

# 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.2 ] Immunological products <b>Special Requirements</b> 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