

Clean Modules Create Market Leading Stem Cell and Fertility Facility in Sheffield

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Clean Modules Ltd., the experts in modular prefabricated Clean Rooms, have completed a groundbreaking facility that combines stem cell research with clinical Invitro Fertilisation (IVF) treatment. Believed to be the first in the world, the unit includes EU GMP Grade B cleanroom laboratories together with Grade C operating theatres in a layout designed to optimise the complex workflow.

Built in a restricted 270m² site within the Jessop Wing of the Royal Hallamshire Hospital for the NHS and University of Sheffield, Clean Modules had a difficult brief and very tight sixteen week timescale to meet the demands of IVF patients waiting for treatment. The commission was for the complete package from planning, project management, build and full IQ OQ PQ validation.

Professor Harry Moore stated; “Clean Modules have created a pioneering new facility that will become the benchmark for other stem cell research centres in the UK and worldwide. We are delighted with the results for both the University and the Hospital.

Senior Embryologist, Rachel Cutting added, “The facility provides our patients with the considerate and straightforward approach, yet behind the scenes there is a complex cleanroom facility delivering a much needed service.”

Clean Modules utilised the experience gained constructing the flagship UK Stem Cell Bank (UKSCB) at the National Institute for Biological Standards and Control (NIBSC) to design and build the facility. This included interpreting the standards governing fertilisation and embryology and MHRA approval. Patient confidentiality was another critical consideration built into the design.

Clean Modules won this major new contract because of their specialisation in the use of cutting edge modular construction, which meant the project could be completed quickly, with minimal disruption to other hospital activities and to a cost effective budget.

The finished facility comprises of two segregated areas controlled by proximity card access. The clinical side includes two Grade C (ISO Class 7) Operating Theatres for egg retrieval and embryo transfer with bespoke one way transfer hatches connected to the culture preparation and IVF laboratories.

The research side has six Grade B (ISO Class 5) cleanroom laboratories each dedicated to a specialist task. In the Embryology, Andrology and Micromanipulation rooms, Class 2 Grade A cabinets are used to provide safe clean working environments. The Cryo Preservation Laboratory is equipped with controlled rate freezing and Dewar liquid nitrogen storage to hold stem cells prior to use.

To meet the stringent requirement covering stem cell research, including a stand alone air handling system, Clean Modules installed a complete Facility Monitoring System (FMS) validated to GAMP4 and CFR21 part 11. This sophisticated computer controlled data acquisition and monitoring system continuously checks particle levels, room pressures, temperature and humidity in the cleanrooms. A consequence of the development in monitoring systems is the absence of traditional Magnehelic pressure gauges.

The FMS system also monitors the liquid nitrogen storage vessels, freezers, refrigerators, incubators and gas levels to ensure conditions are optimised for cell preservation. Variation outside set parameters is covered by an alarm system monitored twenty four hours a day within the main hospital.

Clean Modules specialise in the design, construction and project management of Clean Room installations, controlled environments, clean air and conditioning systems. In addition to specialist biotechnology Clean Rooms, the company has considerable expertise in a wide range of life science applications including pharmaceutical, medical and hospital applications. They have also built up a considerable expertise in modular and mobile facilities including units pre-built and validated off site.

Clean Modules has grown dramatically in the last ten years, and routinely handles a wide range and size of projects, particularly in the healthcare and life science fields from a few thousand pounds up to multi-million pound projects. The company employs specialist, qualified engineers to design and manage projects and three full construction teams on site. In recent years it has completed over 30 hospital and healthcare related cleanroom suites.

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