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Moderna Biotech Manufacturing UK Limited

# Moderna Permit Application

## Drug Substance Manufacturing Facility: H5 Site Condition Report

DATE
19 December 2023

REFERENCE
0693210

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SIGNATURE PAGE

# Moderna Permit Application

## Drug Substance Manufacturing Facility: H5 Site Condition Report

0693210

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## ACRONYMS AND ABBREVIATIONS

| Acronyms | Description |
|---|---|
| ASR | Application Site Report |
| CMO | Custom Manufacturing Organisation |
| EA | Environment Agency |
| EP | Environmental Permit |
| EP Regulations | Environmental Permitting (England and Wales) Regulations 2016 (as amended) |
| ERM | Environmental Resources Management Limited |
| mRNA | Messenger Ribonucleic Acid |
| Moderna | Moderna Biotech Manufacturing UK Limited |
| m bgl | Meters below ground level |
| SCR | Site Condition Report |

# 1. SITE DETAILS

## 1.1 INTRODUCTION

Moderna Biotech Manufacturing UK Limited (Moderna) is currently constructing and plans to operate the new Moderna Innovation and Technology Centre at the Harwell Science and Innovation Campus, Harwell, Oxfordshire, OX11 0RL, which will consist of a Drug Substance (DS) Manufacturing facility (the Site). The Harwell Campus is located within The Science Vale UK area, an internationally significant location for innovation and science-based research and business, which consists of numerous organisations predominantly working within the innovative technologies sector.

Adjacent to the DS facility, Moderna is developing a separate Clinical Biomarker Building for research and development purposes only. As the Clinical Biomarker Building has limited technical connection to the DS facility (limited to firefighting pumps and sprinklers), it is considered to be a separate building to the Site and it has not therefore been considered any further in the context of this document.

The Site and buildings under construction are owned by the Harwell Science and Innovation Campus Limited Partnership and will be occupied by Moderna under a 15 year lease arrangement. The lease arrangement will include environmental condition obligations for Moderna as the tenant, for when the Site is handed back to the Harwell Science and Innovation Campus Limited Partnership as the landlord.

The Site is a major investment in messenger Ribo-Nucleic Acid (mRNA) manufacturing comprising a new UK-based mRNA DS manufacturing facility which will provide the UK with both endemic and pandemic response capability for Moderna COVID-19 vaccines and future respiratory virus vaccine candidates. Moderna has received supplementary funding from, and has a commitment to, the government to produce 250 million doses of vaccine in a pandemic scenario. The Site is scheduled go operational in November 2024.

The Site will be used to manufacture mRNA vaccines DS to be subsequently filled into syringes/vials (completed at a third-party Contract Manufacturing Organisation (CMO) facility). The Site will manufacture complete drug substances on a discrete batch basis throughout the year.

This Site Condition Report (SCR) has been prepared with reference to the guidance provided by the Environment Agency (EA) in the MAY 2013 document *"Site Condition Report – Guidance and Templates"* Version 3. The layout of this report is consistent with the SCR template presented in this guidance.

The layout of this report is as follows:

- Section 1 – Site details
- Section 2 – Condition of the land at permit issue
- Section 3 – Permitted Activities

## 1.2 SITE DETAILS

| **1.0 SITE DETAILS** | |
|---|---|
| Name of the applicant | Moderna Biotech Manufacturing UK Limited |
| Activity address | Harwell Science and Innovation Campus, Harwell, Oxfordshire, OX11 0RL |
| National grid reference | Grid Reference (6 figure)<br>SU 48252 86536X (Easting), Y (Northing)<br>448252, 186536Latitude, Longitude (decimal)<br>51.575632, -1.3051121 |
| Document reference and dates for Site Condition Report at permit application and surrender | At application - See details in **Section 1.2** below. |
| Document references for site plans (including location and boundaries) | See details in **Section 1.2** below. |

## 1.3 SITE CONDITION REPORT AT PERMIT APPLICATION

This document acts as the Application Site Report (ASR) which has been prepared at the time of permit application in December 2023.

