GUIDELINES

Australian Medtech Manufacturing Centre

Medtech Manufacturing Capability Program

1 Program Summary

1.1 Overview

The Australian Medtech Manufacturing Centre (AMMC) is a $20 million Victorian Government initiative to grow medtech manufacturing in Victoria, creating more jobs, investment, and innovation in the sector.

AMMC aims to encourage medtech manufacturing in Victoria. It will make it easier for medtech product developers to find and access local expert medtech services and infrastructure and to undertake design and /or manufacturing process testing (verification and validation) activities that they may otherwise carry out offshore.

1.2 What is the Program?

The Medtech Manufacturing Capability Program (MMCP) assists Victorian manufacturers and medical technology businesses to build capability to scale up by supporting projects that will verify or validate commercial prototypes, or manufacturing processes and other related activities that will enable local manufacturing. This may include activities that would otherwise be carried out overseas or that would be brought forward by at least a year with the addition of program funding.

Eligible Applicants can apply for funding for projects that are at the prototype and/or scale up stage of the product development cycle. Funding will support any stage of product development from proof of concept through to launch or allow existing medtech manufacturers to scale production for new product/market/customer opportunities (Technology Readiness Levels 3+).

AMMC will administer the program through the Department of Jobs, Precincts and Regions (DJPR).

1.3 Program Objectives

The objectives of the MMCP are to:

- increase the capability and capacity of businesses to manufacture medtech products in Victoria and strengthen the value chain
- enable more Victorian manufactured medtech projects to be generated and delivered creating business growth
- accelerate the development, clinical and regulatory approval, and production of medtech projects to create increased employment and revenue opportunities.

1.4 Program Outcomes

The program aims to increase the size and value of Victoria's medtech manufacturing sector. To do this, the intended outcomes of this program are that:

1. more Victorian manufacturers and medical technology businesses are able to scale up production and improve manufacturing capability

2. more successful product translation of Victorian medical research leading to increased manufacturing related business activity in the state
3. more Victorian small and medium enterprises (SMEs) are entering the medtech supply chain.

Contributing to longer term outcomes that medtech manufacturers are:

- attracting more investment
- employing more Victorians
- creating more higher value or skilled jobs
- generating more export income.

2 Available Funding

The program has a total of $3 million in funding in FY2021-22, grants of between $100,000 to $500,000 (excluding GST) for each successful Applicant.

Recipients will be required to spend 50% of grant award and 50% of cash co-contribution in the first six months after contract signing.

Applicants requesting grants of $200,000 or more, are required to submit an addendum to their project plan including a detailed quality of investment analysis, which will be considered as part of assessment.

2.1 Co-contribution requirements

The Applicant contribution must match the grant value dollar for dollar using their own funds. If the project budget is higher than the grant value and co-contribution combined, the remaining amount must be covered by the Applicant, partner contributions, other grant funds or other sources.

Example:

- If the total project cost is $1,250,000 (excluding GST), the requested maximum Grant contribution would be $500,000 (excluding GST). That is, the Applicant must contribute matched funding of $500,000, with the remaining amount to be covered by the Applicant using own, or other sources as indicated above.

3 Eligibility Criteria

3.1 Eligible Applicants

To be eligible to apply, the business must:

- at the time of application, be developing an eligible medtech product
- have existing operations in Victoria
- be incorporated in Australia
- hold an Australian Business Number (ABN)
- be an employing business registered for WorkCover Insurance with WorkSafe Victoria
- have an annual turnover of $50 million or less
- match any grant funding on a 1:1 cash co-contribution basis

- provide financial reports for the last three financial years to enable DJPR to conduct a financial risk assessment.
- participate in future program evaluation activity.

Applicants must certify, and if requested to do so provide evidence, that they meet the eligibility criteria.

3.2 Project Eligibility

A Project proposed for grant funding must be to develop a manufactured medtech product or for the development of value chain inputs for a manufactured medtech product where the product:

- is or will be for the duration of the project wholly or partially manufactured in Victoria

AND

- is a medical device, the purpose of which is to diagnose, prevent, monitor, treat or alleviate a disease or injury, or modify or monitor anatomy or physiological functions of the body, or is intended to be used in a healthcare environment including medical equipment, scientific instrumentation and consumables or medical disposables (*https://www.tga.gov.au/medical-devices-ivds*) ***(or)***
- an enabling medtech product or device using assistive, additive manufacturing or 3D printing technologies

AND

- is relatively advanced in development, that is at least at proof-of-concept stage equating to GAITS Stage 3, as considered by the Applicant against CIMIT's Guidance and Impact Assessment Tracking System (https://www.gaits.org/web/medtech/guidance) ***(or)***
- has been verified with research and development or other pre-clinical studies.

