QUENVALE
ASEPTICS

CAPABILITIES 2026

Sterile fill-finish services for biologics

Clinical to commercial · Liquid and lyophilised · Vials, cartridges and ready-to-use nests



Sterile fill-finish, built around the isolator.

Three isolator lines, three freeze-dryers and one quality system, twenty minutes apart at Ardelle Park and Kessmoor.

3
isolator filling lines

41 M
units of capacity a year

0
critical findings since 2019

QUENVALE.EXAMPLE

WELCOME

Small enough to know your molecule. Experienced enough to launch it.

Quenvale Aseptics is an independent contract manufacturer of sterile injectables. We fill, freeze-dry, cap and inspect drug product for biotech companies that want a partner who behaves like part of their own team.

When Nerevia's head of CMC first called us, she did not ask about capacity. She asked who would pick up the phone if a stopper bowl jammed at two in the morning during her first clinical batch. It is the question we hear most often.

We are a contract manufacturer of a deliberately modest size: three isolator filling lines, two sites twenty minutes apart, and a team of 212 people who know each client molecule by name rather than by order number. Every programme has one project manager from the first feasibility call to the last commercial batch, and that person sits on the same corridor as the line supervisors, the microbiologists and the qualified persons who release your product.

Size alone is not a strategy. What makes a small site credible is the engineering underneath it: we moved every aseptic operation into closed isolators long before the revised Annex 1 made barrier technology the expectation, and we have spent the years since learning to change formats quickly and to run a freeze-dryer park without a queue.

This brochure describes what we fill, how the process runs from vial washing to final inspection, how much capacity is genuinely available in 2026 and 2027, and how our quality system has fared under inspection. It also tells the story of one programme, because a case study says more about a partner than a list of equipment.

If you are planning a first-in-human study, a transfer from an existing supplier or a commercial launch, we would be glad to talk. The numbers on the back cover reach people, not a switchboard.

Mireille Achterberg
CHIEF EXECUTIVE OFFICER

QUENVALE AT A GLANCE

1997
Founded at Ardelle Park as a hospital-pharmacy spin-out

3
Isolator filling lines, Grade A inside, Grade C background

41 M
Units of annual fill capacity across vials and nests

212
Employees, 38 of them in quality and microbiology

64
Client molecules filled since 2016, eleven now commercial

IN THIS BROCHURE

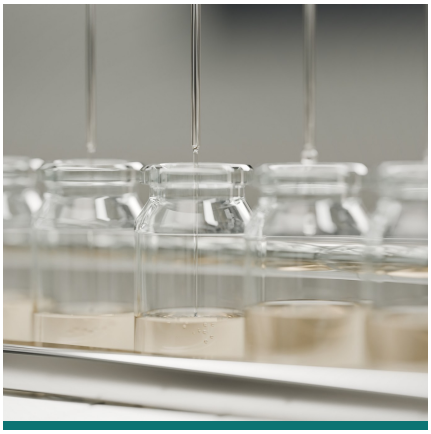
01 Services at a glance 3
02 Liquid fill and lyophilisation 4
03 The process, step by step 6
04 Case study: NV214 7
05 Capacity and facilities 8
06 Quality and compliance 9
07 Working with us 11
08 Contacts 12

Quenvale Aseptics is a fictional company. Every name, figure, quotation and address in this brochure was invented for ToupieSoft as sample content; the photographs are original 3D renders.

SERVICES

One partner from vial wash to final inspection

Six capabilities under one roof and one quality system. Most clients use four or five of them; all of them are available for clinical and commercial supply.



01 Liquid vial filling

Peristaltic and rotary-piston dosing from 0.2 to 100 mL, with 100 % in-process weight checks on clinical lines and statistical checks at commercial speed. Tubular or moulded glass from 2R to 100R, with nitrogen overlay on request.



02 Lyophilisation

Three freeze-dryers with a combined 44 m² of shelf, automatic loading through the isolator and cycle development in our own pilot unit. We transfer existing cycles or build robust new ones from the thermal characterisation of your formulation.



03 Ready-to-use nested formats

Pre-washed, pre-sterilised vials and cartridges in tubs, de-bagged and de-lidded inside the isolator. Ready-to-use components take washing and depyrogenation off the critical path, so small clinical batches can start within days of delivery.



