



Direct Procurement of digital tool for regulatory navigation support

Reference number: ISAB_2020_19

1. Invitation

Innovation Skåne AB in project HealthTech Nordic invites you to a Direct Procurement concerning a digital tool / service for regulatory navigation that can be offered to our start-up members.

The aim is to keep up with the new and changed medical device regulations within EU¹ and HealthTech Nordic predicts that there will be a need for this type of tools throughout the project period.

Please also see ¹ https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

For information about Innovation Skåne AB and HealthTech Nordic, please visit:

<https://www.innovationskane.com/sv/>

<http://healthtechnordic.com/>

2. Requirement of the service and content

Innovation Skåne is looking for a digital tool that can be offered to our start-ups and help them navigate in the regulatory field.

The digital tool must be able to:

- Help navigate and show whether a Product or Software are subject to any of the following regulations:
 - [Regulation \(EU\) 2017/745](#)
 - [Regulation \(EU\) 2017/746](#)
 - Or none of the above
 - Guide and classify the Product or Software
 - Document the content and result of the assessment from the tool (PDF or similar)
 - Show relevant cross references to applicable standards and laws and make them available
 - Identify Notified Bodies
 - Offer unique passwords for each user
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2.1 Deliverance and timeline

The digital tool shall:

- be available as soon as possible, but not later than October 15th 2020
- be used until September 30th 2022

3. The tender shall include the following:

1. Contact details (company information such as name of contact person, e-mail, postal address, phone/mobile) and a brief description of the tenderer (Max 1 A4 page with 12 points text)
2. One (1) reference assignment that is relevant to this Direct Procurement shall be included and presented. The presentation (Max 1 A4 page with 12 points text) shall include:
 - Name of Reference (client/customer)
 - Contact information to Reference (name, mobile, e-mail)
 - Description of the scope and delivery of the assignment

Innovation Skåne reserves the right to assess if the reference assignment is relevant and verifies the tenderers capability and experience or not.

3. Description of the tenderer's availability, support, and service organisation (Max 2 A4 page with 12 points text).

The description shall include:

1. The availability of the tool / service on a monthly or year basis
2. A description of the support chain and response times for example if the tool / service is not available and you cannot log on, problems with views cannot save documentation etc.

4. Describe your price model per number of users **or** fill in the proposed suggested model below. The tool / service shall be free to use for Partner organisations in the project HealthTech Nordic (maximum 16 extra users on top of the user model described below).

Suggested price model:

- 1-20 users, (maximum 2 000 euro/year for all users)
- 21-30 users, (***please put your additional cost per year, if any***)
- 31-40 users, (***please put your additional cost per year, if any***)
- 41-50 users, (***please put your additional cost per year, if any***)

5. Price for education (online) and a short description (Max 1 A4 page 12 points text) of the content and scope of the education.

4. Leave tender and evaluation

The tender shall be e-mailed to us no later than **1st October** and must be valid for at least two (2) weeks after received.

The tender including appendices shall be sent by email to:

susanne.hertzberg@innovationskane.com

The information about which Supplier that has been chosen will sent by email. Innovation Skåne will accept the tender that best strikes the balance between quality and price.

5. Contact person:

For questions regarding the tender process or the content please contact Markus Mårtensson, Innovation Manager, Innovation Skåne, via email markus.martensson@innovationskane.com

Lund, September 17 2020

Welcome to send your tender!

Best Regards

Markus Mårtensson
Innovation Manager
Innovation Skåne AB