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|  **Application for new Manufacturer’s licence**  **Exempt Advanced Therapy medicinal products (MEAT)**  **(Human Use)**  |

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| --- |
| **Section 1 Company information** |
| *Registered Company Name:*       |
| *Address:* |
| *Company contact person :* |  |
| Telephone/Mobile: |       | E-mail: |       |
| Trading Style: |  |

|  |
| --- |
| **Communications and/or invoicing address (if different)** |
|       |
| **In case of person applying on behalf of the proposed registration holder** |
| *Name of the contact:*       |
| ***Contact details:*** |
| Telephone/Mobile: |       | E-mail: |       |

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| --- | --- | --- | --- |
| **Application Date** |  | **Purchase Order Number** |  |

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| --- |
| **Please indicate the type(s) of licence you wish to apply for:**  |

|  |  |
| --- | --- |
| **[ ]**  | **Manufacture and Assembly** |
| **[ ]**  | **Assembly Only** |

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| **Checklist** |
| [ ]  | Completed Application Form |
| [ ]  | Section 1 - need only be completed once per application. |
| [ ]  | Section 2 - one copy for each manufacturing/import site to be named.  |
| [ ]  | Section 3 - one copy for each person to be named on the site signed and dated. |
| [ ]  | Section 4 - one copy for each Contract Laboratory site to be named, countersigned by the Contract Laboratory representative. |
| [ ]  | Section 5 - one copy for each Storage and Handling Site to be named. |
| [ ]  | Section 6 - need only be completed once per application, signed and dated. |
| **Supporting Documentation** |
| [ ]  | Certificate of incorporation issued by Companies House (or similar). |
| [ ]  | Curriculum Vitae information either completed or provided for the nominated Quality Controller or Production Manager.  |
| [ ]  | Signed Technical Agreements (where applicable) are available. |

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|  **Application for new Manufacturer’s licence**  **Exempt Advanced Therapy medicinal products (MEAT)** **(Human Use)**  |

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| **Section 2 Site Information** |
| *Site Name:* |
| *Address:* |
|       |
| *DUNS Number:* | **-                   -** |

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| --- | --- |
|  | **Site Contact Person** |
| Name of the contact:       |
| Telephone/Mobile: |       | E-mail: |       |

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|  **Site Activities** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Are the products for administration to human beings? |  **Yes** |  **[ ]**  | **No** |  **[ ]**  |
|  |
| Animal Human Origin products are present at this site? |  **Yes** | [ ]  |  **No** |  [ ]  |

|  |
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| **Site Types** |

|  |  |
| --- | --- |
| Manufacture  | [ ]  |
| Assembly and Packaging | [ ]  |
| QC Testing  | [ ]  |
| Batch Certification | [ ]  |
| Biological | [ ]  |
| Storage and Handling (picking of goods) | [ ]  |
| Other **(Must be specified)** | [ ]  |
|       |

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| **Site Activities** |

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| **Manufacture of Sterile products Aseptically prepared** |
| **Aseptically prepared** **(Processing operations for the following dosage forms):** |
| Large volume liquids |  **[ ]**  |
| Semi-solids |  **[ ]**  |
| Small volume liquids |  **[ ]**  |
| Solids and implants |  **[ ]**  |
| Other aseptically prepared products: (Please specify) |  **[ ]**  |
|  |
| **Terminally sterilised** **(Processing operations for the following dosage forms):** |
| Large volume liquids |  **[ ]**  |
| Semi-solids |  **[ ]**  |
| Small volume liquids |  **[ ]**  |
| Other terminally sterilised prepared products:**(Must be Specified)** |  **[ ]**  |
|  |
| Batch certification of sterile products |  **[ ]**  |

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| **Advanced Therapy Medicinal Products** |
| Gene Therapy |  **[ ]**  |
| Somatic cell therapy |  **[ ]**  |
| Tissue engineered products |  **[ ]**  |
| Other **(Must be Specified)**e.g. used for combined ATMP products Art.2 of 1394/2007. |  **[ ]**  |
|  |

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| **Sterilisation of excipients and raw materials** |
| Filtration |  **[ ]**  |
| Dry Heat |  **[ ]**  |
| Moist heat |  **[ ]**  |
| Chemical |  **[ ]**  |
| Gamma Irradiation |  **[ ]**  |
| Electron beam |  **[ ]**  |
| Other sterilisation of excipients and raw materials **(Must be Specified)** |  **[ ]**  |
|  |

|  |
| --- |
| **Quality Control Testing - Manufacture** |
| Microbiological: sterility |  **[ ]**  |
| Microbiological: non-sterility |  **[ ]**  |
| Chemical/Physical |  **[ ]**  |
| Biological |  **[ ]**  |

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| **Letting and/or Accepting Contracts** |
| Applicant intends to be contract acceptor (i.e. carries out testing partially/wholly for others) |  **[ ]**  |
| Applicant intends to be contract acceptor (i.e. manufactures partially/wholly for others) |  **[ ]**  |
| Applicant intends to be contract giver (i.e. uses external manufacturers for some products) |  **[ ]**  |
| Applicant intends to be contract giver (i.e. uses external Test houses for some/all testing) |  **[ ]**  |

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| **Other Information** |
| Storage and Handling |  **[ ]**  |
| Distribution |  **[ ]**  |
| Is this site involved in microbiological testing of finished products and/or raw materials? |  **[ ]**  |
| If none of the above. **(Must be Specified)** |  **[ ]**  |
|       |
| Stability Testing |  **[ ]**  |
| Is this site involved in doing finished product testing? |  **[ ]**  |