04 Stoppering

Vibration-free stopper feeds, partial stoppering for lyophilised products and full stoppering with servo-controlled insertion depth. Every stopper position is verified by camera before the vial leaves the isolator.



05 Capping and crimping

Aluminium flip-off seals applied under Grade A air, with residual seal force monitored on every vial. Cap colours, embossing and tamper-evident variants are qualified for each programme and stored as recipes.



06 Single-use fluid paths

Pre-assembled, gamma-irradiated product paths from bulk bag to filling needle. No cleaning validation, no carry-over risk, and a changeover between products measured in hours rather than days.

Every service runs under one quality system, one electronic batch record and one project manager, from the first feasibility call to the last commercial batch.



Freeze-dryer shelves, production unit LY-3, Kessmoor. Render.

LIQUID FILL AND LYOPHILISATION

Two ways to keep a biologic stable

Most of the molecules we fill leave Ardelle Park as solutions. Monoclonal antibodies, enzymes and peptides that remain stable for two or three years under refrigeration do not need the cost and cycle time of freeze-drying, and a well-designed liquid process is faster to transfer and easier to scale. Our three lines dose by peristaltic pump or by rotary piston, chosen according to the viscosity and shear sensitivity of the product rather than the habits of the site.

Each line weighs containers before and after filling. On clinical batches every vial is checked; at commercial speed the system samples a statistically defined share and corrects the dose in real time. Fill-weight data are stored with the electronic batch record, so a reviewer sees the full distribution rather than a summary table.

Protecting the product

Shear, foaming and oxygen are the three things that most often damage a sensitive solution between the bulk bag and the closed vial. We qualify needle geometry and pump speed with each new molecule, overlay with filtered nitrogen when the formulation requires it, and record the time from sterile filtration to stoppering for every batch. Hold-time studies are planned with the client during technology transfer instead of being discovered during the first validation run.

Formats and changeovers

Lines Q1 and Q2 accept tubular and moulded vials from 2R to 100R. Line Q3 at Kessmoor adds nested vials, cartridges and prefilled syringes in ready-to-use tubs. Format parts are product-dedicated where the risk assessment calls for it and colour-coded throughout, and a complete changeover, decontamination included, takes eleven hours on average.

LIQUID FILL IN FIGURES

0.2–100 mL
fill-volume range, vials 2R to 100R

± 0.5 %
fill accuracy at nominal volume, 1 σ

11 h
average full changeover, decontamination included

300/min
peak speed, line Q2



FREEZE-DRYING

Freeze-drying without the queue

Cycle development

Roughly a third of our programmes are lyophilised. Freeze-drying protects molecules that would otherwise degrade in solution, but a poorly designed cycle can waste days of equipment time or produce cakes that collapse, crack or reconstitute slowly. Our laboratory measures the collapse and glass-transition temperatures of each formulation before any cycle is drafted, and a pilot freeze-dryer with the same shelf geometry as our production units lets us prove a cycle at small scale before it reaches the plant.

Loading and unloading

Vials travel from the filling isolator to the lyophiliser on an automatic loading system that never leaves Grade A conditions. Partially stoppered vials are pushed onto the shelves row by row, the chamber is closed and the cycle starts without an operator entering the zone. At the end of the cycle the shelves close the stoppers under vacuum or nitrogen, and the same system returns the vials to the capping line.

Capacity that is actually free

Freeze-dryer time is the bottleneck at most contract sites. We added a third production unit in 2025 precisely so that new programmes could be scheduled within a quarter rather than a year, and we publish the booked share of each unit to our clients every month. When a cycle runs long, the planners know the knock-on effect the same afternoon.

> "A cycle that runs four hours shorter is worth more to a client than a fourth freeze-dryer."
>
> DR AMAIA LINDQVIST, HEAD OF LYOPHILISATION DEVELOPMENT

THE LYOPHILISER PARK

LY-1 Ardelle Park

9.2 m² shelf area, installed 2018. Shares its shelf design with the pilot unit used for cycle development.

LY-2 Ardelle Park

9.2 m² shelf area, installed 2021. Dedicated to clinical campaigns.

