CVIM Facility

Main Contractor Procurement Bidder's Day Presentation 13th June 2024





Introduction and H&S

- Welcome
- Escorting
- Housekeeping
- Fire Alarms and Fire Exits





Structure of the Session

Team Presentation

- The Team
- Centre for Veterinary Vaccine Innovation and Manufacturing
- The Design
- Contract Structure & Requirements
- Project Delivery
- Town Planning
- Questions

Site Tour



The Team

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Integrated Project Team





?
Contractor
Contractor
Design Team









Turner & Townsend alinea

Cost Manager













The Team Today

BBSRC PMO

- Joan Shadwell Programme Manager
- Peter Coxhead Programme Manager

CVIM Core Project Team representatives/consultants

- Julian Seago Process Development and Facility Lead
- Martin Smith CVIM Consultant

Pirbright Institute representatives

- Sylvie Bilgin Project Support Officer
- Graeme Harkess Head of Biorisk and Biological Safety Officer
- Susan Williams Head of Finance
- John Nixon- Procurement Officer
- Lester Demmer- Procurement Manager

Currie and Brown - Project Management

James Morgan – Associate Director Project Manager

Turner and Townsend - Cost Management

• Nic Di Santo – Director



Centre for Veterinary Vaccine Innovation and Manufacturing

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CVIM

- Globally there is a gap in the capacity to translate scientific discoveries into solutions for the most challenging, emerging, and urgent infectious diseases especially in the developmental pipeline for veterinary vaccines.
- The Centre for Veterinary Vaccine Innovation and Manufacturing (CVIM) will support the development and deployment of vaccine technologies to combat neglected and emerging diseases of livestock, including zoonotic diseases that represent a threat to public health.
- CVIM will contribute to global priorities through health security and pandemic preparedness efforts by improving the response to emerging zoonotic diseases and promoting vaccine manufacturing and innovation.



CVIM: Aim

The overall aim is to bridge the gap between basic research and late-stage product development, with CVIM as a preferred partner to accelerate the development and production of vaccines with a focus on orphan livestock and zoonotic diseases, including those that affect primarily Low- and Middle-income Countries (LMICs), as well as strengthening the UK's own emergency response capability.



CVIM Strategic Stakeholders and Funders

- UK Research and Innovation, Biotechnology and Bioscience Research Council (UKRI- BBSRC)
- Bill and Melinda Gates Foundation (BMGF)
- Foreign, Commonwealth and Development Office (FCDO), UK Aid



CVIM Facilities

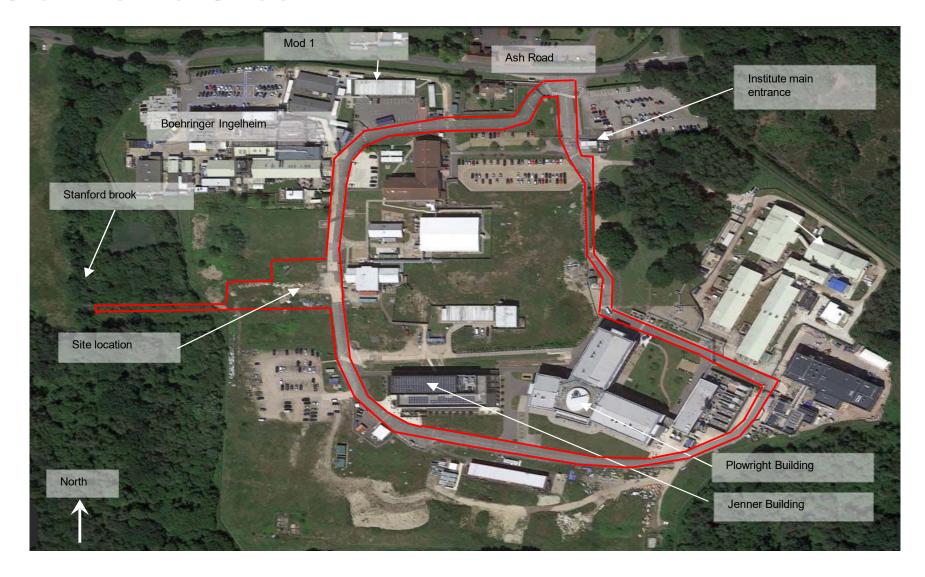
- Part of The Pirbright Institute but scientifically independent
- Consists of refurbished buildings (GLP); access to existing high containment suites and animal facilities; and a new build GMP facility

