**Decentralised Manufacture Designation Application**

This form should be completed by the applicant and should **not be longer than 50 pages (including annexes but excluding references)**

Please complete this form and send it to [DM\_Manufacture@mhra.gov.uk](mailto:DM_Manufacture@mhra.gov.uk)

Application details:

|  |  |
| --- | --- |
| Applicant:  Name and address |  |
| Date of application: |  |
| Type of Decentralised Manufacture Designation Application: | |  |  | | --- | --- | |  | Point of Care Product or intermediate requires to be manufactured or administered in close proximity to the patient for reasons ofmethod of manufacture, shelf life, constituents or method or route of administration. | |  | Modular Product or intermediate is manufactured or assembled in modular (relocatable) units for reasons of deployment. | |

Product details:

|  |  |
| --- | --- |
| International Non-proprietary Name (INN) of the drug substance: |  |
| Pharmaco-therapeutic group  (ATC Code): |  |
| Proposed invented name of the medicinal product if known; pharmaceutical form(s) and strength(s): |  |
| Nature of medicinal product: | |  |  | | --- | --- | |  | Small molecule (chemical origin) medicinal product | |  | Biological medicinal product | |  | Advanced Therapy medicinal product (ATMP) | |
| Route(s) of administration: |  |
| Proposed indication(s): |  |
| Current global regulatory status including:   * Compassionate/specials usage * Pending and refused marketing authorisation applications * Granted marketing authorisations * Orphan designation (if any) |  |
| Have previous applications been made for a Decentralised Manufacturing approach? |  |

Manufacturing licence type for future application   
(subject to successful DM Designation)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Proposed Type of Manufacturing Licence for Decentralised Manufacture: | |  |  | | --- | --- | |  | MIA(IMP) | |  | MIA | |  | MS | |

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List of abbreviations

Summary of manufacture and pharmaceutical development

Summary details of manufacture and pharmaceutical development [Three pages maximum]

Point of Care

Justification for manufacture at Point of Care   
(at or near to the place where the product is to be used or administered)

Describe and justify the necessity for manufacture of the medicinal product at or near the place where the product is to be used or administered, for reasons relating to method of manufacture, shelf life, constituents or method or route of administration.

Modular Manufacture

Justification for Modular Manufacture   
(Manufactured or assembled in a modular unit for reasons relating to deployment)

Describe and justify the necessity for manufacture or assembly of the medicinal product in a modular (relocatable) unit, for reasons relating to deployment.

References

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Annexes (supportive non-clinical and clinical data, if required)