LY-3 Kessmoor

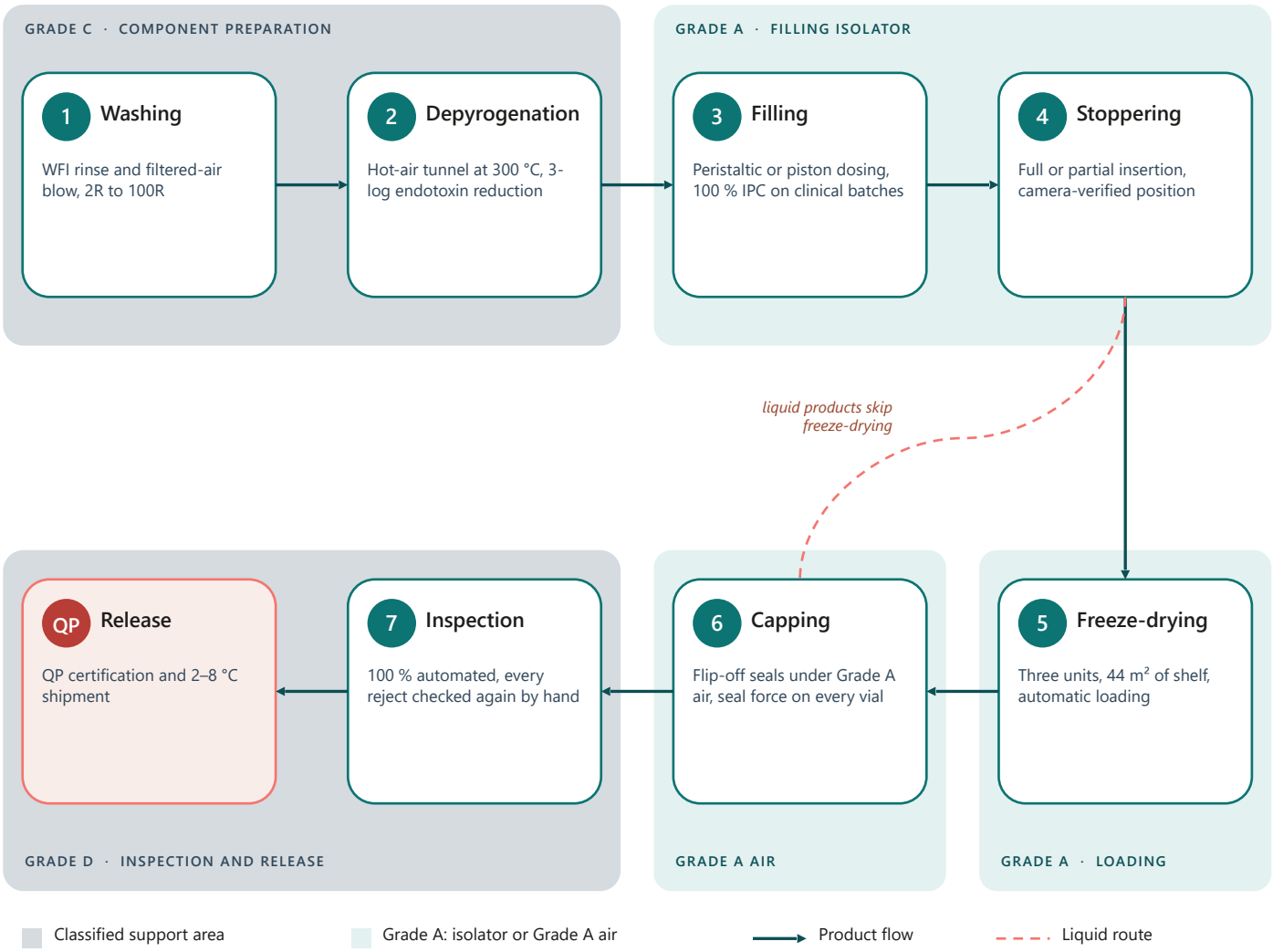
26.0 m² shelf area, installed 2025. Commercial scale, 120,000 2R vials per load.