3.3 Ineligible Applicants

The following are not eligible to apply for the Program:

- a Commonwealth department, agency, or body
- a State department, agency, entity or other body established under *the Public Administration Act 2004 (VIC)* or equivalent legislation of another Australian jurisdiction
- unincorporated associations
- non-employing business
- universities or research organisations.

3.4 Eligible Activities

Eligible activity must relate to the manufacture of medtech in Victoria. The following activities or expenses are examples:

- accessing facilities, capabilities, or services to test, verify and validate, develop or scaleup a - manufactured product for new market opportunities
- accessing clinical know-how and sites to validate or iterate medtech products or gain market feedback as part of achieving local market procurement
- developing standard operating procedures or achieving accreditation for relevant ISO medtech manufacturing standards

- accessing specialist capabilities to address regulatory or quality requirements, R&D tax incentive, product launch, access to markets and advanced training
- purchasing capital equipment to support manufacturing scale up and end-to-end product development.

3.5 Ineligible Activities or Expenses

This Program does not support expenditure which involves:

- costs that are already funded or partially funded by government funding
- usual operational expenditure, including existing staff costs, communications, travel, entertainment, accommodation and office computing equipment
- routine replacement or minor upgrade of plant and equipment
- printing, stationery, postage, and bank charges
- any amount paid on account of goods and services tax
- costs related to preparing the grant application, preparing any project reports and preparing any project variation requests
- building routine websites, sales and promotional activities, marketing or communications campaigns
- retrospective funding for activities that have already begun
- any other expenditure as determined by the department in its sole and absolute discretion.

3.6 Project Timeline

Project components funded by this program must commence in the 2021-22 financial year and be completed within the 2022-23 financial year. The maximum duration of the project from start to completion is 12 months.

4 Assessment Process

Applications will be reviewed for eligibility to the MMCP.

Eligible applications will then be:

1. reviewed and scored individually against the assessment criteria by a panel of internal DJPR and external experts
2. ranked against all other applications
3. DJPR will recommend the applications for approval to the Minister for Industry Support and Recovery, subject to available funding.

The Minister's decisions on all matters pertaining to the award of grant funding under this Program is at the Minister's absolute discretion.

4.1 Assessment Criteria

Eligible applications will be assessed on how well they meet the assessment criteria as outlined below. All supplementary attachments and information provided as part of the application will be taken into consideration during the assessment process.

	Assessment Criteria	Considerations	Weighting

1	The quality of the project (based on section 3.2 Project Eligibility) and how well it will assist the business to build its capability and capacity to manufacture in Victoria to meet a market need.	The proposed project shows: • clearly how the funding of activity will be used to scale up or develop the business to manufacture the product in Victoria. • that the need for the product been researched and identified • how well a market for the product has the been identified and evidenced	30
2	The potential to create employment and revenue opportunities in medtech manufacturing for the business and for Victoria.	Does the project have: • clear, realistic, and achievable outcomes • potential for new clients or markets reached as a result of the product • potential to result in new revenue or investment At the conclusion of the project, likelihood of: • new jobs generated in Victoria including timeline and number • potential to create ongoing employment including timeline and number • existing employees transitioned into higher value or skilled roles including timeline and number • other long-term benefits in Victoria. <u>For grant requests $200,000 and above – demonstrated by the quality of the investment analysis and the outcomes showing at least two of the following:</u> • job creation or retention • export revenue growth • increase in capacity to service existing or new markets • other value-add for Victoria's medtech industry.	30
3	The ability to implement the project	The application demonstrates: • the business's track record and experience in managing similar projects • the project plan including scope, implementation methodology, timeframes, delivery risks and budget • have they identified and have access to the required resources for the successful delivery of the project including access to	20

		infrastructure, finance, capital equipment, technology, intellectual property and regulatory or other approvals • where applicable, organisations partnership arrangements including service providers.	
4	Need for government support	The applicant must demonstrate the following: • need for government funding for the project to go ahead in Victoria • how the grant will benefit the project in terms of scale and timing • how this grant will impact the organisation's ability to be self-sustaining and competitive into the future • whether the funding creates any additional activities for future use for the business following this identified project.	20

4.2 Due Diligence Assessments

Applicants are subject to a risk assessment which verifies business details provided with the Australian Business Register, Australian Securities and Investment Commission, Australian Charities and Not-for-profits Commissioner and WorkSafe.

