

Managing critical change processes at Roche

"We have achieved a significantly higher turnaround of changes with the Infra automated system"

Every component of every system used in the production of Roche's products, including all computer systems, must be fully tested, validated and documented.

Roche's systems validation is verified by both external audits, and Roche's own internal audits across all areas of the business. According to Phil King, Roche's Helpdesk Manager in Sydney, "The auditing requirements are getting tougher every year. As technology enables more thorough auditing, so the expectations have risen."

Potentially, an entire Roche site can be shut down, not because of any actual malfunction in a computer system, but because it has not been validated to the meticulous level required by legislation. As can be expected, says King, "Roche takes the maintenance and operation of its computer systems very seriously."

As a result, Roche also maintains an extremely rigorous IT change management process. Once a system or component, including hardware, software, documentation, security and personnel is defined as a Configuration item, changes can only be performed under a formal Change Control process.

Changes to the Roche business system are tested on two separate servers before going into production, with an approval required before the changes are passed on to each server.



Roche Pharmaceuticals

Founded in Switzerland in 1896, Roche is one of the world's largest healthcare companies, with 70,000 employees across 150 countries.

Specializing in the research and development of pharmaceuticals, vitamins and diagnostics, Roche prides itself on its innovative contributions to healthcare.

IT service management for Roche's business system, SAP for the Asia Pacific Region as well as all other computer systems in Australia, are managed centrally from Sydney, Australia. This support includes the management of all changes to those systems.

The Roche Business Scenario

The Pharmaceuticals industry is a highly regulated one, governed by both local and international bodies and legislation, including for example, the GMP (Good Manufacturing Practice), TGA (Therapeutic Goods Act) and FDA (Federal Drugs Administration Act).

The legislation is designed to ensure that processes such as the labeling of drugs and measuring of quantities of chemicals used to produce them, are 100% accurate.



Infra technology provides a solution

In 1998, Roche Sydney implemented Infra technology to manage its change management processes. Roche's stated objective was to "install a common change management system that used a single database for SAP IT support in the Asia-Pacific region, that would incorporate well-defined security controls as well as provide a clear picture of the status of change requests."

The automation of the change management process through Infra became particularly important in 1998, when the Sydney site became responsible for Roche's SAP system across Asia-Pacific. The change meant that the IT team "needed to be able to validate our systems extremely quickly."

Prior to 1998, Roche had been using two separate databases for IT incident and problem management, and change management. Infra was being used for the former, while change management data was held in MS Access and required a number of manual processes and "a lot of email".

The manual process, says King could be time consuming, generated volumes of paper and had the potential to miss steps. There was also no function to escalate change requests, which could lead to changes becoming stalled at particular tasks.

"It would be very difficult to pass an audit these days with the manual system. Now with Infra, paperwork is practically eliminated, and both the people working on a change and managers requiring an overview can easily see where any change request is up to."

Since the initial implementation, King's team has streamlined and reduced the number of change requests managed through Infra, reflecting a steady improvement in the processes themselves. They currently maintain around eight separate process templates for change: five for the SAP team and one each for the network, Unix and storage management teams.

Naturally, the Infra system itself required validation prior to going live. Infra Corporation was required to complete comprehensive validation documentation for Roche guaranteeing that the system performed the functions it claimed to.

Benefits

Infra has provided Roche with the ability to track and audit changes, and maintain visibility of all changes in progress. This is particularly useful for managing changes required in dispersed locations across the Asia-Pacific region.

The use of a single integrated system enables Roche to effortlessly manage the service support lifecycle of incidents, problems and changes, and maintain a single configuration management database.

A post implementation review conducted by Roche six months after installing Infra for change management confirmed, says Phil King, that "We have achieved a significantly higher turnaround of changes with the Infra automated system. Emails go to the right people at the right time informing them of actions they need to take, and providing all the necessary information." The automation of the approvals process has been a key factor in the faster turnaround time.

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