COMMON SPECIFICATION

- Shelf temperature −55 to +60 °C
- Condenser −80 °C
- Clean and steam in place
- Nitrogen backfill, stoppering under vacuum
- Automatic loading in Grade A
- Wireless product probes
- Cycle data in the batch record

THE PROCESS

Seven steps from washed vial to released batch



One barrier, end to end

Filling, stoppering and the transfer to the freeze-dryers all take place inside closed isolators that are decontaminated with vaporised hydrogen peroxide before every campaign. Operators work through glove ports, and nobody enters the Grade A zone during production. Components arrive either washed and depyrogenated on the line or as ready-to-use nests that are sterile in their tubs.

Controls at every step

Each step in the diagram has its own critical parameters and alarm limits, and all of them are recorded against the batch: rinse conductivity, tunnel temperature profile, fill weight, stopper position, shelf temperature and chamber pressure, residual seal force and inspection reject counts. A deviation is opened automatically when a value leaves its validated range.

Monitoring that means something

Viable and non-viable particles are sampled continuously inside every isolator, and glove integrity is tested before and after each campaign. Trends are reviewed weekly by microbiology and production together, so a slow drift is noticed long before it becomes an excursion.



CASE STUDY · NEREVIA THERAPEUTICS

From 400 clinical vials to a commercial launch in 26 months

How Nerevia Therapeutics moved NV214, a lyophilised antibody for a rare inflammatory disease, from a first-in-human batch to its first commercial campaign without changing filler.

Nerevia Therapeutics entered the spring of 2023 with a promising antibody, a Phase I protocol approved by two ethics committees and no filling partner. Its previous supplier, a large multi-product site, had offered a slot nine months away. NV214 was a humanised IgG1 formulated at 100 mg per mL, a concentration that makes solutions viscous and difficult to dose, and the molecule was known to aggregate if it spent too long in solution at room temperature.

"We needed someone who would treat four hundred vials as seriously as four hundred thousand," recalls Dr Ilse Marchetti, Nerevia's vice-president for chemistry, manufacturing and controls. "And we needed them to still be the right partner if the trial worked."

A first batch in eleven weeks

Quenvale's project team began with a two-week feasibility study. The formulation was characterised in the development laboratory, which measured a collapse temperature of −31 °C, low enough to rule out the aggressive primary-drying conditions the previous supplier had proposed. A conservative cycle of 61 hours was drafted, tested twice in the pilot freeze-dryer and transferred to production unit LY-1.

Viscosity was the second challenge. At 100 mg per mL the solution resisted the peristaltic pump at the speed needed to keep the line balanced, and dosing accuracy drifted towards the end of each tray. The engineers replaced the standard silicone tubing with a thicker-walled

Continued on page 10 →

THE BRIEF

CLIENT
Nerevia Therapeutics, a 140-person biotech

MOLECULE
NV214, a humanised IgG1 at 100 mg/mL

FORMAT
10R vials, lyophilised, 2 mL reconstituted

SCALE
412 vials to 40,150 vials a batch

TIMELINE
26 months, first call to approval

LINE
Q2 at Ardelle Park, LY-1 then LY-3

CAPACITY AND FACILITIES

Capacity you can book, not capacity on paper

41 M
units of annual fill capacity, net of maintenance and media fills

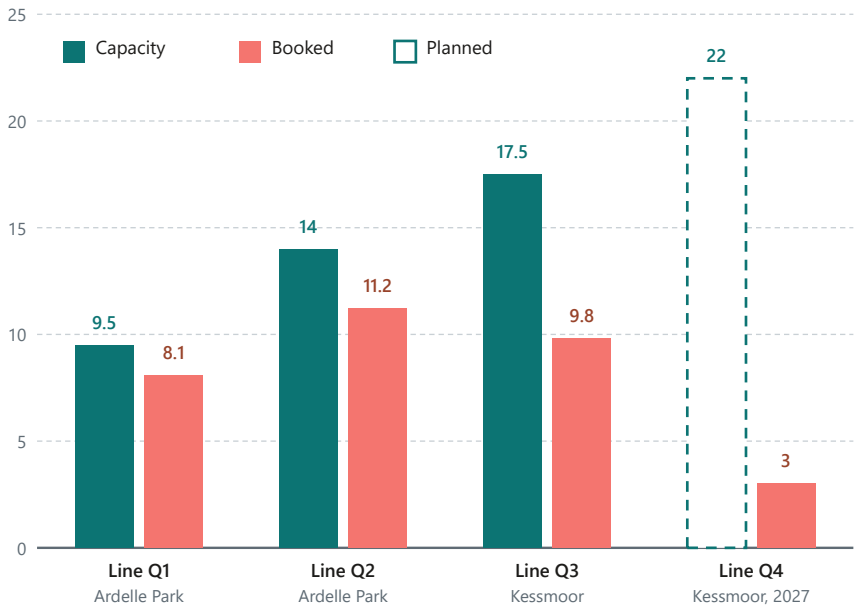
2,450 m²
of classified space across two sites