Where required, subsequent follow up reports will be prepared in line with the EA Guidance document during the life of the permit (encompassing Changes to the activity, Measures taken to protect land, Pollution incidents that may have had an impact on land, Soil gas and water quality monitoring) and at surrender (encompassing Decommissioning and removal of pollution risk, Reference data and remediation, Statement of site condition).

In line with the above, when the time of permit surrender arises a follow up SCR will be produced and submitted for review.

This ASR and subsequent permit application will be submitted to the Environment Agency (EA) for review and approval along with the permit application.

# 2. CONDITION OF THE LAND AT PERMIT ISSUE

| **2.0 Condition of the land at permit issue** | |
|---|---|
| Environmental setting including:<br><br>Article I. geology<br>Article II. hydrogeology<br>Article III. surface waters | As noted in **Section 1.2** this is the ASR which has been prepared for the current permit application in 2023. This report includes details of the Site environmental setting.<br><br>Details are summarised in **Section 2.1** |
| Pollution history including:<br><br>1. pollution incidents that may have affected land<br>2. historical land-uses and associated contaminants<br>3. any visual/olfactory evidence of existing contamination<br>4. evidence of damage to pollution prevention measures | Pollution incidents and historic land uses for the area were reviewed in the 2022 Phase I investigation conducted by Jomas Associates Ltd.<br><br>Details are summarised in **Section 2.2** below. |
| Evidence of historic contamination, for example, historical site investigation, assessment, remediation and verification reports (where available) | • RWE Solutions have produced a Land Quality Statement report which details the remediation and testing of a historic RAF Catapult Pit, dated 2002. The Land Quality Statement report can be found in **Appendix A.**<br>• Jomas Associates Ltd have undertaken a Phase I Desk Study and Phase II Site Investigation in 2022. Jomas Associates Ltd have undertaken a Phase II Site Investigation in support of this ASR and permit application.<br><br>Details are summarised in **Section 2.3** |

| | |
|---|---|
| Baseline soil and groundwater reference data | Soil and groundwater quality has been assessed as part of the Jomas Associates Ltd Phase II investigation in 2022. The site investigation report can be found in **Appendix B.**<br><br>Further details of this are given in **Section 2.3** below. |

## 2.1 ENVIRONMENTAL SETTING

### 2.1.1 SITE LAYOUT

The Site is currently an open parcel of land owned by The Harwell Science and Innovation Campus Limited Partnership and covers an area of approximately 1.86 hectares (ha). Existing road access to the Site is via Frome Road to the South and the Perimeter Road entrance to the campus from Newbury Road. A copy of the Site permit boundary is provided in Figure 2.1 of the main application supporting document.

The planned development will comprise an industrial building with two components, as well as external yard areas providing access and egress routes. The first component is a single storey building on the eastern side to accommodate office space and a staff café. Behind this is a two-storey structure accommodating the manufacturing facility consisting of the mRNA production area, a Lipid Nanoparticle production area, a Chromatography Column pack area, a buffer preparation area and the Quality Control Lab. The facility will also provide areas for utilities and ancillary equipment including cleaning and support areas, storage areas for raw materials, chemicals, waste and cold storage, emergency diesel generators, a chiller and waste effluent treatment plant. Appendix B of the main application supporting document provides the indicative layout plans for the Site.

### 2.1.2 REGIONAL GEOLOGY, HYDROGEOLOGY AND HYDROLOGY

The BGS Geology viewer (accessed 20th November 2023) identifies the superficial geology as Head deposits comprising clay, silt, sand and gravel. The bedrock geology underlying the superficial deposits consists of West Melbury Marly Chalk Formation deposits in the northern area of the Site, and the Zig Zag Chalk Formation deposits in the southern area of the Site.

