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BESPOKE CLINICAL TRIAL MANUFACTURING COMPANY ERAMOL IS SET TO OPEN A NEW CUTTING-EDGE STERILE MANUFACTURING FACILITY AS PART OF ITS PUSH FOR BETTER GLOBAL HEALTHCARE.

Tomorrow's Medicine Today

PROJECT MANAGED BY: LIAM PYWELL

From the very outset, Eramol was built with quality, regulatory rigour, and patient safety at its core. Established by Qualified Persons Eric Che and Peter Mollison in 2013, the clinical trial manufacturing company has been shaped in the image of its Founders.

"Manufacturing quality, regulatory compliance, and attention to detail are embedded in every decision we make, from facility design and equipment selection through to day-to-day operations," explains Commercial Director Nathan Gray. "Our thorough process is a reflection of the people who founded this company and how they approach this line of work."

FULLY END-TO-END OFFERING

Eramol began as a virtual organisation, acquiring its first physical site in 2017 – a packaging and storage facility near Gatwick, UK. This milestone development was followed by the acquisition of a Dublin, Ireland facility, which acts as a gateway into the EU providing packaging and labelling, QP release, storage, and global distribution.

In 2021, Eramol expanded further with the acquisition of its first site in Sevenoaks, Kent. The non-sterile GMP facility specialises in tablets, capsules and oral liquids for both clinical trials and commercial supply. It also offers a fully end-to-end service, including formulation development, manufacturing, packaging, labelling, QC testing, QP release, storage and worldwide distribution.

"Our fully end-to-end offering is a key differentiator," Nathan remarks. "Fewer than 10% of CDMOs in Europe can support clients across manufacturing, packaging, labelling, QC testing, QP release, storage and global distribution under one roof. This significantly simplifies supply chains and reduces risk for our clients."

Most recently, in September 2023, Eramol acquired a second site adjacent to its first Sevenoaks facility, where the company is now building a new Annex 1–aligned sterile manufacturing site. When active, headline features of the new facility will include aseptic filtering and terminal sterilisation capabilities, a robust contamination containment strategy, and less than 1%-line-losses to minimise wastage.

Stage 1 of the facility is scheduled to be complete and operational in the first half of 2026 and represents the next step in Eramol's growth.

"Stage 1 of the build includes approximately 2,000ft^2 of cleanroom space and 7,000ft^2 of office and support areas, bringing Eramol's total footprint including its non-sterile facilities to over 30,000ft^2," Nathan explains. "The introduction of sterile manufacturing capability significantly expands our in-house offering, enabling a truly end-to-end service built on quality, underpinned by more than 40 years of combined QP experience across the business."

"Furthermore, planned for late 2027/2028, Stage 2 will see expansion into an additional 2,000ft^2 of fallow space, increasing sterile cleanroom capacity to approximately 4,000 ft^2. This will enable process scale-up through implementation of automation, support for Phase III and commercial manufacturing, as well as additional dosage formats such as cartridges and pre-filled syringes." >>

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Nathan Gray, Commercial Director, Eramol.

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MINIMISING DRUG PRODUCT LOSS AND MAXIMISING YIELDS

Initially, the new Sevenoaks site will focus on sterile vial fill-finish for Phase I and II clinical trials. The facility will offer both aseptic filtration (up to 5-litre batch sizes) and terminal sterilisation (up to 10-litre batch sizes), allowing Eramol to support a wide range of products including small molecules, biologics, peptides, oligonucleotides, ATMPs/Cell and Gene Therapies, viral vectors and cold-kit radiopharmaceuticals.

"Our new sterile facility has been designed in-house, supported by specialist external consultants and an experienced sterile manufacturing team," Nathan states. "A robust Contamination Control Strategy is central to the design, with a strong focus on minimising contamination risk and reducing product wastage.