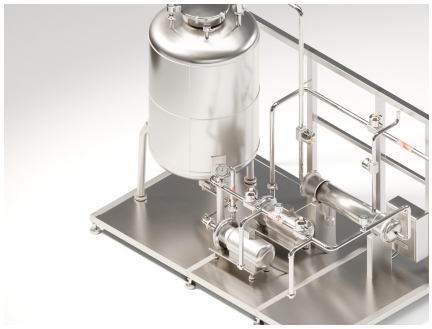
44 m²
of production freeze-dryer shelf

6 m³/h
water for injection by vapour compression

ANNUAL FILL CAPACITY BY LINE, 2026

Million units a year; booked share as of September 2026





Water-for-injection skid, Kessmoor: vapour compression, 6 m³/h, hot loop at 80 °C. Render.

Every figure on this page is a bookable number. Capacity is quoted per line and per year after planned maintenance, media fills and requalification, and the booked share comes straight from our planning system.

ARDELLE PARK

1,500 m² classified

Lines Q1 and Q2: vials 2R to 100R, liquid and lyophilised. Freeze-dryers LY-1 and LY-2, development laboratory, QC microbiology and the Quenvale Academy training isolator.

KESSMOOR

950 m² classified

Line Q3: ready-to-use nested vials, cartridges and syringes, with freeze-dryer LY-3. Warehouse with 2–8 °C and −20 °C storage, and the site's water-for-injection plant.

KESSMOOR Q4

Qualification Q3 2027

A fourth isolator line for high-volume nested formats at up to 400 units a minute. Launch capacity on Q4 can be reserved now, with engineering runs scheduled in the first quarter after qualification.

FREEZE-DRYER BOOKINGS, NEXT SIX QUARTERS

	Q4 26	Q1 27	Q2 27	Q3 27	Q4 27	Q1 28
LY-1	96 %	92 %	85 %	70 %	55 %	40 %
LY-2	88 %	90 %	74 %	60 %	42 %	30 %
LY-3	71 %	64 %	58 %	46 %	31 %	18 %

Share of shelf time booked. Paler cells are open for new programmes.

QUALITY AND COMPLIANCE

Inspected often, surprised rarely

A quality system built for barrier technology

Our quality management system was rewritten in 2022 around the contamination control strategy that the revised Annex 1 requires. Every risk to sterility is assessed once, at the level of the facility, and then traced to the controls on each line: isolator leak rates, the indicators of every decontamination cycle, glove integrity, environmental monitoring and media fills.

Data you can review

Batch records, environmental data and deviations are electronic and linked, so a client auditor can follow a single vial from component receipt to release in an afternoon. Audit trails are reviewed before every batch release and summarised in the annual product review.

People

Thirty-eight of our 212 employees work in quality assurance, quality control or microbiology. Every operator who works at an isolator completes the Quenvale Academy foundation course and requalifies twice a year in an aseptic process simulation.

