Medicines & Healthcare products Regulatory Agency

MHRA

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United Kingdom

gov.uk/mhra

Mrs Nicola Colverson
FISHER CLINICAL SERVICES UK LIMITED
LANGHURSTWOOD ROAD
HORSHAM
RH12 4QD
UNITED KINGDOM

Medicines & Healthcare products Regulatory Agency

MHRA

MIA(IMP) NUMBER: MIA(IMP) 18693 Version: 41

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

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SECTION 1A

1. Authorisation Number

MIA(IMP) Number: MIA(IMP) 18693

2. Name of Authorisation Holder

FISHER CLINICAL SERVICES UK LIMITED

3. Trading Style

4. Address(es) of manufacturing/importing site(s)
(All authorised sites should be listed if not covered by separate licences)

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
11204	FISHER CLINICAL SERVICES UK LIMITED	LANGHURSTWOOD ROAD, HORSHAM, RH12 4QD, UNITED KINGDOM

5. Legally registered address of Authorisation Holder

LANGHURSTWOOD ROAD, HORSHAM, RH12 4QD, UNITED KINGDOM

6. Scope of authorisation and dosage forms

See Annex 2

7. Legal basis of authorisation

See Section 1B of authorisation.

8. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

Olumuyiwa Abimbola

SECTION 1A (continued)

9. Date 04/11/2021

10. Annexes attached

Annex 2

Optional Annexes

Annex 4 (Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 6 (Name of Responsible Person)

Annex 8 (Manufactured/Imported products)

Annex 9 (Storage Sites)

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SECTION 1B

1. This authorisation is granted in accordance with the provisions of the Medicines for Human Use.

2. It permits the authorisation holder named on page 1 of Section 1 of the authorisation to manufacture, assemble and/or import investigational medicinal products for human use in accordance with Regulation 41 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] (as detailed in section 3 of this authorisation) and is subject to the provisions identified on page 2 of Section 1 of this authorisation.

3. In this document a Manufacturers Authorisation for Investigational Medicinal Products may be referred to as MIA(IMP) and the Medicines and Healthcare products Regulatory Agency (acting on behalf of the Licensing Authority as defined in Regulation 6 of The Human Medicines Regulations 2012 (SI 2012/1916) may be referred to as MHRA.

4. The authorisation holder must inform the MHRA, in advance, of any change to the details submitted by him and/or included in this authorisation. All changes must be approved by the MHRA to have effect. If the business should change hands, the company or person taking over the business will have to obtain a new authorisation before commencing the manufacture, assembly or importation of investigational medicinal products.

Attention is drawn to the structure of this authorisation (as detailed on page 4 of Section 1) and to its completeness in accordance with that structure. This is of particular relevance where the holder of the authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.

SECTION 1B (continued)

5. Authorisation Structure

This authorisation is divided into three sections.

(a) Section 1 (this section) identifies the authorisation holder and the responsible officer for the issue of the authorisation. This section would not usually be replaced during routine variations of the authorisation unless the authorisation holder details are varied.

(b) Section 2 lists variations to the authorisation. A replacement section 2 will be issued each time the authorisation is varied.

(c) Section 3 contains the details relating to each site named on the authorisation. Where there is more than one site there will be more than one part to Section 3. When a variation is made to the details of a site named in Section 3 the relevant part of Section 3 will be replaced.

(d) The authorisation holder is required to attach to his authorisation any replacement pages issued by MHRA and to mark or destroy superseded pages as to render them invalid.

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6. Provisions

a) The provisions of Schedule 7 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] shall apply to the authorisation. For manufacture and/or assembly Parts 1 and 2 of Schedule 7 apply and for importation Parts 1 and 3 of Schedule 7 apply in accordance with Regulation 40(4) of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] subject to Regulation 38(2).

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SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
26/04/2004	Initial application
03/01/2006	Remove Henryk Junker as Production Manager and Replace with Ian Morgan. Remove Dean Billington and Henryk Junker as Qualified Persons
27/02/2006	Internal variation to correct discrepancies
10/03/2006	Internal Variation to correct disccepancies. Also variation to be authorised for "Manufacture of solid Multi dose form (including powders and granule).
10/08/2006	Internal variation
17/12/2006	Variation: 1).Remove Mr I Morgan as PM and Mr C Cates as QC and Mr G Briscoe as QP 2). Add Mr S Woodhead as QC and Mr D Morrow as PM, and Mrs S Cartwright as QP 3. Add 5 Contract Laboratories
16/01/2007	Internal variation to amend licence.
28/02/2007	Variation to add 3 QP's Dr R Henry, Mr M Flower, Mr T Rackstraw.
09/11/2007	Variation to remove Ms S J Hobin and Mrs S Cartwright as QPs.
01/10/2008	Variation: 1. Add Mr C J Cates as L/H contact & SC and also to be named as a QC. 2. Add Medicinal Gases as an additional activitiy. 3. Remove Mr Woodhead from personnel records.
23/10/2008	Update licence to EUDRA GMP format
19/01/2009	Variation to (1) Delete Authorisation for Primary Packing of Chewing Gums, Internal Liquids, External Liquids (2) Remove Dr SC Griggs from list of personnel (3) Add Mr RD Constable as QP and QC (4) Add Mrs J Giblin as QP (5) Remove Mr CJ Cates as QC (6) Remove sites 5721, 14581 and 113787
21/10/2009	Variation to change the name of site 444177 Bodycote Prova to EXOVA (UK) LIMITED.