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|  **Application for new Manufacturer’s licence**  **Exempt Advanced Therapy medicinal products (MEAT)** **(Human Use)**  |

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| **Section 3 Site Personnel** |

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| --- |
| **Summary of changes to personnel nominated to work at this site:** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name** | **MHRA** **Number\***  | **Add** | **Delete** | **QC** |  **PM** |  **SC** |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |
|  |  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |  **[ ]**  |

**\*If available**

|  |
| --- |
| **Nominated Person** |
| Name:       |
| Telephone/Mobile: |       | E-mail: |       |
| *Business Address:* |
|       |

|  |  |
| --- | --- |
| **Person number, if already named on a MHRA licence/authorisation**  |  |

|  |
| --- |
| **Person nominated to be named as:** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Production Manager** | **[ ]**  | **Quality Controller** | **[ ]**  | **Site Contact** | **[ ]**  |

|  |
| --- |
| **Quality Controller** |

|  |  |  |
| --- | --- | --- |
| **Documentation** | A copy of the nominee’s Curriculum Vitae is attached, or the relevant sections of this form have been completed. | **[ ]**  |

|  |
| --- |
| **Production Manager** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Manager of Production** | **[ ]**  |  **Supervisor of Production** | **[ ]**  |

|  |  |  |
| --- | --- | --- |
| **Documentation** | A copy of the nominee’s Curriculum Vitae is attached, or the relevant sections of this form have been completed. | **[ ]**  |

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| **Curriculum Vitae – Only required if a CV is not attached to the application** |

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| --- |
| **Qualifications (relevant to this licence)**  |
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| --- |
| **Experience (brief details of employment and responsibilities relevant to this** **licence).** |
|  |

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| --- |
| **PM and QC only - Name and function of the person(s) to whom he/she reports**  |
|  |

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| --- |
| **Area of responsibility**  |
|  |

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| --- |
| **Declaration by nominated person** |
| I confirm that the above particulars are accurate and true to the best of my knowledge and belief. I agree to be nominated as indicated. |
| **Signed** **(Nominated Person)** |  | **Date** |  |
| **Print Name** |  |
| **Signed (Applicant)** |  | **Date** |  |
| **Print Name** |  |

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| --- |
|  **Application for new Manufacturer’s licence**  **Exempt Advanced Therapy medicinal products (MEAT)** **(Human Use)**  |

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| --- |
| **Section 4 Contract laboratory Site Information** |
| *Site Name:* |
| *Address:* |
|       |
| *Company contact:* |  |
| Telephone/Mobile: |       | E-mail: |       |
| *DUNS Number:* | **-                   -** |

|  |  |
| --- | --- |
| The licence/authorisation holder has assessed the laboratory as fit for purpose.  |  [ ]  |

|  |
| --- |
| **Quality Control Testing carried out by the site.** |
| Microbiological: Sterility  |  [ ]  |
| Microbiological: Non-Sterility |  [ ]  |
| Chemical/Physical analysis of finished products |  [ ]  |
| Biological testing of finished products |  [ ]  |
| Stability Testing on finished marketed medicinal products |  [ ]  |
| Is the site involved in finished product testing? |  [ ]  |
| Is this site involved in microbiological testing of finished products or raw materials?  |  [ ]  |
| Other (Please specify) |  [ ]  |
|       |

|  |
| --- |
| **Letting and/or accepting contracts.** |
| Applicant intends to be a contract acceptor (i.e. carries out testing partially/wholly for others).  |  [ ]  |
| Applicant intends to be a contract giver (i.e. uses external test houses for some/all testing).  |  [ ]  |

|  |
| --- |
| **Section 8B: To be completed by the nominated Contract Laboratory** |
| I confirm there is a written contract/technical agreement in place.  |  [ ]  |

|  |
| --- |
| I hereby confirm the contract laboratory are aware they have been named and may be subject to inspection by the MHRA, a written contract/technical agreement is in place and the contract laboratory is in agreement and aware of what is expected of them.To the best of my knowledge and belief the particulars I have provided in are correct, truthful and complete.  |
| **Signed** |  | **Date** |       |

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| --- |
|  **Application for new Manufacturer’s licence**  **Exempt Advanced Therapy medicinal products (MEAT)** **(Human Use)**  |

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| --- |
| **Section 5 Storage and Handling site(s)** |

|  |
| --- |
| *Site Name:* |
| *Address:* |
|       |
| *Site contact person:* |  |
| Telephone/Mobile: |       | E-mail: |       |
| *DUNS Number:* | **-                   -** |

|  |  |
| --- | --- |
| This site is named on a current Wholesale Distribution Authorisation. |  **[ ]**  |

|  |  |
| --- | --- |
| Site Number |  |

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| **Section 6 Declaration** |

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| I/We apply for the grant of a Manufacturer’s Licence for Exempt Advanced Therapy medicinal products (MEAT) to the proposed holder named in this application form in respect of the activities to which the application refers. To the best of my knowledge and belief the particulars I have given in this form are correct, truthful and complete. The applicant undertakes to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the licence. |
| **Signed** |  | **Date** |       |
| **Print Name** |  | **Job Title** |       |

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| --- |
| **For advice or assistance please e-mail:** pcl@mhra.gov.uk |

Version 2.0 Updated 22/12/2021