Australian e-Health Research Centre

Unlock success with our quality management system (QMS)

It may seem premature to contemplate market launch while in the initial stages of product development. However early planning is crucial for optimising resources and ensuring your health technology is market ready.

Why partner with AEHRC?

CSIRO's Australian e-Health Research Centre (AEHRC) has nearly two decades of experience in creating and implementing digital health tools and devices.

Choosing us as a research partner assures product safety and efficacy.

Collaborating with us can also accelerate the translation from concept to market. Our commitment to adhering to TGA and FDA requirements, along with our pursuit of ISO 13485 certification, guarantees a robust QMS. We'll help you streamline the journey to market by providing a comprehensive technical file alongside the product.

You can count on us to adeptly handle the complexities of product development.

The core of successful product design and development relies on a robust QMS. A QMS consists of two vital components – processes and products.

Adherence to high standards

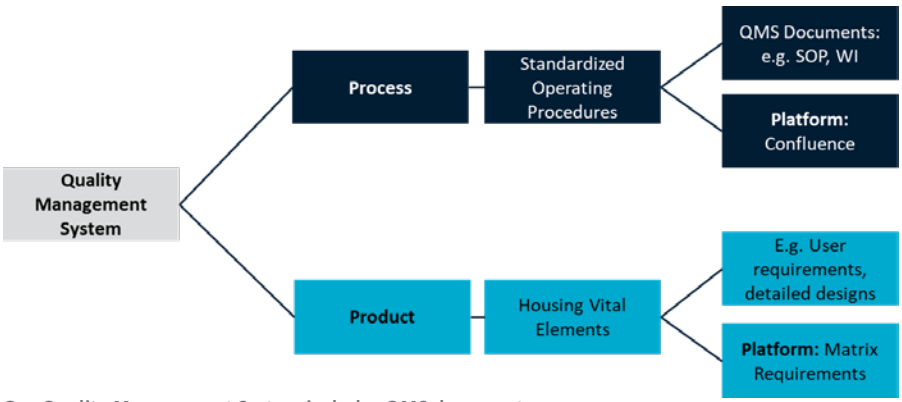
An ideal partner organisation will hold ISO 13485:2016 certification. The credential is a testament to an organisation's commitment to quality and compliance.

Processes

Our meticulously crafted QMS includes QMS documents encompassing all stages of design and development. From rigorous risk management to seamless complaints handling, processes are tailored for excellence.

Products

The cornerstone of the QMS is the comprehensive technical file, housing vital elements crucial for product realisation. It encapsulates user requirements, system specifications, intricate product architecture, detailed designs, risk management and other product related documents.



Our Quality Management System includes QMS documents and a comprehensive technical file

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