01/02/2010	Variation to site 11204: remove Dr RS Henry as QP and add Mr SK Roberts & Mr O Lawal as QP's. Remove site 444177.
01/07/2010	Variation to Site 11204: (1) Replace Mr R D Constable with Miss Emma Davies as QC (2) Remove all QC testing activities
23/02/2011	Variation to remove Mr Trevor Rackstraw from Site 11204
18/07/2011	Variation to replace Miss Emma Davies with Mr Roger Staplehurst as Quality Controller for Site 11204
15/03/2012	Variation to amend contact name, add a Qualified Person, remove Mr C Cates, Mr O Lawal as Qualified persons and add an additional storage site.
26/07/2012	Variation to remove D Morrow as Production Manager and replace with E Davies and S Bell.
19/10/2012	Variation:Add Mr Macdonald as an additional QP.
11/11/2012	RBI - Variation to change name of site 89192 to ILS LIMITED.
13/01/2013	Variation to add Qualified Person M Clevett.
25/06/2013	Variation to delete M Flower as QP from site 11204 and replace with Paul palmer and Colin Cates
06/03/2014	Variation to amend authorisation holder and site contact name to Julie Giblin, add Geoffrey Goodban as QP to site 11204, remove Emma Davies as PM and replace with Paul Fielden to on site 11204, remove Mr R Constable and Michael Clevett as QP
26/08/2014	Variation to add Daniele Bassanese and Nicola Colverson as Qualified Persons
29/04/2015	Variation to add a storage site and removal of Mr Sidney Kenneth Roberts from site 11204.
11/05/2015	Variation to add Stephen Ferguson as a Qualified Person and amend contact person to Julie Giblin.
30/06/2015	Variation to add Richard Williams as a Qualified Person to site 11204
19/08/2015	Variation to change site activities for site 11204 to: - add Capsules, hard shell to Packaging - change site of Physical importation needs to 'Authorised
25/02/2016	Variation: (Site 11204) Add Professor Michael Hannay as a PM Add Dr Wolfgang Zauner as a QP Remove Mr Stephen Bell as PM Remove Mr Paul Fielden as PM
02/06/2016	Variation to site 11204 to: - remove Michael Hannay as PM - remove Paul Palmer as QP - add Andrew Richards (15569170) as PM
13/10/2016	Variation (site 11204): - remove Roger Staplehurst (QC) - remove Colin Cates (QP) - remove Julie Giblin (QP) - add Gordon Macdonald (1931048) as QC

15/02/2017	Variation (site 11204): Remove Mr Dan Bassanese as QP Remove Mr Stephen Ferguson as QP Add Ms Sally J Hobin as QP Amend Site Contact to Mr Gordon Macdonald
13/04/2017	Internal variation site 11204 to add authorization for batch certification 1.2.2.
28/06/2017	Variation to amend licence holder contact from Mr Michael Clevett to Nicola Colverson, site 11204 remove QC G Macdonald with N Colverson, also to become site contact, also add M Clevett as QP.
20/10/2017	Variation: 1. Add Dr Maxine Shaw as an additional QP. 2. Removal of Gordon Macdonald as QP.
19/07/2018	Variation (site 11204): Update site functions Remove Nikki Colverson Remove Gordon McDonnald as QC Add Harry Berlanga as QC and site contact Change address and name of contract laboratory
30/01/2019	Variation to site 11204 □ Remove Mr Andrew Richards (Person ID 15569170) and add Mr Roger Staplehurst (Person ID □ 4600440) as PM. □ Add Sally Hobin (Person ID □ 132712) as QP.
15/07/2019	Variation to add Lynne McConnell as a PM to site 11204. Remove Roger Staplehurst as a PM. Remove Sally Hobin as a QP. Remove Transdermal patches and Suppositories. Add Distribution. Amend site processes/ activities
10/12/2019	Variation (site 11204): - add Naomi Wilmer (6344427) as QP - remove Richard Williams as QP
06/08/2021	Variation to site 11204: Remove Mr Harry Berlanga as QC, QP and Site Contact. Add Ms Dionne Metcalfe as QP. Add Mr Graham Jones as QC and Site Contact
04/11/2021	Variation to site 11204: Add Mr Arun Mahat as QP & add Other importation activities

