Department of Jobs, Tourism, Science and Innovation

Local Capability Fund Guidelines 2023 - National and International Standards Compliance — Health and Medical Life Sciences Round

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Local Capability Fund

Program Objective

The Local Capability Fund (LCF) is a funding program under the Industry Facilitation Scheme (The Scheme). The Scheme is an approved guideline under section 10 of the *Industry and Technology Development Act 1998*.

The objective of the LCF is to provide small and medium-sized enterprises (SMEs) with funding support to enhance their capacity, capability and competitiveness to supply major projects and markets in Australia and overseas.

The Department of Jobs, Tourism, Science and Innovation is aiming to support the <u>Health and Medical Life Sciences Industry Strategy</u> by running a round of the LCF that focuses on companies that align with the objectives of the Strategy.

Objectives of this Round

The specific objective of the National and International Standards Compliance – Health and Medical Life Sciences Round is to assist Western Australian SMEs with the costs of engaging external expertise to carry out the implementation and third party certification of the following national and international standards:

- ISO 9001 Quality management standards to help work more efficiently and reduce product failures (in the context of health and medical life sciences related activities);
- ISO 13485:2016 Medical devices Quality management systems requirements for regulatory purposes

Note: Any certifications funded under this funding program must be implemented in Western Australia.

Key Dates

The National and International Standards Compliance Round will close at 5pm AWST 8 March 2023.

Round Opens	9am (AWST) on 23 January 2023
Round Closes	5pm (AWST) on 8 March 2023
Assessment and notification of outcomes to applicants	Within 14 weeks of application submission
Execution of Financial Assistance Agreement	Within 30 days of notification of outcome
Completion of activities and claim for payment submitted	No later than 3pm (AWST) on 30 June 2024

Level of funding

The level of funding support available under this round of the LCF is 75% of eligible costs (excluding GST) up to a maximum of \$20,000 per successful applicant. For example, to be eligible for the full \$20,000 you would need to have minimum eligible costs of \$26,667 (excluding GST).

Who can apply?

To be eligible for funding applicants must:

- Be a company that operates in the Health and Medical Life Sciences sector, or is in partnership with a company in this field for the purpose of this accreditation.
- Be registered for GST (or provide an explanation why your business isn't registered);
- Have an Australian Business Number (ABN);
- Be a company or trustee incorporated in Australia;
- Be a for-profit organisation or business (i.e. not-forprofits and charities are ineligible);
- Have been operating for at least three years at the time of submitting an application for funding;
- Have its principal place of business (operating facility) in Western Australia and continue to be based in Western Australia for at least the next 12 months following application submission date; and
- Employ less than 200 people.

Previous recipients of funding through the Industry Facilitation and Support Program (IFSP) or the LCF are eligible to apply, subject to:

- The business having complied with the requirements of the Financial Assistance Agreements entered into for the prior funding - including all reporting requirements; and
- The business having received no more than \$300,000 in grant funding under the LCF program and its predecessor (the IFSP) in the last five years, including

this application. Any funding received as part of the \$10 million COVID-19 LCF Rounds run in 2020/21 does not go towards this limit.

Eligible activities

Assistance under this round will be provided for the costs of engaging external expertise/consultants for the purpose of implementation and certification.

Implementation – This includes the following activities:

- Assessment of current systems and practices
- Reviewing existing procedures
- Conducting gap analysis
- Development of manuals, procedures and related documentation
- Staff training relating to the implementation and ongoing maintenance of the related management system

Certification – This includes, but is not limited to, the following activities:

- o Registration and certification fee
- Audit fees for initial certification (expended within the financial year)
- o Travel, accommodation and meals for certification auditor

Note: A condition of this grant funding is that a copy of the certification certificate (or equivalent – to be discussed and agreed to by JTSI) is provided to the Department of Jobs, Tourism, Science and Innovation (JTSI) as evidence of completion prior to any grant funding being paid out.

Ineligible activities

- Surveillance audits.
- Costs associated with the ongoing maintenance of the accreditation.
- Works carried out by consultants without the appropriate expertise or qualifications to deliver the service.
- Works carried out by third parties that are perceived by JTSI not to be at arm's length from the business.
- In-house costs including wages and salaries of staff directly working on the implementation and ongoing maintenance.
- In-kind contributions are not considered as part of the business commitment to activity costs.
- Retrospective activities. (The activity, or expenditure on the activity, must not be undertaken prior to submitting this application.)
- o Activities which are not implemented in Western Australia.

How do I apply?

Eligible applicants must submit their application online via the SmartyGrants portal. A preview of the application form detailing the information required is available through the portal.

Lcf.smartygrants.com.au

Before applying, you must read and understand these guidelines and the Financial Assistance Agreement found on the portal.

Applicants may contact the Life Sciences Team should they require additional assistance or clarification regarding their application.

lifesciences@jtsi.wa.gov.au

How will my application be assessed?

LCF applications will be evaluated after the round has closed.

Applications will be assessed by an independent Evaluation Panel.

The Evaluation Panel comprises officers from within JTSI as well as external expertise, as required.