CVIM GMP Facility

- Will be built on an existing brown field site within The Pirbright Institute boundary
- Will be used for small scale veterinary vaccine manufacture
- Will need to comply with the principles of pharmaceutical Good Manufacturing Practice
- Will need to comply with SAPO2/ACDP 2/GMO2 requirements
- Will need to achieve BREEAM Very Good



Current Site





CVIM: Regulations

The facility design shall comply with the following regulations and guidance (not exhaustive):

- The Specified Animal Pathogens Order (SAPO): the new building shall be added to the site license. The Pirbright Insitute is the "risk owner" and must satisfy itself that adequate and proportionate controls are in place. Work will be at SAPO2.
- The Management, Design and Operation of Microbiological Containment Laboratories (Advisory Committee on Dangerous Pathogens). Work will be at ACDP2
- Genetically Modified Organisms (Contained Use) Regulations. Work will be at GMO2
- The Control of Substances Hazardous to Health (COSHH) Regulations, in particular specific requirements of this building including Schedule 3 (working with infectious agents) and containment of hazardous chemicals (VPH fumigation)
- GMP regulation Eudralex volume Annex 1
- GLP regulation pilot plant and QC facility (Directive 2004/9/EC and Directive 2004/10/EC)
- ISO (BS EN ISO 14644-1) Cleanrooms and associated controlled environments Part1: Classification of air cleanliness by particle concentration



Any Questions?