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MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 3

ANNEX 2 - SITE INFORMATION

SCOPE OF AUTHORISATION

Name and address of site:

SITE NAME:	FISHER CLINICAL SERVICES UK LIMITED
ADDRESS:	LANGHURSTWOOD ROAD, HORSHAM, RH12 4QD, UNITED KINGDOM
MHRA SITE NUMBER:	11204

Type of products handled

Human Investigational Medicinal Products for phase I, II, III clinical trials (optional)

Authorised operations

Manufacturing Operations of Investigational Medicinal Products (according to Part 1)	Authorised
Importation of Investigational Medicinal Products (according to Part 2)	Authorised

ANNEX 2 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1	**Sterile Investigational Medicinal Products**	**Manufacture**
1.1.1	**Aseptically prepared (processing operations for the following dosage forms)**	
	1.1.1.1 Large volume liquids	Not Authorised
	1.1.1.2 Lyophilisates	Not Authorised
	1.1.1.3 Semi-solids	Not Authorised
	1.1.1.4 Small volume liquids	Not Authorised
	1.1.1.5 Solids and implants	Not Authorised
	1.1.1.6 Other aseptically prepared products	Not Authorised

1.1.2	***Terminally Sterilised (processing operations for the following dosage forms)***	**Manufacture**
	1.1.2.1 Large volume liquids	Not Authorised
	1.1.2.2 Semi-solids	Not Authorised
	1.1.2.3 Small volume liquids	Not Authorised
	1.1.2.4 Solids and implants	Not Authorised
	1.1.2.5 Other terminally sterilised prepared products	Not Authorised
1.1.3	***Batch certification***	Authorised

1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	***Non-Sterile Products (processing operations for the following dosage forms)***	
	1.2.1.1 Capsules, hard shell	Authorised
	1.2.1.2 Capsules, soft shell	Not Authorised
	1.2.1.3 Chewing gums	Not Authorised
	1.2.1.4 Impregnated matrices	Not Authorised
	1.2.1.5 Liquids for external use	Not Authorised
	1.2.1.6 Liquids for internal use	Not Authorised
	1.2.1.7 Medicinal gases	Not Authorised
	1.2.1.8 Other solid dosage forms	Not Authorised
	1.2.1.9 Pressurised preparations	Not Authorised
	1.2.1.10 Radionuclide generators	Not Authorised
	1.2.1.11 Semi-solids	Not Authorised
	1.2.1.12 Suppositories	Not Authorised
	1.2.1.13 Tablets	Not Authorised

	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products	Not Authorised
1.2.2	***Batch certification***	Authorised

1.3	Biological investigational medicinal products	Manufacture
1.3.1	***Biological medicinal products (list of product types)***	
	1.3.1.1 Blood products	Not Authorised
	1.3.1.2 Immunological products	Not Authorised
	1.3.1.3 Cell therapy products	Not Authorised
	1.3.1.4 Gene therapy products	Not Authorised
	1.3.1.5 Biotechnology products	Not Authorised
	1.3.1.6 Human or animal extracted products	Not Authorised
	1.3.1.7 Tissue Engineered Products	Not Authorised
	1.3.1.8 Other biological medicinal products	Not Authorised
1.3.2	***Batch certification***	
	1.3.2.1 Blood products	Authorised
	1.3.2.2 Immunological products	Authorised
	1.3.2.3 Cell therapy products	Authorised
	1.3.2.4 Gene therapy products	Authorised

	1.3.2.5 Biotechnology products	Authorised
	1.3.2.6 Human or animal extracted products	Authorised
	1.3.2.7 Tissue Engineered Products	Not Authorised
	1.3.2.8 Other biological medicinal products IMPs	Authorised

1.4	***Other investigational medicinal products or manufacturing activity*** (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).	**Manufacture**
1.4.1	**Manufacture of:**	
	1.4.1.1 Herbal products	Authorised
	1.4.1.2 Homoeopathic products	Authorised
	1.4.1.3 Other	Not Authorised
1.4.2	**Sterilisation of active substances/excipients/finished products:**	
	1.4.2.1 Filtration	Not Authorised
	1.4.2.2 Dry heat	Not Authorised
	1.4.2.3 Moist heat	Not Authorised
	1.4.2.4 Chemical	Not Authorised
	1.4.2.5 Gamma irradiation	Not Authorised
	1.4.2.6 Electron beam	Not Authorised
1.4.3	**Others**	Not Authorised