Any of the following circumstances may be taken into consideration in any decision whether to award a grant:

- Any adverse findings by a regulator regarding an Applicant;
- An Applicant is placed under external administration;
- There is a petition to wind up or deregister the Applicant;
- The Applicant is or becomes deregistered or unregistered (including cancellation or lapse in registration); and

The department may at any time, remove an Applicant from the Application process, if in the opinion, association with the Applicant may bring the department, a Minister or the State of Victoria in disrepute.

The department will undertake a financial assessment of the Applicant to assess the ability of the Applicant to deliver the proposed project. Outcomes from the financial assessment may be taken into consideration in any decision to recommend and award the grant.

5 Application Process

5.1 Prepare an Application

Applicants must undertake the following steps to apply:

1. carefully read these Program Guidelines
2. compile all necessary supporting documents to apply as detailed in the 'Documentation and Information Requirements' section of these Program Guidelines

3. submit application online via the Program website
4. await email confirmation of application submission. Please check spam or junk mail if confirmation email cannot be seen in your inbox.

5.2 Open and Close Dates

- Applications must be submitted in the portal by 5pm on the closing date. Please note that late applications will not be accepted.
- All Applicants will be advised in writing via email of the outcome of their application approximately 30 calendar days from the closing date.
- Opening and closing dates will be listed on the website.

6 Documentation and Information Requirements

Requirement (all grant applications)	Reason for requirement
Project Plan (10 pages maximum) • project description • overview of the implementation timeline • evidence of sufficient internal resources to allocate to the project • any project risks and mitigation strategies • project outcomes and impact for Victoria • budget summary (detailing how grant funds and the Applicant's contribution will be spent on eligible project expenditure, as GST exclusive) • business impact statement.	To provide sufficient information in order to make an assessment of the quality and deliverability of the project as outlined in the assessment criteria.
Evidence of validity of project, including evidence of GAITS development stage, validation, testing, feasibility studies, and/or other work done to date.	To support quality and impact assessment as outlined in the assessment criteria.
Evidence of Co-contribution Funds: Applicants must provide evidence which demonstrates, to the satisfaction of the department, that the Applicant has sufficient funds available for the required co-contribution amount for the project. This may include evidence of: • written confirmation from the Board or business owner that the business can undertake the project and meet the required co-contribution amount • an approved loan facility (including loan amount) • sufficient cash in a bank (current bank statement)	To establish that the co-funding requirements of these guidelines can be met.

• management accounts demonstrating satisfactory cash flow or liquid assets.	
• Quotations, including Scopes of Services for any proposed third-party service providers and/or suppliers • Demonstration that third-party providers have the requisite skills, qualifications, and accreditations to provide authoritative advice on the topic sought	Where professional services are needed to be engaged to demonstrate the appropriateness of the cost, scope, and capabilities of what is being proposed.
• Financial Reports for the last three financial years*. This should be the 'final accounts' with Directors' Report and Declaration and should include: - Profit and Loss Statement - Balance Sheet - Cash Flows - Notes to the accounts. • If the latest financial report is more than six months old: - up-to-date Management or Interim Accounts for the current year including: Profit and Loss Statement and Balance Sheet– in case of public listed corporations, half yearly financial report - for project-based applications, the company's financial projections for the next three financial years, including Profit and Loss–Cash Flow.	For the department to undertake a financial assessment of the Applicant to assess the ability of the Applicant to deliver the proposed project. Outcomes from the financial assessment may be taken into consideration in any decision to recommend and award the grant
Additional requirements for grants greater than $200,000 (ex. GST)	
Addendum to project plan including a Detailed quality of investment analysis (5 pages maximum) demonstrating at least two of the following outcomes: • job creation or retention, • export revenue growth, • increase in capacity to service existing or new markets,	To demonstrate a need for higher funding levels and return on investment for Victoria.

• other value-add for Victoria's medtech industry.	
Letters of Support	To demonstrate market need including identification of confirmed or potential customers and/or technical expert recommendation.

7 Conditions of Funding

7.1 Grant agreements

If successful, Applicants will be invited to enter into a legally binding grant agreement with the Department by a date to be determined by the Department. The grant agreement details all funding obligations and conditions.