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The Design: Architectural

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Building Views



View from southeast



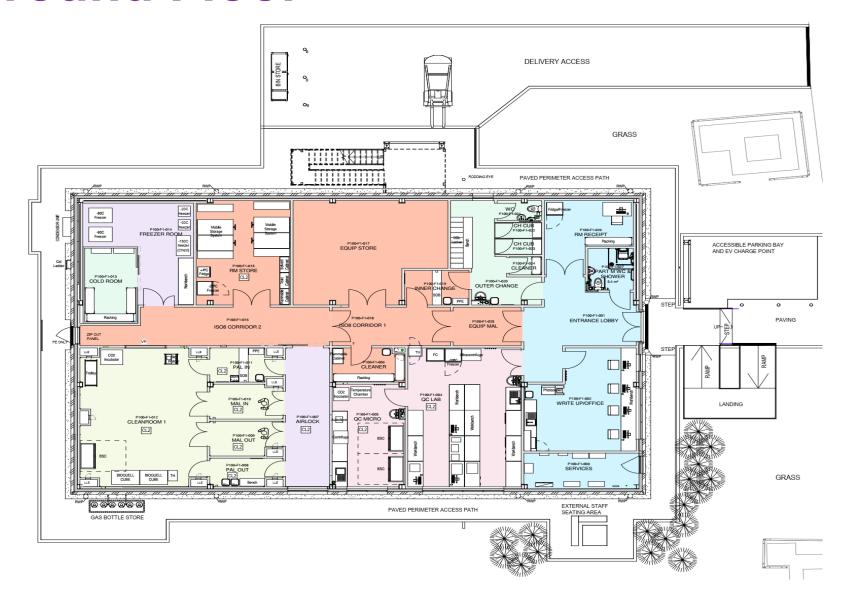
View from northeast



View from southwest

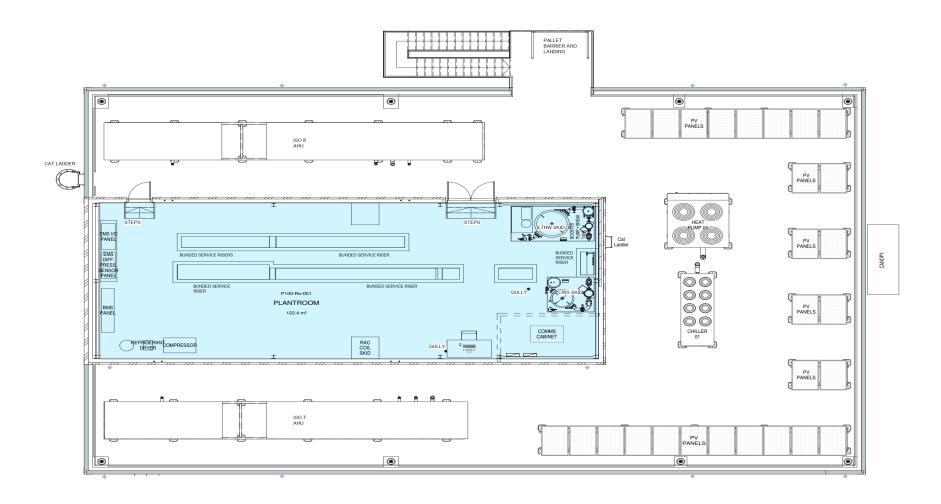


Ground Floor



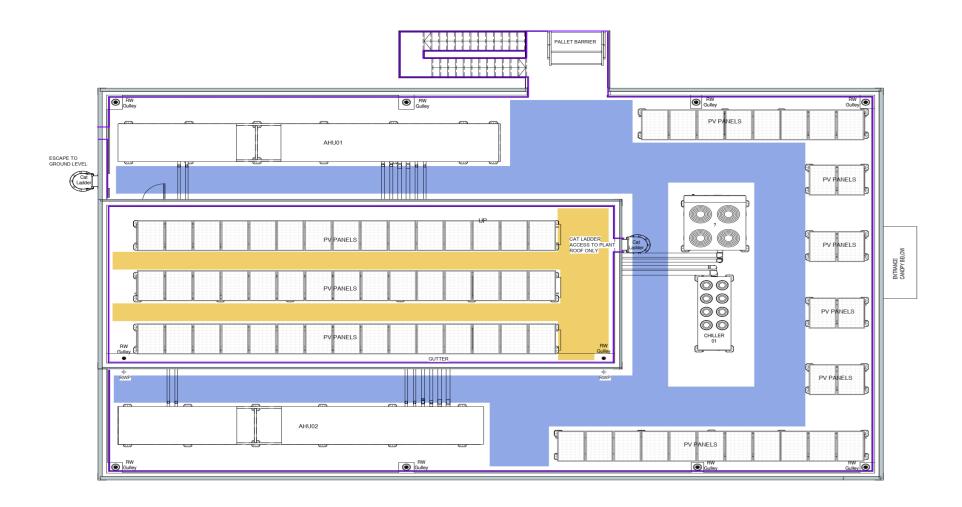


First Floor Plant Room



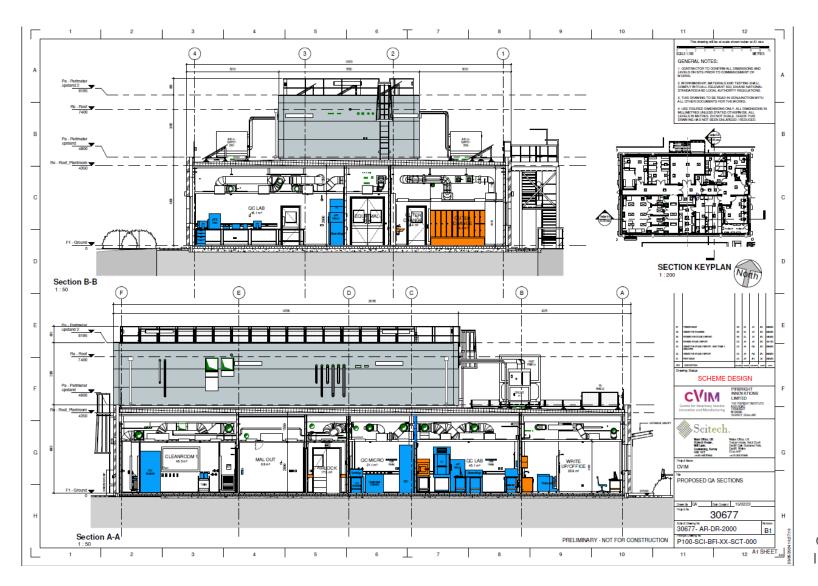


Roof



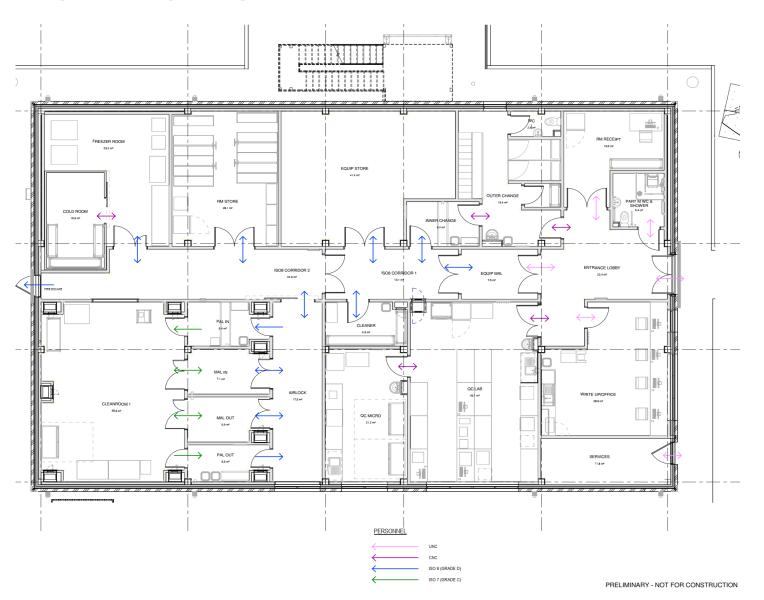


Sections



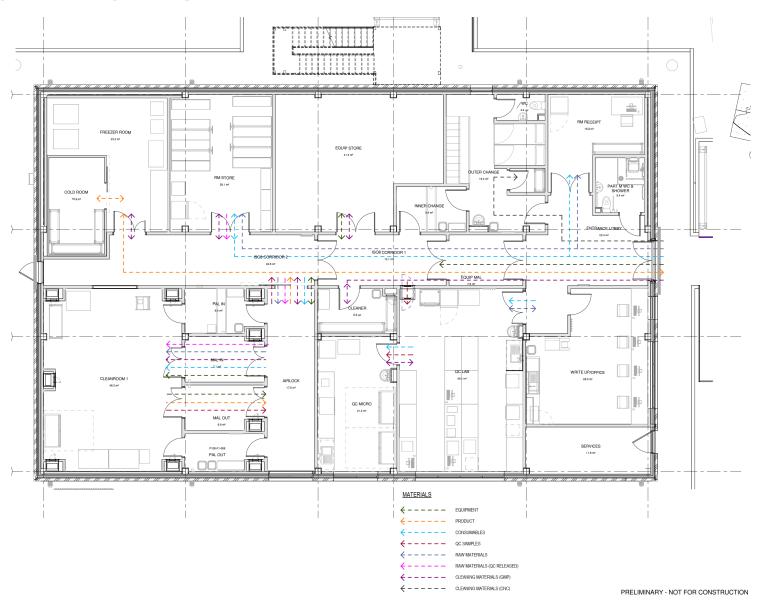


Personnel Flows



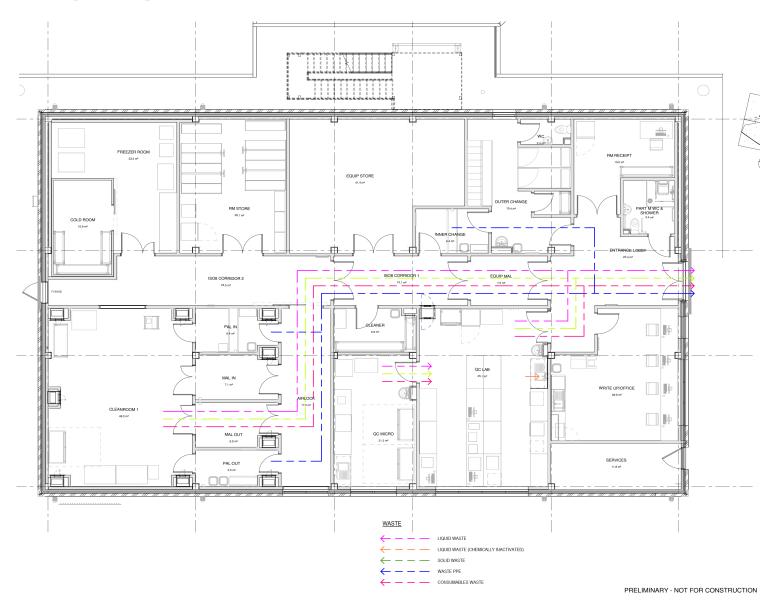


Material Flows





Waste Flows



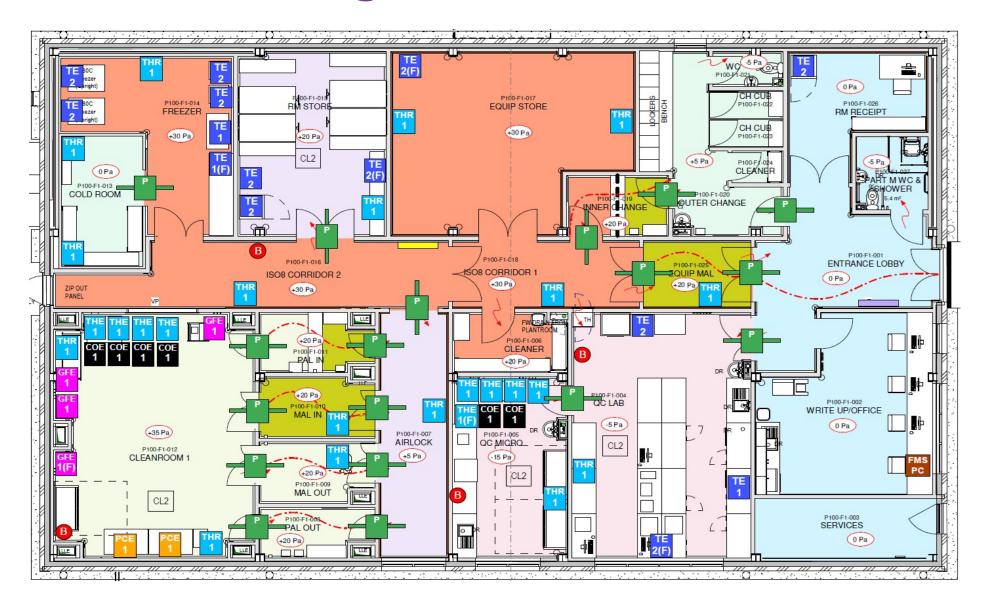


The Design: MEP Engineering

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Pressure Regime