INSPECTION AND AUDIT HISTORY

Authority or audit	Site	Scope	Most recent		Next due
			Date	Outcome	
Regulatory inspections					
EU GMP authority, routine	Ardelle Park	Sterile liquids and lyophilisates	Nov 2025	No critical or major	2028
Pre-licence inspection, NV214	Ardelle Park	Line Q2, LY-1, LY-3	Mar 2025	Two minor, closed	–
EU GMP authority, new line	Kessmoor	Line Q3, ready-to-use formats	Feb 2026	Certificate issued	2029
Third-country accreditation	Ardelle Park	Foreign-manufacturer listing	Sep 2024	Accredited	2029
Client audits and certifications					
Client audit, global pharma	Ardelle Park	Full GMP and data integrity	Jan 2026	No major findings	2027
Client audit, biotech	Kessmoor	Technology-transfer readiness	May 2026	Approved supplier	2027
Cleanroom recertification[1]	Both sites	All classified areas	Jun 2026	Passed	Jun 2027
Environmental management[2]	Both sites	Site operations	Apr 2026	Certified	Apr 2029

[1] ISO 14644-1 particle classification of all Grade A to D areas. [2] ISO 14001 environmental management system. Outcomes are summarised; full reports are available to clients under confidentiality agreement.

CONTAMINATION CONTROL STRATEGY

1 Barrier

Closed isolators, VHP decontamination with chemical and biological indicators, glove integrity tested before and after every campaign.

2 Process

Validated parameters with automatic deviation triggers, media fills every six months per line, and continuous viable monitoring.

3 People

Academy-trained operators, twice-yearly requalification and a no-blame reporting culture for near misses at the isolator.

CASE STUDY · CONTINUED FROM PAGE 7

grade, reduced the needle diameter and introduced a short dwell before the needle withdrew, which eliminated the droplets that had been forming on the vial neck. Fill-weight variation fell from 2.1 % to 0.6 % relative standard deviation.

The first clinical batch, 412 vials of 10R glass, was filled eleven weeks after the feasibility kick-off. Quenvale's qualified person released it nine days later.



Flip-off seals on line Q2. Residual seal force is measured on every vial; the NV214 campaigns run with coral caps that identify the commercial presentation. Render.

Scaling without starting again

The Phase I results arrived early in 2024, and they were better than Nerevia had dared to plan for. The board decided to run Phase II and the registration study in parallel, which meant that batch sizes would rise from a few hundred vials to more than ten thousand within a year, and that the process filed with the regulators would have to be the commercial process from the start.

Many programmes change filler at this point. A clinical site that is comfortable with small batches often lacks the capacity or the automation for commercial volumes, and the transfer to a new manufacturer adds comparability studies, new stability data and months of delay. Nerevia did not want that delay, and Quenvale had designed its lines so that it would not be necessary.

> "We needed someone who would treat four hundred vials as seriously as four hundred thousand."
>
> DR ILSE MARCHETTI, VICE-PRESIDENT CMC, NEREVIA THERAPEUTICS

Line Q2, where NV214 had been filled since the first batch, runs at up to 300 vials a minute with the same isolator, the same filling technology and the same freeze-dryer loading system used for the clinical work. Scaling therefore meant longer runs and a larger lyophiliser rather than a new process. The team qualified production unit LY-3 at Kessmoor for the larger batches and showed, in three engineering runs, that the 61-hour cycle produced identical cake structure, residual moisture and reconstitution time in the larger chamber.

Fewer interventions, better data

Scaling up also exposed a problem that small batches had hidden. During the first long run, operators intervened through the glove ports fourteen times to clear fallen vials at the infeed starwheel. Each intervention followed the validated procedure, but every one is a potential route for contamination and a line in the deviation log that inspectors will read.

Quenvale's engineers filmed the infeed at high speed and found that the 10R vials tipped when the accumulation table pushed them into the starwheel faster than the wheel could index. A modified guide rail and a revised speed profile for the table reduced interventions to two per run. "That change did more for our sterility assurance than any amount of additional monitoring," says Hendrik Vos, Quenvale's head of operations.

Validation and inspection

Process performance qualification took place in the autumn of 2024: three consecutive commercial-scale batches of 38,600, 40,150 and 39,880 vials. All three met their specifications, and media fills on line Q2 continued to show zero contaminated units across 31,000 filled containers.