The recent ground investigation completed by Jomas Associates Ltd in 2022 confirmed the geological sequence overlying the Site in **Table 2.1** (taken from **Appendix B**)

TABLE 2.1 – GEOLOGICAL SEQUENCE OF THE SITE 2022

| **Unit** | **Depth (m bgl)** | | **Strata Thickness range (m)** | **Description** |
|---|---|---|---|---|
| | Encountered from (m bgl) | Base of strata (m bgl) | | |
| Made Ground - Topsoil | 0.00 – 0.30 | 0.2 – 1.20 | 0.2 - >1.20 | Brown sandy gravel/gravelly clay with occasional rootlets. Sand is fine to coarse. Gravel consists of fine to coarse, angular to subrounded flint and chalk [MADE GROUND – TOPSOIL] |
| Made Ground | 0.0 – 0.60 | 0.20 – 0.70 | 0.10 – 0.30 | Concrete/Asphalt – only encountered within WS1, WS8, TP1, TP2, TP3, TP11 [MADE GROUND] |
| Made Ground | 0.20 | < 1.20 (base not proven) | >1.0 (thickness not proven) | Gravel comprising angular concrete and asphalt [MADE GROUND] *WS8 only* |
| Made Ground | 0.20 | 0.55 | 0.35 | Firm greyish white gravelly clay. Gravel consists of asphalt fragments [Made Ground] *TP12 only* |
| HEAD | 0.2 – 0.5 | 0.5 - >2.0 | 0.20 - >1.80 | Brown sandy gravelly CLAY / firm greyish white gravelly CLAY. Sand is fine to coarse. Gravel consists of fine to coarse, angular to subrounded flint and chalk [HEAD] |
| Zig Zag Chalk Formation | 0.5 – 1.6 | > 1,5 - >8.8 (base not proven) | >0.4 - >7.5 (thickness not proven) | Structureless CHALK recovered as very stiff greyish white CLAY with occasional orange staining [ZIG ZAG CHALK FORMATION] *BH1 – BH2, WS2-WS4, TP1-TP4* |
| West Melbury Marly Chalk Formation | 0.35 – 1.30 | >1.5 - >6.3 (base not proven) | >0.70 - >5.00 (thickness not proven) | Structureless CHALK recovered as stiff to very stiff greyish white CLAY with occasional orange staining [WEST MELBURY MARLY CHALK FORMATION] *BH3–BH7, WS6–WS7, TP5–TP14* |

The EA catchment explorer page classifies the groundwater at the Site as having a "*Fail*" in terms of chemical status (2019)[1]. The chemical status is classified as failing for priority hazardous substances mercury, polybrominated diphenyl ethers, and priority substances Cypermethrin, which are found to exceed the Environmental Quality Standard, set out by the Water Framework Directive Regulations. The Site is not shown to lie within a Groundwater Source Protection Zone (SPZ).

A review of the Enviro+Geoinsight Report indicates that there are no source protection zones within 500 m of the Site.

[1] Mill Brook and Bradfords Brook system, Wallingford | Catchment Data Explorer | Catchment Data Explorer

There are no surface water features or water networks reported within 250 m of the Site.

The Site is shown to be located within a Flood Zone 1 area as designated by the flood map for planning page on the UK government website. This indicates that the Site has a low probability of flooding from surface waters.

There are no EA Zone 2 or Zone 3 floodplains reported within 250 m of the Site.

Jomas Associated Ltd correspondence with the Local Authority revealed that they are aware of chlorinated solvent contamination being present in the groundwater beneath the wider Harwell area from chlorinated organic solvents linked to the disposal of chemical wastes into unlined pits located off-site.

## 2.2 HISTORICAL LAND-USES AND ASSOCIATED CONTAMINANTS

A review of the earliest available (1877) historical map indicates that the Site was undeveloped, likely agricultural land. By the map dated 1912, two buildings and a road are shown in the southeast of the Site. Aerial photography from 1944 indicates the presence of numerous aircraft and runways suggesting military airfield use. By the 1970s, the runways are no longer shown, and a sports field is shown on Site. No significant changes then occur up to the most recent maps (including up to the present day).

The land within which the Site is situated was formerly an RAF airfield, before being taken over by the Atomic Energy Research Establishment (AERE, later the United Kingdom Atomic Energy Authority, UKAEA). A catapult pit located off-site, adjacent to the southeastern section of the Site boundary was constructed by the RAF but then used by AERE as a waste transit pit for the storage of radioactive materials, before being backfilled in the 1950s. At the turn of the millennium, UKAEA investigated and subsequently remediated/restored the catapult pit and infilled it with clean material (details in **Section 2.3** below). The feature is still visible on recent aerial imagery (2023), but was not observed during the initial walkover conducted by Jomas Associates Ltd.

