Application for the Register for Exemption

Please refer to the HPRA ‘Guide to Registration of Processes Exempted under Article 61(5) of the Clinical Trial Regulation’ available on [www.hpra.ie](http://www.hpra.ie).

Registrant Details

|  |  |
| --- | --- |
| Name or corporate name of registrant |       |
| Permanent or legal address of site where the process(es) will occur  |       |
| Eircode |       |
| Type of site  | [ ]  Hospital[ ]  Health Centre [ ]  Clinic (includes retail pharmacy)  |
| Name of person submitting the application |       |
| Contact telephone number |       |
| Email address |       |

details of processes

1. **Re-packaging and re-labelling processes**

1.1 [ ]  Re-packaging

Please provide details of the proposed re-packaging activity:

1.2 [ ]  Re-labelling

Please provide details of the proposed re-labelling activity:

1.3 Person responsible for the process(es):

1.4 Qualification of the person responsible for the process(es):

1.5 Professional body registration number:

1. **Preparation of radiopharmaceuticals used as diagnostic IMPs**

2.1 [ ]  Preparation of a non-sterile radiopharmaceutical product

2.2 [ ]  Preparation of a sterile radiopharmaceutical product

2.3 Person responsible for the process(es):

2.4 Qualification of the person responsible for the process(es):

2.5 Professional body registration number:

**3 Preparation of investigational medicinal products in a pharmacy in accordance with a medical prescription or in accordance with pharmacopoeia**

3.1 *[ ]* Preparation of non-sterile investigational medicinal product

3.2 *[ ]* Preparation of a sterile investigational medicinal product

3.2.1 [ ]  Large volume liquid

3.2.2 [ ]  Small volume liquid

3.2.3 [ ]  Semi solid

3.2.4 [ ]  Solid

3.3 Person responsible for the process(es):

3.4 Qualification of the person responsible for the process(es):

3.5 Professional body registration number:

Declaration and signature

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| I hereby declare that, to the best of my knowledge and belief, all the particulars given in this application are correctly stated.

|  |  |
| --- | --- |
| Signature:       | Date:        |
|  |  |
| Print name:        | Title/position:        |

 *Notes:* Applications must bear the signature of the person who will be responsible for the processes. Where the application is on behalf of a limited company, the declaration must be signed by a director or the secretary and, in the case of a partnership, by a partner. |

Send to:

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