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| |  |  |  | | --- | --- | --- | |  |  | **Veterinary Medicines Directorate**  Woodham Lane, New Haw  Addlestone, Surrey  KT15 3LS  United Kingdom  Tel: +44 (0)1932 336911  Fax: +44 (0)1932 336618  Search for VMD on GOV.UK |   **APPLICATION FOR A NEW EQUINE STEM CELL CENTRE AUTHORISATION (ESCCA)**  *This form should be used by applicants who wish to obtain an ESCCA that authorises premises in the UK used for the collection, processing, storage, and administration of equine stem cells for use as an autologous treatment for non-food producing horses.*  **An incomplete application form may delay the application process.**  **If submitting in hard-copy, please use block capitals.**    **Further guidance about this application type is available in Veterinary Medicines Guidance Note (VMGN) No. 15 entitled ‘Manufacturing Authorisations’.**  **SECTION 1 – ADMINISTRATIVE DETAILS** |  |

**1.** **Name and Address of Proposed Authorisation Holder:**

Company Name:

Address:

**2.** **Contact Details for this Application:**

Name:

Email Address:

**3.** **Invoice Details:** Email address of where the invoice should be sent to.

Email Address:

**4.** **e-Issuing Details:** Email address of where the authorisation documentation should be sent to (if different from 2 above).

Email Address:

**SECTION 2 – PROPOSED AUTHORISATION DETAILS**

3a. The name of the supervising veterinary surgeon(s)

AND/OR

3b. The name of the person who is suitably qualified to operate the centre

4. The address of the premises where the stem cells will be isolated and stored (If different to 1 above)

**SECTION 3 – MANUFACTURING DETAILS**

5. Describe the method of collection, isolation, harvest and storage process

6. Provide details of the facilities, resources and equipment

7. State the proposed shelf-life of the product

8. Provide details of the Quality Assurance/Quality Control Scheme:

9. State the name of the person responsible for manufacture and release of the product(s)

10. State the name of the person responsible for pharmacovigilance

11. Provide a summary of the action taken to assure animal welfare

12. Provide a summary of the action taken to minimise the risk of spreading disease during the collection, storage, manufacture and administration of the equine stem cells

13. Please confirm that draft labels have been supplied and are in accordance with the labelling requirements set out in the Regulations.

Yes  No

14. Please confirm if the site holds a valid GMP certificate. If so, please include a copy of the certificate as part of the application package.

Yes  No

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| **SECTION 4 – Declaration**  I apply for the application as described above. I confirm that the information given in support of this application is correct at the time of submission. | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
| **If any information provided in this application is later found to be false or incorrect, the Secretary of State may suspend or revoke the authorisation.** | | | | |