

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA 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

VALNEVA SCOTLAND LIMITED, 1 OAKBANK PARK PLACE,
MID CALDER, LIVINGSTON, EH53 0TN, UNITED KINGDOM

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

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI
2012/1916)

Confidential

29/01/2026

Annex 1 and/or Annex 2

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.1] Large volume liquids

[1.1.3] Batch certification

[1.3] Biological 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 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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

VALNEVA SCOTLAND LIMITED, 1 OAKBANK PARK PLACE, MID CALDER, LIVINGSTON, EH53 0TN, UNITED KINGDOM

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Special Requirements

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