Management processes today.

*"S&N UK's Metal-On-Metal Group came about from the acquisition of Midland Medical Technologies. The Management Group realized that significant improvements were needed*

*to take the division forward and the first step was to recruit a Quality Manager to ensure that the company had all the necessary systems and procedures in place,” says Dave Telling.*

The Medical Device industry is subject to ISO 13485, which has specific QMS requirements where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements. The standard requires that S&N UK can demonstrate that a QMS is implemented and maintained.

*“ISO 13845 is the recognized Quality Management Standard for Medical Devices and the existing paper-based system was approved to this standard. However, we realized that to support the forecast growth we needed more control than the manual legacy system afforded,” continues Dave Telling.*

Finding an automated solution to address S&N UK’s needs required the company to perform a thorough review of the QMS market, eventually settling on Proquis SBS.

“We looked at a number of software solutions and chose Proquis because it offered module in addition to the typical QMS modules batch control. This would enable us to book goods in and also see our existing stocks. Proquis would allow us to see our inventory on screen and allocate specific materials to batches. This would give us more accurate control of our processes and underpin Quality Management,” he says.

With Proquis SBS, S&N UK implemented the Fault Logging, Calibration, Maintenance and Document Control modules. The system provided all S&N UK needed in a QMS right up to the point it fixed its sights on the lucrative North American market, which was ready for a hip resurfacing product.

### **Upgrading the system to meet US requirements**

The US Food and Drug Administration requires that all software is validated and complies to the rigorous Code of Federal Regulations Part 21 (CFR 21) for auditing, system validations, audit trails, electronic signatures, and documentation as part of business operations and product development. This would prove an initial obstacle to S&N UK’s venture into the US, but help was on the horizon.

Following discussions with Proquis experts, S&N UK chose to upgrade its QMS to Proquis Enterprise to meet FDA requirements. In May 2007 S&N UK rolled out the revised solution, using specific modules that would enable it to tap into the US market. These were Issues & Actions, Equipment Control, Document Control and Audit Management. “Once the system had been successfully validated in accordance with FDA 21 CFR requirements, it was used successfully during recent FDA approval audits. Once this approval process completes it will enable the business to trade its product in North America,” says Dave Telling. Now S&N UK could pursue its North American sales goals.

### **BHR puts Proquis Enterprise into action**

S&N UK’s senior quality assurance manager explains how the company uses the system: “We subdivide Issues & Actions into issue types. This module is then used for incoming non conformance receipts, internal manufacturing non conformance and internal audit non conformance. With such tight control we can then apply the measures FDA requires called Corrective Action Preventative Action or CAPA to address the issues. By capturing all non conformances, CAPAs can be allocated to specific people and tracked through the system. This now means that we now have all staff involved in Quality Management.”

All calibration is managed by the Proquis Equipment Control module. Each piece of calibrated equipment has its measurements registered within the system. This can then be used to create and allocate a calibration schedule, with automatic notifications sent directly to the Senior Inspector.

“The integration between Proquis and Microsoft Outlook has enabled key individuals within the business to be automatically notified of calibration requests. This automation has allowed the Quality Engineers to use their time more effectively to study the calibration results instead of chasing equipment.

“We can also use the system with equipment that needs external calibration. The calibration certificate is scanned into the system and retained in the equipment record,” he continues.

The Document Control module can register and hold all documents but we have started with only the QMS documentation. This provides a secure and tamperproof system. According to Dave Telling “The Document Control module has provided automation of a key process. This ensures that documents are approved and released in correct sequence without failure. It is also provides management with a clear overview of document status.”

“We have eradicated paper documentation and the system ensures that we have no un-controlled documents. The document viewer allows read access only so that all staff can see the documents they are interested in via a PC with a web browser. In addition, Proquis allows us to set system parameters to allow eligible people to comment and amend documents with a full audit trail that shows exactly who made changes and when they were made. This gives me the control I need”.

Using the Audit Management module, S&N UK schedules, plans, monitors, records and reports all of its internal audits. “No other audit record need exist outside of Proquis,” he adds, reporting that “Proquis allows us to not only schedule and plan our audits; we can also update progress of each audit. Any evidence we pick up during the audit is scanned into the system and held on a specific audit file. Any findings that are classed as non-conformance are linked directly to Issues & Actions, which then puts in place the necessary follow up actions. Once an audit is complete, we can assign final closure and verification via the system.”

### **Minimizing effort, maximizing gains**

Dave Telling has clearly identified Quality Management gains from implementing Proquis Enterprise. “The overall key benefit of the system is the modular approach it provides for managing a Quality System. This approach encourages all users to methodically execute and record activities, thus providing for a full systematic review,” he says.

As far as system purchase costs are concerned, Proquis Enterprise has now paid for itself and the S&N UK is set for repeated successes as it pushes forward its ambitious plans for its groundbreaking hip resurfacing system.

“The return on investment on Proquis was achieved in approximately 12 months by minimizing effort and manpower associated with day-to-day Quality Management. This benefit was further amplified during subsequent notified body audits,” concludes Dave Telling.

### **About Smith & Nephew**

Smith & Nephew is a global medical technology business, specializing in Orthopedic Reconstruction, Orthopedic Trauma and Clinical Therapies, Endoscopy and Advanced Wound Management products. Smith & Nephew is a global leader in arthroscopy and advanced wound management and is one of the leading global orthopedics companies.

Smith & Nephew is dedicated to helping improve people's lives. The Company prides itself on the strength of its relationships with its surgeons and professional healthcare customers, with whom its name is synonymous with high standards of performance, innovation and trust. The Company operates in 32 countries around the world. Annual sales in 2007 were \$3.4 billion.