Applications are assessed against their eligibility as well as the round objectives, and are then scored against the following evaluation criteria:

- o Relevance and Need
- Level of Impact
- o Capability, Capacity and Financial Viability
- Value for money

To mitigate risk, a Risk of Failure report is obtained through Illion (formerly Dun & Bradstreet) for recommended applicants. A High Risk of Failure on the report will be taken into consideration when determining successful applications. The final decision on applications where a High Risk of Failure report is returned will be at JTSI's discretion.

Illion is an independent, third party used to carry out due diligence and is not associated with, or part of, JTSI. Further information on Illion can be found on their website.

Applicants will be notified of the outcome of their application via the email address provided in the application form.

Financial Assistance Agreement

Approval of funding is subject to the applicant entering into a Financial Assistance Agreement (FAA) with JTSI.

Applicants must read the FAA template prior to submitting an application. This template includes the non-negotiable terms and conditions that successful applicants will be required to agree to when entering into an FAA with JTSI in order to receive funding.

When must the project be completed by?

All activities must be completed, and claims for payment submitted to JTSI by 3pm (AWST) on 30 June 2024. Claims for payment are to be made online through the SmartyGrants portal.

Payment of grant

The LCF is a re-imbursement scheme and therefore successful applicants will need to pay for the activity prior to making a claim for the approved grant funding. The grant will be paid as a lump sum reimbursement on completion of all agreed activities. Progress instalments will not be considered except in exceptional circumstances.

The grant payment will be made on submission of a Tax Invoice to JTSI for the GST exclusive value of the grant and must be

accompanied by copies of suppliers' invoices and receipts as proof that the activity has been paid for in line with the application and FAA.

Claims for payment, and submission of the above documents, are to be made online via the SmartyGrants portal.

JTSI must receive the claim for reimbursement by 3pm (AWST) on 30 June 2024. If a claim for payment is not received by this date the grant approval will lapse and the funding agreement terminated.

Note: A copy of the certification certificate must be provided to JTSI as evidence of completion before the grant funding is paid out.

Tax Information

JTSI is registered for GST and has been issued with Australian Business Number (ABN) 90 199 516 864.

Grants paid under the LCF are not regarded as payment for a supply to JTSI. Therefore, JTSI will not increase the grant to include GST, nor will it reimburse a grant recipient for GST paid to a third party.

Grants are assessable income for taxation purposes. We recommend you seek independent professional advice on your taxation obligations or seek assistance from the <u>Australian Taxation Office</u>. JTSI does not provide taxation advice.

How many times can I apply?

Only one application per round per financial year is allowed for each applicant. Unsuccessful applicants may not reapply in the same financial year for the same round.

This is also subject to the applicant having received no more than \$300,000 through this grant program in the last five years, including this application. Any funding received as part of the \$10 million COVID-19 LCF Rounds run in 2020/21 does not go towards this limit.

Reporting requirements

Approval of funding is subject to the applicant entering into an FAA with JTSI.

The FAA requires the applicant to provide a report at six months and 12 months after the end of the financial year that the grant is awarded. These reports are to be submitted through the SmartyGrants portal.

The FAA also stipulates that at any time within **two years** of receiving payment, JTSI may contact the applicant for verbal updates on business performance generally.

Amendments to guidelines

JTSI reserves the right to amend these guidelines and related documentation through the course of the round, if required.

Contact

If you have any questions regarding this assistance program, the application form or your business' eligibility for funding please contact:

lifesciences@jtsi.wa.gov.au

Guidance for completing your application

The application form is broken into a number of different sections. The following will guide you through each section to ensure that you are providing the required information in your application.

Overview of applicant's business operations

What is the major industry sector in which the business operates?

Please select the industry sector from the drop down menu that best reflects the sector in which the business operates. These are based on the Australian and New Zealand Standard Industrial Classification (ANZSIC) which is a standard classification developed by the Australian Bureau of Statistics for use in Australia and New Zealand for the analysis of industry statistics. If the business operates in multiple sectors, select the industry for which the business generates the highest value of turnover.

What are the business's core business and products/services?

Provide an explanation of the business's core business and products.

E.g. Is the business a direct supplier to the sector? If there are major projects within a sector/market that the business has supplied to, provide details of the project and what work the business did.

Evaluation criteria

Relevance / Need

What are the barriers and issues currently faced by the business?

How will the implementation of the proposed standard/management system help you or your partner's health and medical life science product development to grow?

Things you may wish to consider in addressing this criterion are the improvements to your business's operations and the obstacles that the business will be able to resolve. This may include meeting pre-qualification requirements, increasing technical capability, improving internal processes, and staff upskilling and training.

Level of impact

You should endeavour to answer all questions in this section in two parts. First, what the expected outcome is — this should be a number if possible, for example five new contracts. Second, provide an explanation of how that outcome would occur from the activity you are seeking funding for.

Quantify and qualify

Assessors of your application will be looking to see that your answer is quantified (there is a number), that it is achievable by undertaking the funded activity (your explanation of how the outcome will occur), and that it is realistic for the business.