The funding offer may be withdrawn if the Grant Agreement is not executed and returned to the Department by the successful Applicant by the date to be set by the Department.

The project must not commence until a grant agreement has been duly executed by both the Department and the successful Applicant.

Once the agreement has been executed, the successful Applicant will be required to commence the project within the agreed timeframe. If a successful Applicant does not commence the project by the commencement date, the Department terminate the agreement in accordance with its terms.

7.2 Publicity/Acknowledgement

Successful Applicants must agree to cooperate with the department in the promotion of the program. This may include involvement in media releases, case studies or promotional events and activities.

Successful Applicants must not make any public announcement or issue any press release regarding the receipt of a grant without prior written approval from the department.

The department may publicise the benefits accruing to the successful Applicant and/or the State associated with the provision of the grant and the State's support for the Project. The department may include the name of the successful Applicant and/or grant amount in any publicity material and in the annual report.

The department may request successful Applicant fact checks any text and seek approval to use any owned imagery associated with the activity prior to the publication of any such promotional materials.

8 Intellectual Property (IP)

Successful Applicants will retain ownership of any intellectual property relating to their project that they:

- have created at the time of entering into a grant agreement with the department; and
- create in the course of exercising their rights and performing their obligations under the grant agreement with the department.

9 Reporting for Program Evaluation

As a condition of funding, successful Applicants will be required to participate in any program monitoring and evaluation activities initiated by the department. This may include completing surveys

throughout the program to measure progress to achieving outcomes, and for up to three years after program completion. Non-compliance could impact future applications to other department programs.

Reporting is critical to the department in understanding program impact, supporting continuous improvement in program design and delivery, and delivering more effective grant programs to the people of Victoria.

Funding recipients will be required to provide independent financial audit reports at project completion. An audit report will verify the funding recipient spent MMCP funding in accordance with the funding agreement.

10 Privacy and confidentiality

Information provided by the Applicant for the purpose of this application will be used by the department for the purposes of assessment of applications, program administration and program review. In making an application, the Applicant consents to the provision of their information to State and Commonwealth Government departments and agencies for the purpose of assessing applications. If there is an intention to include personal information about third parties in the application, please ensure they are aware of and consent to the contents of this privacy statement.

Any personal information about the Applicant or a third party will be collected, held, managed, used, disclosed or transferred in accordance with the provisions of the *Privacy and Data Protection Act 2014 (Vic)* and other applicable laws.

Personal information will be disclosed and shared with an external panel of industry experts, under a confidentiality arrangement, which assists DJPR with the evaluation of applications.

Enquiries about access to personal information, or for other concerns regarding the privacy of personal information, can be emailed to the DJPR Privacy Unit by emailing privacy@ecodev.vic.gov.au.

The DJPR privacy policy can be obtained from our website at www.djpr.vic.gov.au/privacy.

11 Discretionary nature of the Program

Notwithstanding anything to the contrary in these Guidelines, the department reserves the right to do any of the following at any time for any reason with or without notice (not an exhaustive list):

- cancel the Program
- withdraw, amend or replace these Guidelines and any application terms
- request further information from an Applicant in relation to their application
- suspend or cease the assessment of any application.

The department may, in its discretion, make any decision it deems fit with respect to any application and is not required to adhere to any of the processes or procedures specified in these Guidelines.

11.1 GST

Grant amounts are indicated as GST exclusive, however if you are registered for GST, your invoice to DJPR should include GST.

12 Conflict of Interest

A conflict of interest occurs when someone has competing professional or personal interests or duties.

Applicants must advise the department of any real, potential, or perceived conflict of interest relating to a project for which it has applied for funding.

To the extent that a Victorian Government staff member has a real, potential, or perceived conflict of interest will be dealt with as set out in the Code of Conduct for Victorian Public Service Employees (Section 61) of the *Public Administration Act 2004 (Vic)* and any other relevant policies applying from time to time.

13 Use of Third-Party Grant Writers

If a third-party grant writer is used:

- Applicants are reminded that they are responsible for ensuring all information in the application is accurate and correct
- any generic responses to questions in the application may detract from success in the application assessment stage
- the department reserves the right to seek proof of any data or information provided in the application
- no part of any approved grant amount can be applied to the costs of a third-party grant writer
- a declaration letter acknowledging that Applicants have reviewed and accept the content of the application submitted must be attached to the application.

14 Further Resources

Further information regarding this program can be found here: https://business.vic.gov.au/grants-and-programs

If you have any questions during the application period, please contact ammc@ecodev.vic.gov.au or call the Business Victoria hotline on 13 22 15.

