MedTech Accelerator - Rapid Regulatory Support Fund

2 Oct 2024

This is the application form to apply to the MedTech Accelerator - Rapid Regulatory Support Fund run by CPI on behalf of the Office for Life Sciences. The application form is to apply for financial aid with accessing regulatory affairs support.

* Required

* This form will record your name, please fill your name.

Disclaimer

1. The personal information in this form will be used for the administration of the funding programme and used as per CPI's privacy policy which can be found at https://www.uk-cpi.com/legal/privacy-policy.
   Do you agree to this?

   ◯ Yes

   ◯ No (ineligible to apply)

2. The funding in this competition is governed by these terms and conditions (https://www.uk-cpi.com/rapid-regulatory-support/terms-and-conditions). Please can you review and confirm that you are willing to proceed on this basis should you be successful in your application?

- ◯ Yes
- ◯ No (ineligible to apply)

Company and applicant information

These questions will not be scored and will be used only to identify you and the company you are applying on behalf of. Please complete the questions in one sitting, as it is not possible to save your answers during the process. It will be possible to save a copy of your answers after submission.

3. Company name *

4. Your name (person filling in the application) *

5. Your job title (person filling in the application) *

6. Your email address (person filling in the application) *

7. Your phone number (person filling in the application) *

8. Company registration number *

9. What is your company's VAT registration number? *

Please enter "Not registered" if you have not registered for VAT

10. Registered address - First line *

11. Registered address - Second line

12. Registered address - Town/City

13. Registered address - County *

14. Registered address - Postcode *

15. Registered address - Country *

- ◯ England
- ◯ Northern Ireland
- ◯ Scotland
- ◯ Wales

16. Website *

If applicable, if you do not have a website, then please link to your social media or Company's House URL.

17. Name, job title and contact details of **main point of contact** for this application at your company if this is not the person filling in the application. *

    Please put NA below if the person filling in the application is happy to be the contact person

18. Name, job title and contact details of main point of **contact for finance** at your company if this is not the person filling in the application. *

    Please be aware, if your application is successful, as part of our fraud prevention protocols we will contact this person to confirm bank details before making a payment to you

Qualification questions

These questions will not be scored however they will be used to understand if you meet the qualifying criteria for the project. You must answer 'yes' to all of the below questions to meet the qualifying criteria.

19. Is your company an SME?

To be a small or medium-sized company, you must meet at least 2 of the following conditions:

- the annual turnover must be no more than £36 million
- the balance sheet total must be no more than £18 million
- the average number of employees must be no more than 250

from Government definition for accounting purposes: https://www.gov.uk/government/publications/life-of-a-company-annual-requirements/life-of-a-company-part-1-accounts#medium-sized-company-accounts *

- ◯ Yes
- ◯ No (ineligible to apply)

20. Are greater than 30% of your company's activities based in the UK? *

- ◯ Yes
- ◯ No (ineligible to apply)

21. Is your company currently developing, producing and/or selling medical technology or an in-vitro diagnostic?

    This is as defined in the Medicines & Medical Devices Act 2021 (https://www.legislation.gov.uk/ukpga/2021/3/enacted) or EU CE Mark requirements set out in Regulation (EU) 2017/745 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745) or Regulation (EU) 2017/746 (https://eur-lex.europa.eu/eli/reg/2017/746/oj).

    If you have multiple devices/products that will benefit from this funding, please answer the below questions regarding the devices/products that will receive the most benefit from the funding programme. If you would normally answer yes to the answers *

    - ◯ Yes - Medical technology
    - ◯ Yes - In-Vitro Diagnostic (IVD)
    - ◯ Both Medical technology and IVD
    - ◯ No (ineligible to apply)

22. Does your company have the capacity to receive up to £30,000 of support under Minimal Amounts of Financial Assistance (MFA) provision of the Subsidy Control Act 2022?

    You must have had less than £315,000 funding over the last three fiscal years (current fiscal year and previous two) this includes any funding received as MFA, De Minimis aid or Small Amounts of Financial Assistance under the TCA, as well as the funding you're applying for in this programme.

    More information on MFA can be found here: https://www.gov.uk/government/publications/subsidy-control-a-guide-for-beneficiaries/subsidy-control-a-guide-for-beneficiaries#minimal-financial-assistance-subsidies *

    - ◯ Yes
    - ◯ No (ineligible to apply)

23. Do you agree that you will use this funding only for regulatory advice, support or remedial actions in order to develop or sell MedTech products or services?