1.5	*Packaging*	**Packaging**
1.5.1	***Primary packing***	
	1.5.1.1 Capsules, hard shell	Authorised
	1.5.1.2 Capsules, soft shell	Authorised
	1.5.1.3 Chewing gums	Not Authorised
	1.5.1.4 Impregnated matrices	Not Authorised
	1.5.1.5 Liquids for external use	Not Authorised
	1.5.1.6 Liquids for internal use	Not Authorised
	1.5.1.7 Medicinal gases	Not Authorised
	1.5.1.8 Other solid dosage forms	Authorised
	1.5.1.9 Pressurised preparations	Not Authorised
	1.5.1.10 Radionuclide generators	Not Authorised
	1.5.1.11 Semi-solids	Not Authorised
	1.5.1.12 Suppositories	Not Authorised
	1.5.1.13 Tablets	Authorised

	1.5.1.14 Transdermal patches	Not Authorised
	1.5.1.15 Other non-sterile medicinal products	Not Authorised
1.5.2	**Secondary packing**	Authorised

1.6	**Quality control testing**	
	1.6.1 Microbiological: sterility	Not Authorised
	1.6.2 Microbiological: non-sterility	Not Authorised
	1.6.3 Chemical/Physical	Not Authorised
	1.6.4 Biological	Not Authorised

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

ANNEX 2 – SITE INFORMATION (continued)

Part 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity
- authorised importation activities include storage and distribution unless informed to the contrary

2.1	**Quality control testing**	**Import**
	2.1.1 Microbiological: sterility	Not Authorised
	2.1.2 Microbiological: non-sterility	Not Authorised
	2.1.3 Chemical/Physical	Not Authorised
	2.1.4 Biological	Not Authorised
2.2	**Batch certification of imported medicinal products**	
2.2.1	***Sterile Products***	
	2.2.1.1 Aseptically prepared	Authorised
	2.2.1.2 Terminally sterilised	Authorised
2.2.2	***Non-sterile products***	Authorised
2.2.3	***Biological medicinal products***	
	2.2.3.1 Blood products	Authorised
	2.2.3.2 Immunological products	Authorised
	2.2.3.3 Cell therapy products	Authorised

	2.2.3.4 Gene therapy products	Authorised
	2.2.3.5 Biotechnology products	Authorised
	2.2.3.6 Human or animal extracted products	Authorised
	2.2.3.7 Tissue Engineered Products	Not Authorised
	2.2.3.8 Other biological medicinal products	Not Authorised
2.3	**Other Importation Activities**	
	2.3.1 Site of Physical Importation	Authorised
	2.3.2 Importation of Intermediate which undergoes further processing	Not Authorised
	2.3.3 Biological Active Substances	Not Authorised
	2.3.4 Other Importation of QP certified IMPs from a country on the 'approved country for import list'	Authorised

Any restrictions or clarifying remarks related to the scope of these importing operations:

ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

Person Number	Name	Personnel Type			
		QP	TQP	PM	QC
10775237	Dr Maxine Shaw	Yes	No	No	No
19900738	Ms Lynne McConnell	No	No	Yes	No
14765961	Dr Wolfgang Zauner	Yes	No	No	No
6344427	Ms Naomi Wilmer	Yes	No	No	No
17672810	Ms Dionne Metcalfe	Yes	No	No	No
23899122	Mr Graham Jones	No	No	No	Yes
5761171	Mr Michael Clevett	Yes	No	No	No
10815870	Mr Geoffrey Goodban	Yes	No	No	No
20335821	Mr Arun Mahat	Yes	No	No	No

Key to Roles:

QP – Qualified Person
TQP – Transitional Qualified Person
PM – Production Manager/Supervisor
QC – Person responsible for Quality Control

ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
17556174	EUROFINS BIOPHARMA PRODUCT TESTING UK LIMITED	UNIT 6 COCHRANE SQUARE, BRUCEFIELD INDUSTRIAL ESTATE, LIVINGSTON, EH54 9DR, UNITED KINGDOM

ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
11204	FISHER CLINICAL SERVICES UK LIMITED	LANGHURSTWOOD ROAD, HORSHAM, RH12 4QD, UNITED KINGDOM
411870	THERMO ELECTRON LIMITED	THERMO FISHER SCIENTIFIC, FISHER BIOSERVICES DIVISION, UNIT 1, WOODSIDE, DUNMOW ROAD, BIRCHANGER, BISHOP'S STORTFORD, CM23 5RG, UNITED KINGDOM
11485563	FISHER CLINICAL SERVICES LIMITED	AURORA HOUSE, FLEMING WAY, CRAWLEY, RH10 9NL, UNITED KINGDOM