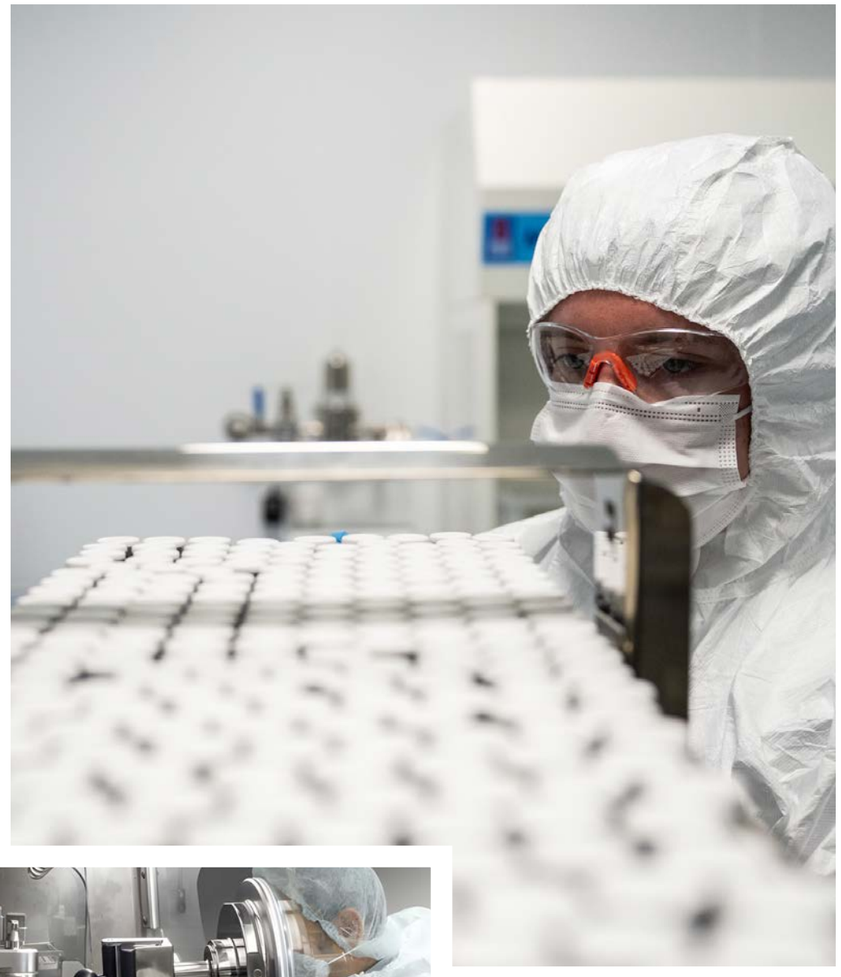
"Minimising drug product loss and maximising yields is increasingly important for early-stage biotechs working with scarce or high-value materials, which will make our new site a true differentiator," he adds. "We expect wastage levels under 1%, compared with European averages that are often 10% or higher." >>

ADAPTABLE, CLIENT-FOCUSED APPROACH

Privately-owned and private-equity-free, Eramol remains a relatively small and highly agile organisation. It is a feature that allows the company to adapt quickly, communicate closely, and respond flexibly to project changes. This adaptable, client-focused approach recently helped the organisation deliver on a complex packaging, labelling, QP release and distribution project for a Schedule 1 controlled drug programme.

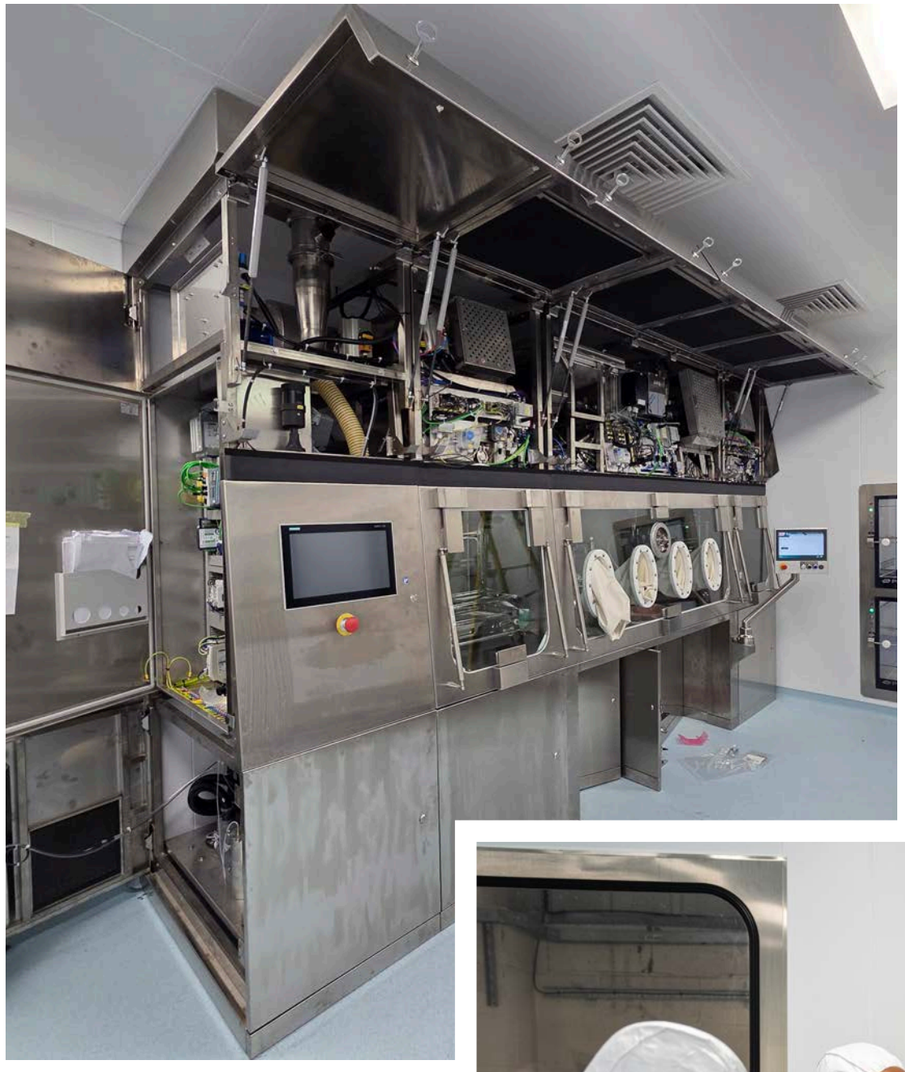
“The product in question was a combination nasal device with highly specialised packaging and regulatory requirements,” Nathan says. “It required distribution across the UK, EU, US and Australia, with 2–8 °C refrigerated storage requirements.