Potential sources of contamination derived from historical reports and Phase 1 assessments are as follows:

- Potential for Made Ground associated with removal of previous structures, including bungalow structures in the southeast of the Site and runways.
- Low bunds of unknown composition in north and east of the Site.
- Reported chlorinated solvent contamination within groundwater from disposal of waste in unlined pits – (off-site)
- Report of stored radioactive materials, in addition to the potential presence of beryllium within historical RAF Catapult Pit – (located off-site, adjacent to the southeastern section of the Site boundary).

## 2.3 BASELINE SOIL AND GROUNDWATER DATA

**RWE Solutions, RAF Catapult Pit, Land Quality Statement (TR/051700/016), October 2002**

A catapult pit was constructed at RAF Harwell in the late 1930s/early 1940s to house a prototype pneumatic catapult designed to assist the take-off of bomber planes. The structure comprising

a circular pit and two radial trenches, located off-site, adjacent to the southeastern section of the Site boundary, was backfilled with construction spoilt during the early years of the UK nuclear development program at Harwell. Some historic records indicated that radioactive materials and beryllium have been stored in the pit and a historic site investigation detected the presence of uranium near the bottom of the pit in one location. In pursuit of its program of dealing with historic nuclear liabilities and releasing land for beneficial use, the UKAEA decided to remediate the catapult pit by removing its contents and replacing them with clean fill.

The remediation process, which occurred during November 2001 and June 2002, was designed to remove any residual risk to the public, to groundwater and to the environment in general from the radioactive material and the chlorinated solvents reported within groundwater from disposal of waste in unlined pits. Excavation of the structure was undertaken within large weather protection facilities (WPF) to minimise the impact to the general public and the local environment. Air samplers were positioned at four points at the perimeter fence to monitor levels of radioactivity and metals. During the excavation of the catapult pit, material was subject to comprehensive in and ex-situ monitoring/assay to ensure waste was correctly sentenced for disposal. Both chemical and radiological analysis was performed on samples by a UKAS accredited laboratory to provide support and validate onsite activities. On completion of the excavation of the RAF catapult pit a series of further validation surveys were undertaken on the empty structure to ensure that no residual contamination remained. The surveys comprised:

- Health Physics contamination surveys of all exposed surfaces
- Smear samples taken from exposed surfaces for radiological and beryllium analysis
- Soil sample collection from orifices for radiological and chemical analysis

The validation survey demonstrated that the RAF Catapult Pit structure was remediated to the specifications outlined by the UKAEA and that all wastes were removed with no radioactive materials remaining on Site. The structure was filled with imported material to reinstate the site back to its original condition.

A further survey on completion of the backfilling was undertaken in which gross gamma (radiation) readings were taken over the Catapult Pit structure and the surrounding area. The purpose of this survey was to demonstrate that the backfill materials used for Site reinstatement exhibited a gross gamma count of the same or lower than prior to the remediation works. Post remediation survey results found that the area was comparable to gross gamma data gathered during pre-characterisation investigation.

In summary, the previous assessments concluded that the following pollution linkages were broken after the successful removal of all materials (the source) from the pit and trenches (described further below)

- Radioactive materials; and
- Chlorinated solvents.

**Radioactive materials**

Removal of all radioactive waste from the structure has broken the pollution linkage by removal of the source (contaminated soil) thus removing hazards to receptors. Established working

methodologies ensured that workers dose uptake during the works was kept as low as reasonably practicable resulting in the project dose restraint objective (DRO) not being exceeded. Removal of the source will ultimately cease production of radiologically contaminated leachates percolating down to groundwater residing in the underlying chalk aquifer.

**Chlorinated Solvents**

During remediation a potential source of groundwater contamination was removed (a small quantity of Trichloroethane, TCE) thus removing the potential for further contamination. It must be noted that chlorinated solvents are problematic due to their recalcitrance, especially in chalk aquifers, and their density which results in them sinking in groundwater. Residual quantities may still be encountered in borehole water samples. Additionally, solvents other than TCE (Carbon tetrachloride, Chloroform) have been found in local boreholes, and have been encountered in groundwater beneath the Harwell Site.

