

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 11149
<b>2: Name of authorisation holder</b>	ROYAL FREE LONDON NHS FOUNDATION TRUST ROYAL FREE LONDON NHS FOUNDATION TRUST, RADIOPHARMACY NUCLEAR MEDICINE, THE ROYAL FREE HOSPITAL, POND STREET, LONDON, NW3 2QG, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	ROYAL FREE LONDON NHS FOUNDATION TRUST, PHARMACY DEPARTMENT, THE ROYAL FREE HOSPITAL, POND STREET, LONDON, NW3 2QG, UNITED KINGDOM  ROYAL FREE LONDON NHS FOUNDATION TRUST, CENTRE FOR CELL, GENE & TISSUE THERAPEUTICS, POND STREET, LONDON, NW3 2QG, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	ROYAL FREE LONDON NHS FOUNDATION TRUST, PHARMACY DEPARTMENT, THE ROYAL FREE HOSPITAL, POND STREET, LONDON, NW3 2QG, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<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>	29/05/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**ROYAL FREE LONDON NHS FOUNDATION TRUST**, RADIOPHARMACY NUCLEAR MEDICINE, THE ROYAL FREE HOSPITAL,  
POND STREET, LONDON, NW3 2QG, 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)

[ 1.1.1.4 ] Small volume liquids

[ 1.1.1.6 ] Other aseptically prepared products  
Radio Pharmaceuticals

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.3 ] Cell therapy products

[ 1.3.1.4 ] Gene therapy products

[ 1.3.1.6 ] Human or animal extracted products

[ 1.3.1.8 ] Other biological medicinal products  
Proteins, Peptides

[ 1.3.2 ] Batch certification

[ 1.3.2.2 ] Immunological products

[ 1.3.2.3 ] Cell therapy products

[ 1.3.2.4 ] Gene therapy products

[ 1.3.2.6 ] Human or animal extracted products

[ 1.3.2.8 ] Other biological medicinal products  
Proteins, Peptides

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

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

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**ROYAL FREE LONDON NHS FOUNDATION TRUST**, PHARMACY DEPARTMENT, THE ROYAL FREE HOSPITAL, POND STREET,  
LONDON, NW3 2QG, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

## **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 ] Semi-solids

[ 1.1.1.4 ] Small volume liquids

[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)

[ 1.1.2.1 ] Large volume liquids

[ 1.1.2.2 ] Semi-solids

[ 1.1.2.3 ] Small volume liquids

[ 1.1.2.5 ] Other terminally sterilised prepared products

Ampoules, Creams, Powders, Medicated Dressings, (sent away for sterilisation by irradiation), and Bone Wax.

[ 1.1.3 ] Batch certification

### **[ 1.2 ] Non-sterile investigational medicinal products**

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

[ 1.2.1.1 ] Capsules, hard shell

[ 1.2.1.5 ] Liquids for external use

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.13 ] Tablets

### **[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.1 ] Blood products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.6 ] Human or animal extracted products

[ 1.3.1.8 ] Other biological medicinal products

Proteins, Peptides

[ 1.3.2 ] Batch certification

[ 1.3.2.1 ] Blood products

[ 1.3.2.2 ] Immunological products

[ 1.3.2.6 ] Human or animal extracted products

### **[ 1.4 ] Other investigational medicinal products or manufacturing activity**

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

[ 1.4.2.1 ] Filtration

[ 1.4.2.2 ] Dry heat

[ 1.4.2.3 ] Moist heat

### **[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.2 ] Capsules, soft shell

[ 1.5.1.5 ] Liquids for external use

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.1.13 ] Tablets

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

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

[ 2.1.1 ] Microbiological: sterility

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical

[ 2.1.4 ] Biological

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

**[ 2.3 ] Other Importation Activities**

[ 2.3.1 ] Site of Physical Importation

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**ROYAL FREE LONDON NHS FOUNDATION TRUST**, CENTRE FOR CELL, GENE & TISSUE THERAPEUTICS, POND STREET,  
LONDON, NW3 2QG, UNITED KINGDOM

Human Investigational 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 Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.5 ] Solids and implants [ 1.1.1.6 ] Other aseptically prepared products ATMPs [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.3 ] Cell therapy products [ 1.3.1.4 ] Gene therapy products

[ 1.3.1.7 ] Tissue Engineered Products

[ 1.3.1.8 ] Other biological medicinal products

INTERMEDIATE MATERIALS: TISSUE CULTURE SUPERNATANTS

[ 1.3.2 ] Batch certification

[ 1.3.2.3 ] Cell therapy products

[ 1.3.2.4 ] Gene therapy products

[ 1.3.2.7 ] Tissue Engineered Products

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.4 ] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

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

[ 2.1.1 ] Microbiological: sterility

[ 2.1.4 ] Biological

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.3 ] Cell therapy products

[ 2.2.3.4 ] Gene therapy products

**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.4 ] Other

Importation of QP certified IMPs from a country on the approved country for import list