BMS and Facility Monitoring System (FMS)

- Building to operate as a standalone facility using a dedicated BMS
- BMS to comply with Pirbright site wide standards: Schneider
- BMS integration with existing site wide BMS: Schneider
- FMS (Environmental Monitoring System) is a dedicated and standalone system to monitor and log the necessary GMP critical environmental parameters
- FMS to have local alarm notification inside the facility
- FMS to interface with Pirbright's site wide Alarm System Management system



Plant Floor and Roof

First Floor and Roof and includes location of:

- Pumps and heat exchangers for water systems including LTHW and CHW
- Air Source Heat Pumps
- Chiller
- Domestic water pump and tank arrangement for hot, cold, Cat5 and drinking water systems
- AHUs
- Air compressor plant
- IT Comms rack
- PV panels

Electrical Service Room on the ground floor (South East corner)

- Main electrical panel/termination point for incoming electrical supply
- Electrical panel for process equipment
- Manual transfer switch panel for mobile generator
- DC/AC PV cell inverter and G99 panel for PV installation



Critical Elements

- The cleanroom suite is served by a dedicated AHU; HEPA on intake and extract
- The cleanroom suite will be regularly fumigated using VHP vapour
- The ISO8 and CNC areas will use a common AHU; HEPA on intake and terminal HEPA for QC areas
- Mechanical ventilation for Unclassified areas
- Fire Strategy developed and reviewed with Building Control