The pre-approval inspection in March 2025 lasted four days and covered the filling line, the freeze-dryers, the environmental monitoring programme and the data-integrity controls of the electronic batch record. It closed without critical or major observations. NV214 received its marketing authorisation in June 2025, twenty-six months

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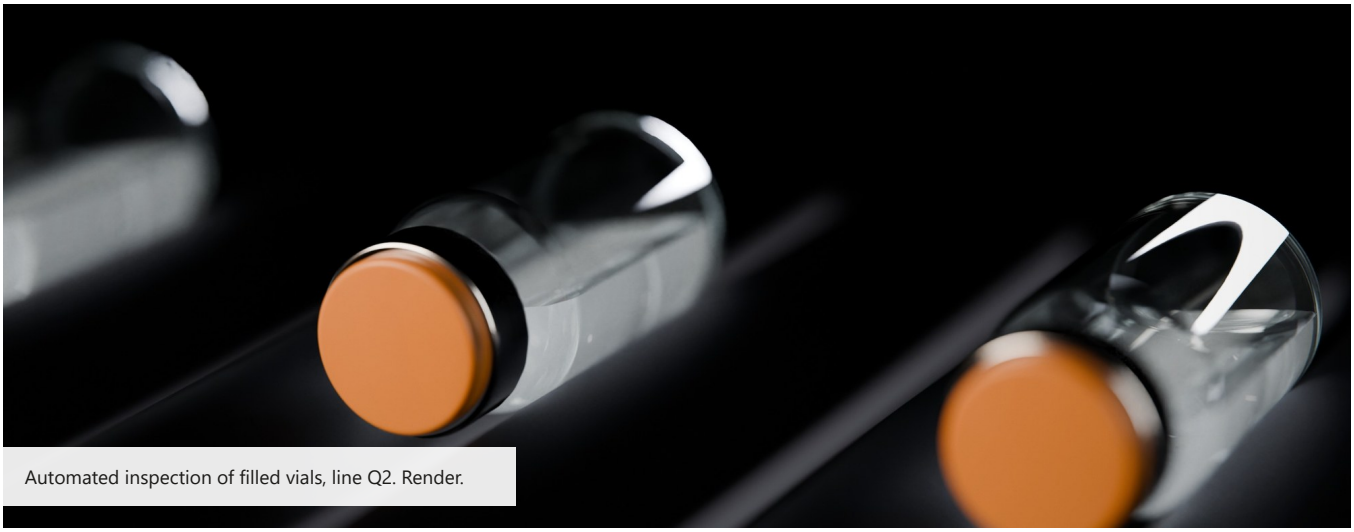
CASE STUDY · CONTINUED FROM PAGE 10

after the first call to Quenvale.

What came next

Nerevia now fills NV214 in six campaigns a year, with a safety-stock agreement that reserves freeze-dryer capacity for an additional campaign at three months' notice. The two companies meet every quarter to review trends in yield, deviations and lead times, and Quenvale has begun the technology transfer of Nerevia's second molecule, a subcutaneous formulation that will run on the ready-to-use line at Kessmoor.

"What I value most is that nothing had to be relearned," says Dr Marchetti. "The people who filled our first four hundred vials are the people who filled our launch batches. They knew the molecule, they knew its quirks, and they knew us."



Automated inspection of filled vials, line Q2. Render.

NV214 IN NUMBERS

26
months from the first call to marketing authorisation

0.6 %
fill-weight RSD after the tubing and needle changes, down from 2.1 %

14→2
glove-port interventions per commercial run

0
critical or major observations at the pre-approval inspection

WORKING WITH US

Five stages, one project manager

Enquiry	Feasibility	Transfer	Clinical	Commercial
Day 1	2 weeks	8–12 weeks	From week 11	From month 6
One project manager, named from the first call	Formulation data, risk review and a fixed quotation	Recipes, cycles, analytical methods, engineering runs	Batches released by our qualified persons	PPQ, inspection support and booked supply

Start with a two-week feasibility study. Send us your formulation data and target presentation; you will receive a risk review, a timeline and a fixed quotation within ten working days.



QUENVALE
ASEPTICS

Talk to us about your next batch

BUSINESS DEVELOPMENT

Sofia Brennan-Okafor

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ARDELLE PARK

Lines Q1 and Q2, LY-1, LY-2

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KESSMOOR

Line Q3, LY-3, Q4 from 2027

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+44 1632 960 571
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Quenvale Aseptics SA is a fictional contract manufacturer. Names, figures, quotations, addresses and telephone numbers (from the range reserved for drama) are invented sample content produced for ToupieSoft; the images are original 3D renders.