Appendix A: Glossary

Term	Definition
AMMC	Australian Medtech Manufacturing Centre established by the Victorian Government as part of its 2020/21 budget[1].
CIMIT	Consortia for Improving Medicine through Innovation and Technology, Boston, USA[2]
Complex medical equipment	The sub-set of Therapeutic Goods Administration (TGA) classified medical devices that are physically large and/or involving multiple functions and components. These are most likely Class IIa or IIb medical devices under

	TGA classifications and include items used in surgery or ICU including ventilators, dialysis units, life support monitors.
Diagnostic(s)	The sub-set of TGA classified medical devices involved in diagnosis or a health state of wellbeing or disease. Diagnostics are based on objective measurement of a biological characteristic (or biomarker) by a sensor or biochemical reaction and provision of a readout to inform diagnosis.
GAITS	Guidance and Impact Tracking System developed by CIMIT for the purpose of assisting medtech developers to plan and track product development.
IVD	In Vitro Diagnostic, a type of diagnostic test and sub-set of medical devices as outlined by the classification of testing systems by the TGA.
Manufacturer	Manufacturer means a company or business that is in advanced stages of product development (prototyping and beyond) or one that already has a product either in clinical trials or in the market
Medical device(s)	Any device intended to be used for medical purposes by section 41BD of the *Therapeutic Goods Act 1989* Including AiMDs (Active Implantable Medical Devices). Products in these device classes require more complex ISO 9001/13485 manufacturing and development processes, identified by the Victorian Government as an area of potential competitive advantage.
Medtech Supply chain	The collection of companies and organisations that provide necessary inputs or components that enable medtech products and services. Supply chain components range from low cost/high volume products like screws and chemicals for plastics production through to high cost/low volume technology platforms or testing equipment.
Medtech Value chain	The collection of capabilities that support development of a product or service, beginning within a clinical problem, leading to ideation, and stretching through proof of concept, development, testing and productisation phases to market supply.
PPP	Private Public Partnership, such as between the public healthcare system and a commercial medtech company
Scale up	Scale up means the process of converting a laboratory-developed or Research and Development method or procedure into a method, procedure, or protocol useful for manufacturing a commercial product, considering variables such as, but not limited to, efficiency, yield, cost, safety, reproducibility, and stability. Scale up includes (a) installation, evaluation, and validation of the necessary equipment, (b) establishment, evaluation, validation, and finalization of the necessary process controls, (c) demonstration of the ability to produce a batch size of the proposed commercial production batch for the Product, and (d) demonstration of compliance with all other applicable laws, regulations and good manufacturing practices
Technology Readiness Levels 3+	Critical Function, i.e., Proof of Concept Established. Applied research continues and early-stage development begins. Includes studies and initial laboratory measurements to validate analytical predictions of separate

	elements of the technology. Examples include research on materials, components, or processes that are not yet integrated. At **Technology Readiness Level** (TRL) 3 experimental work is intended to verify that the concept works as expected. Components of the technology are validated, but there is no strong attempt to integrate the components into a complete system. Modeling and simulation may be used to complement physical experiments. When active research and design begin, a technology is elevated to TRL 3. Generally, both analytical and laboratory studies are required at this level to see if a technology is viable and ready to proceed further through the development process. Often during TRL 3, a proof-of-concept model is constructed. Once the proof-of-concept technology is ready, the technology advances to TRL 4.
Validation and Verification	The United States' Food and Drug Administration (FDA) defines verification as "confirmation by examination and provision of objective evidence that specified requirements have been fulfilled." In other words, verification tests whether design outputs match design inputs. Used to ensure the medical device design is on track per the requirements, verification typically includes tests, inspections and analysis on the various layers and sub-systems of the product. Validation is the testing process that proves the device works as intended for the consumer. Defined by the FDA as the process of "establishing by objective evidence that device specifications conform with user needs and intended use(s)," validation testing can be done through usability studies, pre-clinical studies, or clinical trials. Unlike verification that tests the device at the sub-system level, validation tests the device itself or, more specifically, the user's interaction with the device. Verification can be in development, scale-up, or production. This is often an internal process. Validation is intended to ensure a product, service, or system results in a product, service, or system that meets the operational needs of the user. This is explained in FDA's Design Control Guidance for Medical Device Manufacturers guidance document available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-control-guidance-medical-device-manufacturers