The Design: Civil and Structure

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Critical Elements

- Piled Foundations with ground beams
- Precast concrete suspended floor
- Stick build steel frame
- Composite metal deck roof slab
- Attenuation Pond and discharge to Stanford Brook
- Ground Conditions: Made ground over Windlesham Formation to depth



Ecological Considerations

- CVIM site area has been cleared and reptile fences are in place
- Extensive ecological surveys have been completed including Great Crested Newt assessment
- Any vegetation clearance must undertaken as advised by the Ecological Reports
- It has been recommended that 1xrefugia and 2xhouse sparrow nest boxes are installed
- Good practice measures (such as covering excavations) are recommended to prevent entrapment of wildlife



Any Questions?

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Contract Structure and Requirements

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What are we looking for?

As part of the tender return the following is required:

- Appendix 1 ITT
 - Confidentiality Agreement needs to be complete to be present at bidders' day
 - Form of offer This document needs to be signed by two authorised persons
 - Parent Company Guarantee If applicable
- Appendix 2 Evaluation Please refer to Evaluation Methodology document prior to issuing responses to the following
 - Common Assessment Standard (CAS) Question set
 - Method statement question set and presentation brief
 - Selection Questionnaire (Part 3 SQ) document
 - Pricing Document please note commercial returns not in this format will not be considered
- Appendix 3 Contract
 - As part of your tender return acceptance of the contract terms must be given in writing
 - If amendments are to be considered, a schedule of amendments is to be provided for review by the team

The Contract

- NEC4 Option A Fixed price w/ Activity Schedule
- Addendum issued 11th of June, please confirm receipt of amended version (Rev 4)

Changes include;

- Contractor responsible for the entire design, and risk.
- Non selection of option X15
- No sectional completion
- Defining 'beneficiaries' with regards to collateral warranties
- Amending references to 'appendices' in lieu of annex's (As per our ITT folder structure)
- Contract data[] included, for example, delay damages (X7) of £1,500 per day and payment terms of 30 days (X16).



The Contract

- Amendments / Non exhaustive list of key clauses
 - The activity schedule linked to pricing document.
 - X7: Delay damages for Completion of the whole of the works are £1,500 per day.
 - X13: Performance bond amount is 10% of the Prices.
 - X16: Retention. The retention free amount is Nil. The retention percentage is 3%.
 - The Contractor may not give the Client a retention bond.
 - The Contractor takes on the role of Principal Designer and Contractor (Clause 11.2 C-H)
 - Requirements to be met by the Contractor before completion (Clause 11.2 (2))
 - Force Majeure clause amendment Clause 11.2(7A), 19.1-4
 - Ambiguities & inconsistencies (clause 17) note risk is the Contractors (clause 17.2.4)
 - The contractor is responsible for the site conditions (Clause 20.1), statutory undertaker works (Clause 20.7), licences, consents etc

Centre for Veterinary Vaccine Innovation and Manufacturing

The contractor is responsible for the entire design (Clause 22) Includes
 RIBA Stage 3' level of design' as prepared

The Contract

- Insurances, Warranties, Performance Bonds and Parent company guarantees (Clause 87)
 - Public Liability £10m each and every
 - Employers Liability £10m each and every
 - Professional Indemnity £5m each and every for duration of project and 12 years following PC
 - The insurance against loss of or damage to the works, Plant and Materials is to include cover for Plant and Materials provided by the Client for an amount of £10m.
 - PCG required (Option X4, Schedule 3) or Performance Bond 10% of the prices (X13, Schedule 4)
 - Contractor collateral warranty (Schedule 1)
 - Subcontractor warranties required (Schedule 2)

Other

Retention 3% - 50% release on PC, remainder 12 months post completion (X16)

Please review amendments fully



Any Questions?