The remediation of the RAF Catapult Pit was successful in meeting the pre-remediation goals. All wastes were removed from the structure thus breaking any present or future pollution linkages. Remediation targets for the project were met for both chemical and radiological parameters as summarised below:

- Direct probe measurements of exposed surfaces of the Catapult Pit demonstrated that surface contamination did not exceed 4.0Bq/cm$^2$ (β).
- Dose rate surveys of the RAF Catapult Pit demonstrated that radiological conditions were as background (<0.15μSv/hr)
- Smears of the concrete surfaces did not reveal contamination levels above 0.4Bq/cm$^2$(α) AND 4.0Bq/cm$^2$ (β)
- Smears collected for beryllium analysis showed no beryllium contamination
- Validation survey soil sample analysis identified that some metals and radiological activity exceeded the 95$^{th}$ percentile values as calculated from the background survey. All these soils were removed from the RAF Catapult Pit, therefore no contamination remained in the structure.

Following backfilling, field measurements of gross gamma counts were taken and were found to be comparable to data gathered prior to commencement of the remedial works.

The full Land Quality Statement is presented within **Appendix A.**

**Jomas Associates Ltd, Zone 5 & ESA Harwell Campus, Didcot, Geo-environmental and Geotechnical Assessment Report (P4397J2609), November 2022**

The Site investigation works were undertaken between the 7$^{th\ of}$ September and 15$^{th}$ September 2022, and comprised the following:

- 8no. Windowless Sample Boreholes to depths of up to 2.00 m bgl
- 7no Cable Percussion Boreholes to depths of up to 8.80 m bgl
- 16no Trial Pits to depths of up to 3.50 m bgl
- Soil Infiltration Testing to depths of up to 3.50 m bgl
- CBR Testing by DCP method to depths of up to 1.00 m bgl

- Monitoring Well Installation to depths of up to 8.00 m bgl

Monitoring wells were installed in all of the cable percussive boreholes and five of the windowless sample boreholes, with response zones in the Made Ground, Head, West Melbury Chalk Formation and Zig Zag Chalk Formation.

With the exception of asphalt fragments noted within the Made Ground of WS1, WS8 and TP12, no other visual or olfactory evidence of potential contamination was identified within the investigation locations.

Following generic qualitative risk assessments, no elevated concentrations of contaminants were detected in soils in excess of generic assessment criteria for the protection of human health within a commercial end-use scenario.

No asbestos containing materials of fibres were detected in the Made Ground samples analysed in the laboratory.

The risk to end users associated with vapour risk inhalation from soils was considered negligible.

Concentrations of chromium, lead, nickel, copper and zinc were found to exceed environmental water quality standards. However, no groundwater was reported during drilling or subsequent monitoring (to a depth of 8.00m bgl), and no nearby surface waters features or abstractions have been identified, therefore a significant risk to controlled waters has not been identified.

Based on the calculated GSVs, and in consideration of the conceptual site model, the Site is classified as Characteristic Situation 1 (CS1) with no formal gas protection measures considered to be necessary.

The full Site investigation report is presented within **Appendix B**.

# 3. PERMITTED ACTIVITIES

| 3.0 Permitted activities | |
|---|---|
| Permitted activities | The main commercial activity taking place at the Site is the production of pharmaceuticals (complete drug substance containing Active Pharmaceutical Ingredient (API)). This activity is captured under Schedule 1, Part 2 of the Environmental Permitting (England and Wales) Regulations 2016 (as amended) (EP Regulations). |
| Non-permitted activities undertaken | The non-permitted activities undertaken on the Site include.<br>• Wastewater treatment and disposal,<br>• Water treatment,<br>• Storage, treatment and disposal of waste,<br>• Surface water drainage,<br>• Combustion plant,<br>• Storage and handling of chemicals, Raw materials and finish product,<br>• Refrigeration,<br>• Chiller,<br>• Compressed air, and<br>• Firewater management |
| Document references for:<br>1. plan showing activity layout; and<br>2. Environmental risk assessment. | As part of this ASR, the environmental setting, results of the investigation (soil and groundwater analysis) and current environmental risk assessment are provided as part of the permit application |

The Site will utilise a number of different chemicals and raw materials for the drug substance process and associated activities.