Please note the assessors of your application will take into consideration the annual turnover figures of the business that you provide to measure whether the expected outcomes for contracts, employees and estimated income are a realistic projection.

There may be some aspects of the section where you do not expect that there will be outcomes from the funded activity. This is okay, not all businesses would have outcomes in all categories necessarily, and not all funded activities may lead to some of the outcomes listed. However, you should try to answer as many of the categories as you can and if you answer 'N/A' to all of them then this will result in a low score for this section.

The categories outlined are what you will be required to report against at six months and 12 months if your application is successful.

Capability, Capacity and Financial Viability

Describe the business's commitment, capacity and capability in terms of personnel to implement and maintain the ongoing certification of the standard/management system.

Where possible, you should aim to answer the three parts of this question: commitment; capacity; and capability.

How is the business committed to carrying out this activity? Is this something that is being driven from the top of the business? Is the activity part of any planning the business is undertaking?

Even though the business may be using external consultants or suppliers to deliver the activity, this will still require some amount of the staff's time and/or a financial commitment from the business, does the business have this capacity?

Don't forget that the Local Capability Fund provides full payment on completion of the activity not before, so the business needs the financial capacity to carry out the activity before it is provided with the funding.

Does the business and its staff have the capability to carry out the activity, particularly when it comes to the maintenance of the ongoing certification? Will the staff require training to support the implementation and maintenance of the standard? If they will require training has the business factored this into plans?

The above may guide you in answering this question. Good applications give assessors an idea of where the certification fits into the business's goals and whether the business has ability to not only carry out the activity but also to benefit from it.

Value for money

It is critical that you a) seek competitive quotes for the activity the business is seeking funding for, and b) provide copies of those alternative quotes with your application. It is expected that the business will get at least two quotes for each activity.

The importance of alternative quotes and research

If you do not provide alternative quotes, you must provide an explanation as to why you have not sought/provided them. There will be some situations where it is simply not possible/feasible to get alternative quotes, such as when there is only one supplier of a particular product or service. This is acceptable but you need to explain this so that assessors can understand why there are no alternative quotes.

Assessors will be considering whether the activity you are seeking funding for represents value for money for the government (and for the business) and without alternative quotes it is very difficult for them to properly consider this.

Provide a good explanation of why you have chosen the particular consultant/supplier. Does it represent better value for money (remember that 'value for money' does not always mean cheapest)? Will the service be delivered faster than the alternatives (and so you will be able to see the benefits of the activity sooner)?

Financial viability and risk

If you answer yes to any of the questions in the application form, you must provide an explanation of what occurred, the current position and what outcomes occurred (if any). The evaluation panel considers whether providing funding would present a risk, and so it is advised that you provide an explanation that is detailed enough (without being too long) to

demonstrate that while senior officers of the business may have had business ventures that haven't worked out in the past that the current business is sustainable.

Up to date financials

When providing a copy of the latest financial statements, you must provide a copy of both the balance sheet and the profit and loss statement for the last financial year (if you are applying in 2022/23, you must provide financial statements for the 2021/22 financial year). The financial statements must cover the entirety of the financial year they are for (i.e. do not provide financial statements that only cover part of a financial year). If the financial statements do not show figures for previous years then please provide copies of the previous year's financial statements as well.

If the latest financial statements have not yet been audited, then please provide an unaudited copy with an explanation of when these will be expected to be audited.

If there are significant drops in the detail you provide, please provide an explanation regarding these. Any significant drops may suggest that there is some financial risk involved in providing funding to your business, so a good explanation of why these drops occurred will help to assure assessors that your business is financially viable and sustainable.

Tips

- 1) Always double check your application. It is worth getting someone else to read over it, if possible, before you submit it to ensure it makes sense.
- 2) Remember that assessors may not be experts in your field. Overly technical answers may be difficult for assessors to understand which could lead to lower scores. When writing your application it is useful to write it in a way that anyone could understand, not just those who work in your industry. A good way of doing this is to imagine you are promoting your business via your website or social media where the public will need to understand the core activities of your organisation.
- 3) Give yourself enough time before the closing date to be able to source quotes and relevant documents. Applications without quotes or relevant documents will be scored lower and these documents can often take a bit of time to get hold of, with quotes sometimes taking a number of weeks. If you start an application a day before the closing date and don't have the necessary documents ready to go then you might run out of time to get them.
- 4) Good applications provide sufficient detail but are also concise. You need to be able to provide the important details required for the application in a succinct way. Again, it is worth double checking your application and getting someone else to look over it to make sure that it is detailed, but to the point.
- 5) Assessors are only able to make a recommendation based on the information you provide in your application. If there is something important that will help your application stand out then do not forget to include it.
- 6) Always read the eligibility criteria and the eligible activities carefully to ensure you are eligible to apply, and that the activities you are seeking funding for are eligible. A good application takes time to write, so if you

are ineligible you don't want to spend time on an application that will be rejected straight away. If you have queries about whether you are eligible (or an activity is eligible), feel free to contact the Life Sciences team.