

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 21659
<b>2: Name of authorisation holder</b>	VALNEVA SCOTLAND LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	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
<b>4: Legally registered address of authorisation holder</b>	VALNEVA SCOTLAND LIMITED, OAKBANK PARK ROAD, MID CALDER, LIVINGSTON, EH53 0TG, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	27/01/2025
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids <b>[ 1.3 ] Biological medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.2 ] Immunological products [ 1.3.2 ] Batch certification

[ 1.3.2.2 ] Immunological products

**[ 1.4 ] Other products or manufacturing activity**

[ 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

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

**Special Requirements**

Live Cells

**[ 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

MHRA-GMMP

MHRA

MHRA-GMMP

MHRA