Project Delivery



Key Elements to successful delivery

- Integrated Project Team approach
- Understanding of requirements
- Well integrated specialist design elements
- Quality Management
- Open and transparent pricing with full market engagement
- Open and transparent management of programme & risk
- Understanding of client CVV requirements



Integrated Project Team





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Contractor
Contractor
Design Team









Turner & Townsend alinea

Cost Manager





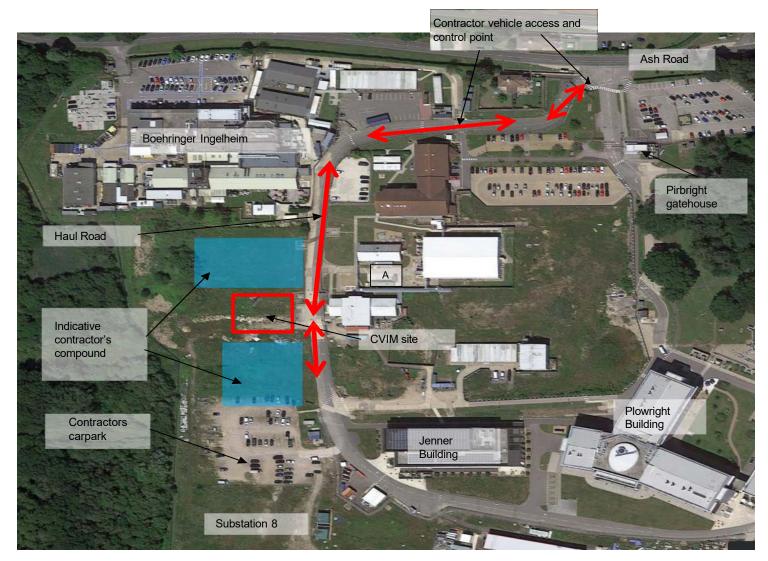






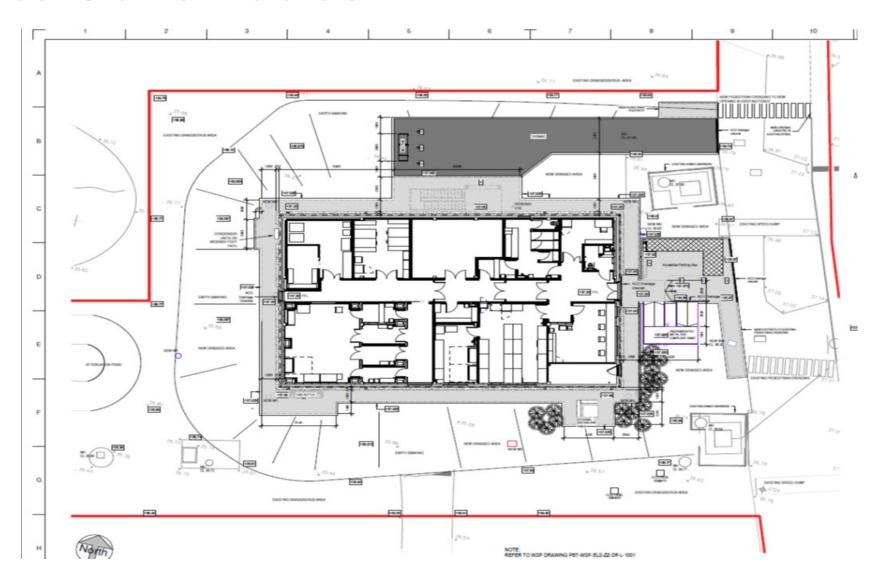


Site Logistics





Site Schematics





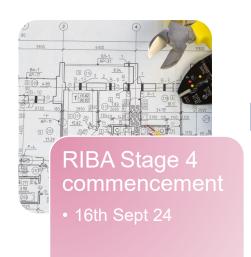
Key Tasks

Key Task/Milestone	Date				
Tender Stage					
Notice published (Open Procedure)	24 th May 2024				
Invitation to Tender issued through Contracts Finder or on Request	24 th May 2024				
Receipt of the signed Appendix K - Confidentiality Agreement	ASAP				
Full tender pack issued on receipt of signed Appendix K - Confidentiality Agreement					
Bidders Day	13 th June 2024				
Deadline for receipt of questions relating to the tender	12:00 (Noon) 21 st June 2024				
Answers to questions circulated	28 th June 2024				
Date for receipt of Tender Submissions	12:00 (Noon) 05 th July 2024				
Evaluation of Tender Submissions	8 th July - 19 th July 2024				
Notification of Evaluation Decision	26th July 2024				
Clarification Meetings/Interviews	5 th August 2024				
Contract Award Stage					
Notification of award decision & commencement of standstill period	16 th August 2024				
Expiry of 10-day standstill period	27 th August 2024				
Contract Award	28 th August 2024				
Contract Commencement Date	28 th August 2024				