“To protect product integrity, we validated new nitrogen-sealing technology and introduced compressed air systems to enable storage in nitrogen-filled pouches, preventing oxidation. A bespoke carton design was developed to eliminate the risk



of unintentional device actuation during transport, while innovative booklet labelling solutions ensured full Annex 13 compliance despite extremely limited label space on the device.”

The project also involved multiple strengths and open-label phases, which Eramol addressed through clear colour-coded labelling strategies to ensure accurate dosing and site clarity. When German regulatory authorities requested urgent label text changes mid-study, Eramol implemented a flexible single-panel labelling solution and rapidly sourced updated



manufacturing and distribution services, offering bespoke capabilities and rapid turnaround times for small- to large-scale projects. Powering this proposition is a deft balance between people and technology.

“People are central to Eramol,” Nathan affirms. “We are driven by a shared purpose – delivering medicines to patients – and by building a collaborative, highly skilled team aligned around quality and compliance.

“At the same time, we actively embrace technology where it adds value. We are currently developing a new website that will include AI-enabled functionality, and across the business we are exploring how AI and automation can enhance efficiency while remaining fully GMP-compliant. ››

booklet labels, avoiding delays to clinical timelines.

“Post-Brexit regulatory complexity was managed seamlessly through Eramol’s UK and EU Qualified Persons and the establishment of an EU depot, enabling compliant QP release and distribution into both regions,” he adds. “This project highlights how Eramol brings together technical expertise, regulatory agility and global distribution to deliver fully integrated clinical supply solutions for complex programmes.”

UNBEATABLE VALUE PROPOSITION

As Nathan suggests, Eramol demonstrates an unbeatable value proposition for

"We also use technology to support our sustainability goals, including solar installation, EV charging infrastructure, and initiatives aimed at achieving carbon neutrality by 2035."

Moving forward, Eramol is ideally positioned to tackle the demands of the future in one of the world's most challenging and dynamic markets. With its new Sevenoaks facility preparing to open its doors, and supported by an eminent workforce and cutting-edge technology, Eramol is ready to enter its next phase of growth.

"Beyond bringing the sterile facility online, we are exploring expansion into the fallow space to support higher levels of automation, later-phase manufacturing, and additional delivery formats such as pre-filled syringes and cartridges," Nathan concludes. "We also expect our headcount to exceed 50 in the near term, and we have several further investments planned, including expansion of our Dublin facility.

"Meanwhile, we continue to see strong growth in advanced therapies, particularly cell and gene therapies and ATMPs, alongside increasing interest in radiopharmaceuticals. Our sterile facility has been designed with the flexibility to support these rapidly evolving modalities.

"Finally, and more broadly, clients are placing greater emphasis on communication, scientific expertise, and regulatory support, as well as on protecting their drug products by minimising wastage and contamination risk and moving away from a transactional outsourced manufacturing slot model to a collaborative partnership-based model. These are areas where Eramol has always focused, and where we believe our QP-led approach adds real value."

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