

SOFTWARE IV&V SERVICES FOR BIOMEDICAL APPLICATIONS

IV&V Australia's consultants are highly experienced in providing Independent Verification and Validation services to biomedical companies developing software-based systems.

What is Software IV&V?

IV&V stands for *Independent Verification and Validation*. IV&V is the process of:

- Verifying that the output of each software phase meets its requirements, and
- Validating that the software, at the end of the development effort, meets the overall project objectives.

What are our Biomedical IV&V Services?

IV&V Australia has a depth of expertise in providing Software IV&V Services to the biomedical device industry.

We have significant experience in the development and test of software and systems to meet regulatory requirements for a range of applications, including embedded device software and desktop applications.

Product Evaluations

We can provide an independent assessment of a product to identify its true development status and/or quality:

- **Design verification and validation testing:** We can conduct independent verification and/or validation testing of your medical device or other system software.
Our test lab is accredited by NATA (the National Association of Testing Authorities) to ISO 17025. We can issue you with a NATA-endorsed test report, which will be recognised by regulatory bodies throughout the world.
Our processes comply with the software testing elements of IEC 62304.
- **Document and process reviews:** We can assess the completeness and appropriateness of design and test documentation, as well as assess their conformance to standards.

Strategy Evaluations

- **Software strategy evaluations:** We can provide independent assessment of a project or organisation's software development capability.
- **Strategic reviews:** We can ensure that project plans are effective and are being followed.

Specification Activities

We can assist you with a range of specification activities:

- **Prepare system and software specifications:** We can help you develop Requirements and Specification documents, and provide an independent view to ensure that they are complete and unambiguous.
- **Concept selection:** We can help you choose between competing system design options.
- **Requirements tracing:** We can ensure that contractual and regulatory requirements are being carried through into implementation and testing.

Risk Management

We can assist you with a range of risk management activities:

- **Hazards analysis:** We can help you perform formal Hazards Analyses of your products as required by regulatory bodies.
- **Process reviews:** We can review your risk management activities against various risk management standards, to ensure that you meet the appropriate regulatory requirements.

Commercialisation Assistance

- **Phase transition:** We can assist you with the transition from Research to Development, as you turn your prototype into a product.

Who are our customers?

Organisations to whom IV&V Australia have provided these services include:

- Applied Physiology
- Sunshine Heart
- Impedimed
- Sonomat
- Micronix
- Resmed
- Cogstate
- Polartechinics
- Colocare
- Cochlear