**Table** 3.1 provides a list of raw materials used on site, their storage location and containment.

Storage of bulk raw materials (diesel fuel and firewater) will adhere to BAT, Oil Storage Regulations 2001, where relevant, and the CIRIA C736F guidance on containment systems. Likewise, all storage inside buildings will be in accordance with GMP standards and according to safety data sheet information. Further details on storage of raw materials can be found in the permit application supporting document.

## TABLE 3.1 – RAW MATERIALS USED ON SITE

| Substance | Storage Location | Containment |
|---|---|---|
| Inorganic Salts | Warehouse | Storage rack in warehouse |
| Buffer (Tris Base and HCl) | Warehouse | Storage rack in warehouse |
| Dithiothreitol | Warehouse | Cabinet with integral bunding |
| Alkyl polyamine | Warehouse | Cabinet with integral bunding |
| EDTA | Warehouse | Storage rack in warehouse |
| Sodium Hydroxide pellets | Warehouse | Storage rack in warehouse |
| Sodium Hydroxide (10 mol/L) | Warehouse | Cabinet with integral bunding |
| Resin in Ethanol | Warehouse | Cabinet with integral bunding |
| Glacial acetic acid | Warehouse | Cabinet with integral bunding |
| Hydrochloric acid (6 mol/L) | Warehouse | Cabinet with integral bunding |
| Ethanol | Warehouse | Cabinet with integral bunding |
| Sucrose | Warehouse | Storage rack in warehouse |
| Polyethylene glycol | Warehouse | Storage rack in warehouse |
| Plasmid template | Warehouse | Cold Storage Room |
| LMX | Warehouse | Cold Storage Room |
| Enzyme | Warehouse | Cold Storage Room |
| Nucleotides | Warehouse | Cold Storage Room |
| SAM Powder | Warehouse | Storage rack in warehouse |
| CIP 100 | Warehouse | Bunded Pallet |
| CIP 200 | Warehouse | Bunded Pallet |
| Vesta Syde | Warehouse | Cabinet with integral bunding |

| Substance | Storage Location | Containment |
|---|---|---|
| Septihol | Warehouse | Cabinet with integral bunding |
| Sporklenz | Warehouse | Cabinet with integral bunding |
| Acetonitrile | QC Lab | Cabinet with integral bunding |
| Formic Acid | QC Lab | Cabinet with integral bunding |
| Methanol | QC Lab | Cabinet with integral bunding |
| Isopropyl Alcohol | QC Lab | Cabinet with integral bunding |
| Ethanol | QC Lab | Cabinet with integral bunding |
| 1,1,1,3,3,3-Hexafluoro-2-propanol (HFIP) | QC Lab | Cabinet with integral bunding |
| Hydrochloric acid (1 mol/L) | QC Lab | Cabinet with integral bunding |
| Sodium Hydroxide (1 mol/L) | QC Lab | Cabinet with integral bunding |
| Sodium Hypochlorite | QC Lab | Cabinet with integral bunding |
| Phosphate Buffers | QC Lab | Cabinet with integral bunding |
| Tetrahydrofuran | QC Lab | Cabinet with integral bunding |
| N, N-Diisopropylethylamine (DIEA) | QC Lab | Cabinet with integral bunding |
| TRIS EDTA, 10 – 100X | QC Lab | Cabinet or storage rack |
| TRIS HCl, 1M | QC Lab | Cabinet or storage rack |
| Chloroform | QC Lab | Cabinet with integral bunding |
| Hydrogen Peroxide, 30% | QC Lab | Cabinet with integral bunding |
| PCl (Phenol, Chloroform, isoamyl alcohol) | QC Lab | Cabinet with integral bunding |
| Diesel | External (double walled and double bunded) | Double skinned and bunding |

APPENDIX A

# APPENDIX A RWE SOLUTIONS, RAF CATAPULT PIT, LAND QUALITY STATEMENT (TR/051700/016), OCTOBER 2002

APPENDIX B

# APPENDIX B JONES ASSOCIATES LTD, ZONE 5 & ESA HARWELL, DIDCOT, OX11 0FD. GEO-ENVIRONMENTAL AND GEOTECHNICAL ASSESSMENT, P4397J2609 – NOVEMBER 2022

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