    This funding can't be used within your company. It can only be used to pay an independent, third party, regulatory affairs consultant. There is no support available for your company's labour and other associated costs. If you are unsure about whether your project is in scope, please contact the Project Support Team (medtech.accelerator@uk-cpi.com) *

    ◯ Yes

    ◯ No (ineligible to apply)

24. Do you understand this funding will be paid on a reimbursement basis; funding will be transferred to you when a valid invoice for work is submitted prior to the claim deadline, and the funds must then be used by you to pay the regulatory support provider? *

    ◯ Yes

    ◯ No (ineligible to apply)

25. Do you agree to be contacted by the project team during and after the project (up to 24 months after) for discussions on how the project has impacted you and your customers and the issues you and your industry faces? *

    ◯ Yes

    ◯ No (ineligible to apply)

Project details - part 1

Note, these questions are not scored but must be completed

26. At what stage is your company's product or service? *

- ◯ On the market
- ◯ At an advanced development stage / ready to launch
- ◯ Prototyping stage
- ◯ Concept / feasibility stage

27. Is your company's product or service any of the following? *

If your product or service is across multiple areas, please select the one most relevant.

- ◯ Anaesthetic and respiratory technology
- ◯ Assistive Technology
- ◯ Cardiovascular and vascular devices
- ◯ Dental and maxillofacial technology
- ◯ Digital health
- ◯ Drug Delivery
- ◯ Hospital hardware including ambulatory
- ◯ Implantable devices n.e.c.
- ◯ In vitro diagnostic technology
- ◯ Infection Control
- ◯ Medical Imaging/Ultrasound Equipment and Materials
- ◯ Mobility Access
- ◯ Neurology
- ◯ Ophthalmic Devices/Equipment
- ◯ Orthopaedic Devices
- ◯ Radiotherapy equipment
- ◯ Re-usable diagnostic or analytic equipment n.e.c.
- ◯ Single use technology n.e.c.
- ◯ Surgical Instruments (reusable) n.e.c.
- ◯ Wound Care and Management
- ◯ Other

Details of your product and need for support - Scored

Note that these questions are **scored** and the highest scoring applications will receive funding. We reserve the right to follow a portfolio approach for our distribution of funds.

In your answers, please focus on only the product or products that you are requesting support for from this programme.

It may be worth writing your answers outside of this survey and copy and pasting into this when you are ready, in case the page times out and you have to start again.

28. What is the function of, and the societal need for, your company's MedTech **product/service?** (400 word limit) *

    Guidance: Please detail the unmet need (clinical or otherwise) for your product(s) or service(s) and its function (or intended use) i.e., how it meets that need. Please outline how you know there is an unmet need and identify where the product/service will be primarily deployed/used. Give enough information so the reviewers can understand what your innovation, product or service does or what it is intending to do, and what benefits it will provide to patients.
    Note, if the product/service is already on the market then please articulate the need or unmet need it has been filling.

29. What is your company's **business case** for the product(s) described in the previous question? (400 word limit) *

    Guidance: Please give an outline of your commercial plans including revenue. For example, you could outline how your product is currently performing on the market or is forecast to generate revenue, your value proposition, routes to market, market share and your growth plans. Are you or do you expect to be selling/exporting your product(s)/service(s) outside of the UK?

30. What does your company **need this funding** for? Why do you need funding support? (600 word limit) *

    Guidance: Please provide a breakdown of the estimated costs you are requesting and what regulatory support you intend to procure with the funding. Why do you need this funding support and what will be the impact on your business? Please highlight if you anticipate achieving any regulatory milestones such as device classification, establishing a QMS or achieving market certification. How would you ensure good value for money for this funding competition? What will be the impact on your business if you did not secure this funding? Why can you not secure this funding from elsewhere? How will you access regulatory advice if your application is rejected?

Funding and support request

This section is not scored but funding requests must be under £30,000 and if a non-UK consultant/supplier is requested, it must be well justified.

31. What is the level of funding you are requesting? *

    The maximum funding amount per company is £30,000.

32. What or who is the regulatory service provider you are planning on engaging with? *

33. If the regulatory service provider is not based in the UK, please provide a justification as to why you are not using a UK based consultant.

34. Please provide contact details for this regulatory service provider *

    Please include:
    Name,
    Email address,
    Contact phone number

35. Has your company had regulatory funding from CPI before through the Health Technology Regulation and Innovation Programme (HealthTRIP) *

    - ◯ Yes
    - ◯ No

36. Please explain how this is different from the work you've previously had funding for *

We will not fund the same work twice.