

# SCHWARZ PHARMA

## Company description

SCHWARZ PHARMA develops and markets innovative drugs with a focus on the therapeutic areas of neurology and urology. In 2004 the company achieved global sales of € 947 million, with 78% of this from markets outside Germany. SCHWARZ PHARMA increased expenditures for research and development to € 198 million, advancing the development of innovative drugs for the treatment of Parkinson's disease, Restless Legs Syndrome, epilepsy, neuropathic pain and overactive bladder syndrome and others. These expenditures are funded by own cash flow, which in 2004 achieved a level of € 47 million. Schwarz Pharma is an early adopter of business intelligence (BI), placing them at the forefront of all new developments in this area. Their BI implementation revolves around their most business critical department: R&D.

## Critical business issue

Dr. Christian Ruedel, Director of Scientific Information Engineering at Schwarz Pharma faced the following serious challenges in his BusinessObjects implementation:

- Strict internal and external rules and regulations for drug development companies demanded written documentation for all software programs and systems development processes.
- Compliance with GxP (Good Clinical Practices) required specific registration of any modifications.
- The distribution of highly confidential information needed best-of-breed authorization capabilities.
- And more end-user involvement was needed to keep their BI system intuitive, comprehensive, and easy to access for all researchers.

## Reasons

Reasons for these challenges were:

- Existing rules and regulations from various agencies, such as the US Food & Drug Administration, vary from country to country and from authority to authority. For BusinessObjects, this meant written documentation for every single program change which resulted in excessive man hours.
- Difficulty tracking historical data on system changes within BusinessObjects.
- BusinessObjects provided security and authorization capabilities, but required a full-time employee to do the job.
- And last but not least – the segregation of duties and segregation of development stages was difficult to achieve within BusinessObjects itself.

## Capabilities

Dr. Juergen Raabe, Project Manager for the implementation of BusinessObjects version 5.x, was on a mission to find a solution that would help Schwarz Pharma comply with governmental and internal regulations easily, and allow for the necessary segregation of duties and system development life cycle stages. NOAD's EQM provided these capabilities.

## Result

Instead of writing hundreds of pages of descriptive text, workflows, manuals etc., on every change and for every single authority over and over again, EQM allowed Schwarz Pharma to perform the exercise only once, and then apply it to their entire BI environment.



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The domain access concept provided by EQM made a huge difference in accuracy and speed of report distribution and accessibility. Thanks to EQM, safe and secure report access is now rapidly arranged by domain, function, and person.

By virtue of its different development stages and early end user input, EQM made the Schwarz Pharma BI production environment fool-proof and error-free.

NOAD's team of expert consultants completed the EQM installation at Schwarz Pharma in just one week. This included the complete system set-up, software installation and training of Schwarz Pharma's BI team. Within three weeks they imported dozens of universes, hundreds of documents and objects, and achieved technical realization. The entire process took a total of 4 weeks. To put this into perspective, Schwarz Pharma worked 1.5 years on the descriptive process for government regulations alone!

An additional benefit EQM provided was that implementing QM aided the validation of BusinessObjects 5.1.8 from a GxP-compliance perspective because it created a starting point for an electronic audit trail that would track changes made to BusinessObjects universes and documents that did not previously exist.

In conclusion, because of EQM, BusinessObjects maintenance activities take less time and are much more efficient. Therefore, working with the system is considerably more enjoyable. Now, instead of working on "putting out fires", the team can actually work on improving the system. Schwarz Pharma considers this to be their biggest return on investment!