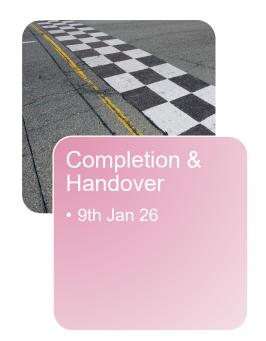


The Programme











Project Risks

Ref	Date Raised	Proximity	Risk Category	Risk Area	Risk Description	Impact Threat (1- 5) Opportun ity (-1 - 5)2	Likelihood (1 - 5)3	Risk status	Further Mitigation	Open / Closed
CVIM24	19.05.22 Feasibility	< 1 Month	Procurement	Procurement	Supply Chain. Tender returns are higher than the budget estimate.	4	3	18	- Market is sense checked at every cost update - Insolvencies is a market issue at present	Open
CVIM28	07.12.22	1-3 Months	Design development	Design development	Ambiguity in design information.	4	3	18	Full contractor review of stage 3 design information - regular design reviews to be undertaken	Open
CVIM07	19.05.22 Feasibility	3-6 Months	Construction	Procurement	Contractor Insolvency. Main contractor may file for insolvency.	3	3	13	- part of PQQ - Dunn & Bradstreet involvement - CRS involvement with collateral warranties	Open
CVIM13	19.05.22 Feasibility	3-6 Months	Financial	Financial	Unexpected contamination. Risk that during site clearance and construction investigation / survey unexpected contamination is found.	3	3	13	ground examination has not found any contamination Ground has been identified as poor, but the design has been completed on the premiss of poor ground conditions	Open
CVIM31	07.12.22	6-12 Months	Financial	Financial	Risk of inflation being outside of industry norms	3	3	13	The inflation calculations have been reviewed against the most recent data.	Open
CVIM46	07.12.22	> 12 Months	Construction	Compliance	Commissioning requirements not met	3	3	13	To be reviewed with commissioning contractor	Open
CVIM36	07.12.22	1-3 Months	Construction	Utilities	Encountering unidentified services or former use complexities within site boundary.	2	4	12	GI survey didn't find anything to raise cause for concern outside that of the poor ground conditions. The piling and structural design has been completed with this in mind.	Open
CVIM06	19.05.22 Feasibility	6-12 Months	Construction	Res	Disease Outbreak. Risk of site closure and Pirbright resource re- assignment due to disease outbreak response. - Pirbright site closure and resource reassign causing delay.	4	1	10		Open
CVIM08	19.05.22 Feasibility	3-6 Months	Stakeholders & Communication	Interdependencies	Logistics. Risk of logistical complications on campus. Caused by unexpected operational activities and future projects currently unknown.	3	2	9	8-week lookaheads and close collaboration with Pirbright clerk of works	Open
CVIM37	07.12.22	3-6 Months	Construction	Construction	Noise / dust / vibration during construction.	3	2	9	Noise dust vibration monotoring to be provided	Open
CVIM10	19.05.22 Feasibility	1-3 Months	Design development	Compliance	Net Zero Carbon. Risk that Net Zero Carbon target cannot be achieved within the budget and time allocation as required by planning and in support of BREEAM.	2	3	8	Not negatively impact NZC calculation through material or equpment choice	Open
CVIM14	19.05.22 Feasibility	3-6 Months	Design development	Scope	Environmental issues. Risk that environmental issues and ongoing monitoring, prevents timely site clearance / contamination.	2	3	8	Tree survey & ecology reports have been recieved and reviewed and implemented	Open



Any Questions?



Town Planning



Planning

- Masterplan approved July 2016
- Masterplan conditions need to be met: e.g.
 - CEMP
 - Hours of working
 - Pirbright Design Code
- CVIM Application (reserved matter) submitted May 2024



The Master Plan Vision





Any Questions?



Site Tour

