

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 57623
<b>2: Name of authorisation holder</b>	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, 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>	24/05/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED**, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE,  
NEWCASTLE, ST5 5SP, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.4 ] Small volume liquids <b>Special Requirements</b> Pathogenic Organisms (Biosafety Level 3 or 4)

**[ 1.2 ] Non-sterile products**

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.6 ] Liquids for internal use

**Special Requirements**

Live Cells

[ 1.2.1.17 ] Other non-sterile medicinal products

Manufacture of low bioburden bulk drug substance solutions

**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

[ 1.3.1.4 ] Gene therapy products

**Special Requirements**

Live Cells

[ 1.3.1.5 ] Biotechnology products

**Special Requirements**

Live Cells

[ 1.3.1.8 ] Other biological medicinal products

Antibodies, Antibody conjugates, Live microbial products, Therapeutic Virus, Plant extracted materials

**Special Requirements**

Live Cells

[ 1.3.2 ] Batch certification

[ 1.3.2.2 ] Immunological products

**Special Requirements**

Live Cells

[ 1.3.2.4 ] Gene therapy products

**Special Requirements**

Live Cells

[ 1.3.2.5 ] Biotechnology products

**Special Requirements**

Live Cells

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

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

[ 1.4.2.3 ] Moist heat

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical

[ 2.1.4 ] Biological

**[ 2.3 ] Other Importation Activities**

[ 2.3.1 ] Site of Physical Importation

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA