CECMED's Innovation Office Enquiry Form to innovative products and technologies

First Section. General Overview (About you)

1. **Company Name:**

2. **What type of organization are you?**
   - **_____Pharmaceutical Company**
   - **_____Biotechnology Company**
   - **_____Academic Institution**
   - **_____Hospital**
   - **_____Medical devices Company**
   - **_____Other (Specify below)***

   ***Other (please specify)**

3. **First Name and Surname of the applicant:**
4. **Address (please specify primary address if there is more than one):**
5. **City:**
6. **Country:**
7. **Phone Number:**
8. **E-mail address:**
9. **Postal Address:**
10. **Is your company is registered in Cuba? Yes_____ No_____**

Second Section. Project or Product details (About your product)

1. **Which product area(s) does your product relate to?**

   _____ Antibody

   _____Blood products

   _____ Allergy

   _____ Human Vaccines

   _____Human Medicines and/or drug combinations

   _____Advanced Therapy Medicinal Product

   _____Medical Device

   _____Other (Specify below)**

   ** **Synthetic Molecule/Nanomedicine/Novel formulation/Novel Manufacturing method, etc**

2. **Reasons for the advice request (Maximum 250-300 words)***

   ***Please clarify in the application if your product should be catalogued as First Priority Product.**

3. **Product Name and Active Substance:**

4. **Therapeutic Indication:**

5. **Scope of the Scientific assessment:**
   - **_____ Research Concept and Design (pre-advice)**
   - **_____Formulation**
   - **_____Pre-clinical**
   - **_____Clinical Studies**
   - **_____Manufacturing Process/ Product development**
   - **_____Regulatory Procedural Issues**
   - **_____ Post-approval monitoring**

6. **Short description of key manufacturing steps (Raw materials/laboratories/facilities/flowchart/quality/non-clinical aspects)****

7. **Short description of the mode of action respectively the effect of the medicinal product****

   ****An independent document containing all relevant information may be attached, and shall not exceed 15-20 pages. Briefing document must be submitted at least 3 weeks before the meeting.**

   ****If additional information, tables or summaries are submitted, they should be relevant to the consulting.**

   ** Specific questions can be submitted (please clarify your position and rationality to each question).**

   ****Open questions or that are outside the object of the consultancy, or that suggest a product pre-evaluation, are not be accepted.**

<u>Third Section. Formal aspects of your project or product</u>

1. **¿Do you have product license? _____Approved**

   _____Submitted

2. **Other licences or authorizations ___Yes ____No**
   ***Please specify which**

3. **Are your product in the market? ____Yes ____No**
   ***Please specify which country or countries?**

4. **Clinical Trials _____Submitted ____Completed ____Withdrawn**

   Phase_____ ID_____

   Country or Countries (please specify)_____

5. **Was your product or project subject to earlier Scientific Advice or international consultant?**
   _____Yes _____No Agency_____ Year_____

   ***Please enclose Scientific Advice Minutes, if available.**

<u>Fourth Section. Meeting Request</u>* _____Yes ____No _____# of dates*

_____# participants

***Preferred dates should not be placed in the same week**

***Face-to-face meeting(s) can be requested or cancelled by the Office of Innovation after the application form has been evaluated and reviewed**