



“Objective provides us with a solution that connects our people, helping them to **collaborate and improve our business processes.**”

Mr Lionel King, Vice President of Quality Assurance & Regulatory Affairs, ResMed



ORGANISATION

ResMed

INDUSTRY

Health and Life Sciences

USERS

1400

SOLUTION



BENEFITS AT A GLANCE

- Reduced Costs
- Reduced time to market
- Quality assurance
- Business process improvement knowledge

ResMed meets stringent biomedical regulations and expedites time to market.

ResMed Limited is Australia's largest manufacturer and exporter of medical devices. As a long-term Objective customer, ResMed embarked on a global roll out of Objective's content, collaboration and process management solution. With over 1400 users in 18 countries, Objective is used to help speed products to market, as well as meet stringent local and international biomedical regulations.

ResMed is a leading developer, manufacturer and distributor of products for the diagnosis and treatment of sleep-disordered breathing (SDB) and other respiratory disorders. As a global leader, its products are distributed in over 70 countries and the company has enjoyed more than ten years of consistent revenue and profit growth.

“Objective and ResMed have worked together for over ten years and enjoyed a long and productive relationship. Objective has supported our growth and understands our focus is not on growing the company but treating SDB and developing products to improve the quality of life for our patients and their families,” said Mr Lionel King, Vice President of Quality Assurance & Regulatory Affairs, ResMed.

With rapid international growth, ResMed needed to resolve the difficulty of managing large amounts of information stored both electronically and in hard copy across their geographically dispersed global manufacturing sites.

“Scalability of the solution was very important to ResMed as the company continues to experience international growth,” said Mr King.

“At ResMed, Objective is considered a mission critical system that underpins our entire unstructured information requirements. It enables continual improvements in the development of our products, it automates and streamlines business processes, and supports our compliance obligation with stringent international regulatory requirements,” said Mr King.

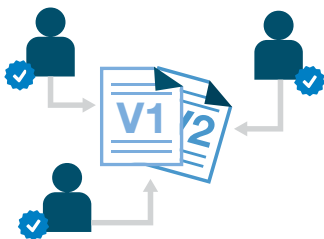
KEY BENEFITS



**SPEEDS
PRODUCTS TO
MARKET**



**HELPS
COMPLIANCE
WITH FDA, TGA
ISO 9000 & MORE**



**VERSION CONTROL
REVIEWS & APPROVALS
MADE EASY**



**INSTANT ACCESS
TO INFORMATION WHEN THE
AUDITOR CALLS**

Objective manages both electronic documents and hard copy records for ResMed, including work instructions, procedures, bills of materials, specifications, user instruction manuals, label artwork and marketing material.

The solution supports offshore manufacturing sites with parallel global performance and 24 hour-a-day availability.

AUTOMATED APPROVALS

“Objective provides us with a solution that connects our people within ResMed, helping them to collaborate and improve our business processes,” said Mr King.

A significant advantage of the solution for ResMed is its automated approvals capability. Previously, the transportation of documents for review and approval during the design and manufacturing phases, between the research and development team in Australia and the product managers in the US, was taking anywhere up to two weeks.

“Documentation was either couriered or emailed, with approvals and changes coming from many different people. This meant more paperwork, more time to combine the changes and then more time again to get further approvals,” said Mr King.

“Generating and controlling the evolution of documents electronically via Objective reduces the risk of error and streamlines the approval process - the version control is excellent.

“As soon as a document is ready for review, the Objective notification system alerts all people involved in the pre-defined process that it is available for review. Staff with appropriate privileges can log onto the system, review the document, know when and who has made changes or approved the document.

“Instead of sending hard copy documents out to the approvers, we just need to send one notification to the designated individuals, they log into Objective and the process can be completed within minutes if necessary. If changes need to be made to the document an approver can reject the document and add in comments for referencing by the author.

“Only when a document is approved by all the requisite departments is it published and hence made available to the broader audience.

“This has really helped us streamline our approval process,” said Mr King.

SAVES TIME, PAPERWORK AND LABOUR

All manufacturing documentation is stored in Objective. The manufacturing teams can log into Objective and see what they are building, as well as checking the specifications for any parts that come in from different suppliers to make sure they are correct. This was previously done by hard copy, with documentation stored on rows of shelving.

The process of meeting stringent audit requirements of international regulatory bodies, such as the US Food & Drug Administration (FDA), the Australian Therapeutic Goods Administration (TGA) and ISO 9000 quality systems, can challenge a company's ability to commercialise products quickly.

To meet the requirements of audits by international regulatory bodies, ResMed needs to be able to produce documentation in a timely manner on all processes involved in a product's development.

Using Objective, ResMed is able to comply with regulatory standards and streamline the document approval process that can help expedite time to market for new products.

“When auditors call we can now access any document they request within seconds, instead of leafing through hard copy folders,” said Mr King.

FACILITATES CRITICAL WORK PROCESSES

In addition to quality assurance and compliance management, Objective has delivered a number of other strategic benefits. One of these benefits is in the area of change management and the dynamic response to change.

“Being able to analyse the flow of information allows us to easily identify any hurdles in our processes and ensure maximum efficiencies,” said Mr King.

“Our ability to effectively track documents and share information means that we can continue to look at ways we can improve the development of respiratory products and comply with stringent regulatory requirements.

“Objective provides the technology to support our innovation, allowing us to experience benefits from improved process management and helping ResMed to deliver world class products that will improve the lives of our customers and their families.”

MOVING FORWARD

ResMed’s recent upgrade to Objective 7.4, will allow them to explore Objective’s strong web applications capability whilst utilising information directly from the Objective repository.

“We have the option of providing our own staff, external contractors, suppliers and distributor’s information with read-only or authorised access via a fully functional Objective web-based interface.

“This will extend the value of our existing content by making it more accessible to wider range of people,” said Mr King.



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Mr Lionel King, Vice President of Quality Assurance & Regulatory Affairs, ResMed

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ABOUT OBJECTIVE CORPORATION

Objective Corporation (ASX:OCL) creates information and process governance solutions that are effortless to use and enable organisations to confidently advance their own digital transformation.

Designed for regulated industries, these solutions turn the imperative of compliance, accountability and governance into an opportunity to streamline business processes and deliver the innovative services that customers expect.

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With a heritage in Enterprise Content Management (ECM), Objective's expanded solutions extend governance across the spectrum of the modern workplace; underpinning information, processes and collaborative work-spaces.

Through a brilliant user experience, people access the information they need to progress processes from wherever they choose to work.

Objective