

EISAI LTD CASE STUDY



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Eisai Ltd ensures peace of mind by achieving software compliance.

Eisai Ltd manages the functions of marketing and sales, finance, medical information, market research and business development for the pharmaceutical R&D operations of Eisai Europe and Eisai UK.

The company has three principal therapeutic areas of interest: Alzheimer's Disease where it has made available the first compound in the UK for the management of symptoms of this debilitating disease; Epilepsy where Eisai has recently marketed a product for adjunctive treatment of partial seizures; and acid related diseases such as duodenal and gastric ulcers, and reflux disease.

Due to its role in the pharmaceutical industry, Eisai is subject to stringent regulations and has implemented high standards of compliance across the organisation. As part of its ongoing compliance commitments the company turned its focus to the IT infrastructure and in particular to ensuring that correct software licences were in place.

Bente Roa, Corporate Affairs Personal Assistant, explains the reasons behind this: “With compliance playing an increasingly important role we wanted to ensure that our efforts in this area were not confined to our core pharmaceutical activities, but also applied throughout our entire organisation. The IT system is the foundation of the company's communications and as such we wanted to ensure that our legal obligations in this area were fulfilled.”

“The nature of the company's work means that we use many different types of software, from SAP and Oracle to specific pharmaceutical applications, and therefore have a large number of licences to manage across 250 PCs. Keeping abreast of all new installations and upgrades is no easy task and the implementation of any system that would enable us to control this process more effectively had to be a good thing.”

The FAST process

Eisai turned to FAST for help. “At first, the path to software compliance seemed a long and daunting one. However, working towards the FAST Standard for Software Compliance (FSSC-1:2004) has enabled us to approach the process more easily. Divided into distinct sections, the programme allowed us to

initiate procedures one step at a time as well as set realistic short term targets. Not only this but it made it much easier for us as we knew exactly what we had to do to get the Gold Award.”

The first step was for a member of the corporate affairs team to attend a FAST Software Management Training Day. This covered a number of topics including legislation, software licensing, auditing and reconciliation, followed by a basic examination of the principles of the FAST programme. This helped to prepare the team for the task that lay ahead.

Following the workshop, the next task was to review the organisation's current policies and procedures relating to the purchase and use of software. Alongside these, the company implemented comprehensive disciplinary procedures for enforcement of the policies, demonstrating the seriousness of the programme and encouraging employee buyin. All staff were required to read and sign Eisai's new software policies before the process could continue.

Once these policies were in place, Bente's team needed to evaluate the number of software installations against the licences in place.

“This was not an easy task,” explains Bente. “Previously, some departments had been buying specific company software without going through the central purchasing department. We had to inform all departments that all software should now be purchased from the central IT purchasing administrator and also ensure we had copies of all licenses that were not held with the IT administrator.”

With this data to hand, the next step was to carry out an enterprise-wide audit on the company's PCs to evaluate the software being used by each member of staff enabling the team to identify which individuals were using what software. From this, it could be established whether new licences needed to be purchased, unused software deleted and whether certain applications could be uninstalled and reinstated on other PCs to avoid purchasing unnecessary licences.

Eisai decided that the most accurate method was to use an electronic auditing tool and the process began by evaluating a number of options that would be both cost-effective and provide all the necessary information. Eisai selected Visual Audit Pro and the audit process got underway.

In order to maintain accurate and up-to-date software records, the company realised that such audits would have to be conducted on a regular basis - a timeconsuming task.

With this in mind, the team recognised the importance of implementing a much simpler system than the one that existed previously. "Historically, software data had been stored in various spreadsheets which made finding the right information difficult. However, by implementing a more streamlined system, any employee could pick up the auditing and management of the company software without any difficulties if they had to, without having to undergo the laborious process once again."

In order to address this, Eisai decided to purchase 'Software Organiser' - a piece of software which worked alongside Visual Audit Pro and which would enable the company to accurately reconcile, store and update all the necessary data in a single database.

Once all the information was entered into the Software Organiser, Eisai could merge its electronic audit (from Visual Audit Pro) with the information in the Software Organiser. The team was then able to identify at a glance and rectify any licensing shortfalls to ensure that the number of licences in place matched the number of applications on the company's PCs.

"It was a great relief when we had reconciled all the data," commented Bente. "We saw that there was very little discrepancy over the number of licences we had in place. We were over-licensed on some software applications and under-licensed on others but in the end we only had to spend £3,000 on new licences to become fully compliant. Not only this but the reconciliation allowed us to identify redundant software on individual machines, releasing available licences for use on other PCs."

Once licensing shortfalls had been rectified, Eisai presented its application for registration to the FAST Standard for Software Compliance FSSC-1:2004 to FAST, which was approved following an on-site inspection. Consequently, the company was awarded the Gold Award of the FAST Standard. Since achieving the Gold Award the organisation has submitted two years of audit and reconciliation data and is on course to

receive the Platinum Award by the end of 2005, for three consecutive years of registration to the FAST Standard.

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Return on investment

"We would have struggled to achieve software compliance without FAST's help," concluded Bente. "Throughout the programme, the FAST team provided plenty of support. They demonstrated a great understanding of the issues we faced and always provided us with the answers we needed."

"The process has created a good return on investment for the company. More than anything however, achieving compliance has given us peace of mind. According to FAST's advice, we carry out regular software audits and always retain the most up-to-date information by keeping three separate copies of each licence: one in A-Z software files, another hard copy in an invoice file and a third stored in a fireproof safe. Therefore, we know we can demonstrate compliance even if the worst happens."

For more information please call **0844 815 5742**, email **contactus@fast-compliance.co.uk** or visit **www.fast-compliance.co.uk**

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