

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA(IMP) 21659

2: Name of authorisation holder

VALNEVA SCOTLAND LIMITED

3: Address(es) of manufacturing site(s)

VALNEVA SCOTLAND LIMITED , OAKBANK PARK ROAD,
MID CALDER, LIVINGSTON, EH53 0TG, UNITED KINGDOM

4: Legally registered address of authorisation holder

VALNEVA SCOTLAND LIMITED, OAKBANK PARK ROAD,
MID CALDER, LIVINGSTON, EH53 0TG, UNITED KINGDOM

5: Scope of authorisation and dosage forms

ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation

Part 6 of The Medicines for Human Use (Clinical Trials)
Regulations 2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

Confidential

8: Authorisation Date

29/01/2026

9: Annexes attached

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

VALNEVA SCOTLAND LIMITED , OAKBANK PARK ROAD, MID CALDER, LIVINGSTON, EH53 0TG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS
[1.1] Sterile Investigational Medicinal Products
[1.1.1] Aseptically prepared (processing operations for the following dosage forms)
[1.1.1.1] Large volume liquids
[1.1.1.3] Batch certification
[1.3] Biological investigational medicinal products
[1.3.1] Biological medicinal products
[1.3.1.2] Immunological products
Special Requirements
Live Cells
[1.3.1.5] Biotechnology products

- [1.3.2] Batch certification
- [1.3.2.2] Immunological products
- Special Requirements**
- Live Cells
- [1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activity

- [1.4.1] Manufacture of:
 - [1.4.1.3] Other
 - Master Cell Bank and Working Cell Banks
- [1.4.2] Sterilisation of active substances/excipients/finished products:
 - [1.4.2.1] Filtration

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical
- [1.6.4] Biological