OFFER INQUIRY

Purchaser	BRASTER S.A. Cichy Ogród 7, Szeligi 05-850 Ożarów Mazowiecki POLAND
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Project name	CE & FDA certification support
Brief description of the project	Lead BRASTER S.A to the CE and later FDA registration for the Braster Tester with Mobile Application and Telemedical system
Source of project	related to the program INNOMED, task 5

The aim of the project is CE and later FDA registration delivery of BRASTER in BRASTER Tester with Mobile Application and Telemedical System.

Our goal is that we are leaded by YOUR COMPANY to CE certification and later on also to FDA. The assumption should be that we BRASTER do as much as we can ourselves with all the direction, templates examples, checks, correction and if requested support in preparation or execution from the leading side. That's why we need an offer that answers it well. The phases scope should be well described in the scope so that we could have the target cost. It is assumed we could have more precise scope split between BRASTER and YOUR COMPANY. We could think of starting from the phase 1 and may be 2 at first taking into consideration potential of further co-operation. Phase 1 is assumed to be not only Risk Management but all kind of support in proper definition of the steps that have to be taken, leading BRASTER in it, supplying with all the needed information, templates and documents examples, calls, Q&As etc.

The project delivery is described in the below attached phases (the program is just example and might miss or mislead a bit – you are expected to review it and propose corrections):

Phase	Description	By
1	**60601 3.1 edition preparation** Practical Workshop with YOUR COMPANY Engineer resulting with: • Preparation of RM Process acc. ISO14971 and implementation it within Braster • Creation of RM Plan for Braster Tester; Creation of complete RMF for Braster Tester • Safety consultancy regarding hardware and software • leading to 60601-1 compliant construction of Braster Tester ready for EU+US+CAN certification	Q1 2016
2	**Usability documentary and testing support**	Q1 2016
3	**Early Engagement "60601-1, 3.1 Edition" Services:** Anticipates Site or YOUR COMPANY Office Visit to Support the Following (1 Day Review): • Provide General Construction Comments Based On This Review • Support Questions Specific to Standards Specified • General Review of the Certification Process • Provide Meeting Notes As Appropriate Note - Meeting Notes will be "Handwritten" or electronic and serve as completion of this project and be consider our "Closing Letter". No certification will be provided as a result of this preliminary evaluation. Any findings during this preliminary investigation will be considered preliminary only.	Q2 2016
4	**Biocompatibility according to ISO 10993 under GLP**	Q2 2016
5	**Certification Testing and CE certification support**	Q2 2016
6	**ISO 13485 certification**	Aug 2016
7	**FDA registration**	1H 2017

Price breakdown

An offer and project proposition should include price breakdown as below:

Phase	Phase name	Step	YOUR COMPANY Scope	BRA scope	Start date	Finish date	Manxh cost [€]	YOUR COMPANY time [h]	YOUR COMPANY cost [€]
1	60601 3.1 edition preparation								-
2	Usability documentary and testing support								-
3	Early Engagement "60601-1, 3.1 Edition" Services:								-
4	Biocompatibility according to ISO 10993 under GLP								-
5	Certification Testing and CE certification support								-
6	ISO 13485 certification								-
7	FDA registration support								-

The cost breakdown template and example is attached in the excel file named "Project scope 20160130_PR.xls"