TEST TRIANGLE
Trusted Partner in IT Consulting

Case Study

Amneal Pharmaceuticals

Client Overview

Amneal Pharmaceuticals is a global pharmaceutical company with a strong focus on inhalation products, particularly Metered Dose Inhalers (MDIs) and Dry Powder Inhalers (Paediatric). At the time of engagement, Amneal's inhalation portfolio consisted of seven products, with:

- Two products approved and in commercial manufacture
- Five MDI products progressing through clinical trials

To support this expanding pipeline, Amneal embarked on a significant scale-up programme, including the introduction of high-speed production lines, new equipment, facility and cleanroom modifications, and associated validation and quality system enhancements.

The Dry Powder (Paediatric) segment was already in active production, with potential future upgrades anticipated.
In parallel, Amneal was progressing with laboratory modernisation, increasing the use of electronic systems. This made Computer System Validation (CSV), data integrity, and regulatory compliance critical capabilities within the Quality and Laboratory functions.

Quality Organisation & Resourcing Context

Amneal's Quality Assurance team comprised 14 personnel, made up of both permanent employees and contractors.
Test Triangle had an established relationship with the site, having previously:

- Successfully placed permanent QA professionals who remain with Amneal.
- Supplied contract QA resources on six-month contracts:
  - One contractor extended to two and a half years, providing long-term continuity.
  - Another completed the initial contract before relocating to Dublin.

This history positioned Test Triangle as a trusted recruitment partner with a deep understanding of Amneal's site, culture, and compliance expectations.

Test Triangle Recruitment Approach

Test Triangle followed its proven private-sector recruitment model, ensuring speed, quality, and compliance throughout the process:

1. Requisition Intake.
2. Detailed role requirements, regulatory expectations, and site-specific needs were confirmed with Amneal stakeholders.
3. Targeted Sourcing & Screening.
4. Candidates were sourced through Test Triangle's pharmaceutical network, with rigorous screening for:
   - Hands-on GMP experience.
   - Regulatory knowledge (EU GMP, FDA, HPRA).
   - Technical competence and cultural fit.
5. Amneal reviewed shortlisted candidates and conducted interviews.
6. Contracting & Onboarding.
7. Once a candidate is selected, the Finance Department are looped in to manage service agreements and ensure a smooth onboarding process.

Recruitment Challenge

The rapid expansion of Amneal's inhalation manufacturing capabilities created an immediate need for:

- Highly skilled QA and QC professionals.
- Hands-on GMP expertise across manufacturing, validation, laboratory, and microbiology.
- Candidates capable of operating in a fully onsite, highly regulated environment.
- Flexibility to support both permanent growth and contract-based project work.

In addition, the client required Production and Manufacturing personnel to support pharmaceutical production lines during scale-up, particularly individuals experienced in cleanroom operations and regulated batch manufacturing.

Advanced Sourcing & Talent Reach

To support the speed and scale required for Amneal's expansion, Test Triangle has its own realtime talent platform called Techfynder with technology-enabled sourcing capabilities to ensure broad market coverage and rapid access to qualified GMP talent.

We also used an API-based recruitment distribution system that publishes approved roles simultaneously across selected specialist job portals. In parallel, each role is matched against Techfynder's internal talent database of over 2 million candidates, built across the pharmaceutical, life sciences, and regulated manufacturing sectors. This integrated approach ensures:

- Wide and immediate market visibility for each role
- Targeted access to pre-screened GMP, QA, QC, validation, and manufacturing professionals
- Faster shortlisting without compromising on compliance or quality
- Reduced time-to-hire during scale-up and inspection-critical phases

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Amneal Roles Delivered

Test Triangle supported Amneal with both permanent and contract hires across a wide range of fully onsite GMP roles at the Co. Tipperary manufacturing site, including:

Quality Assurance & Validation

- QA Validation Specialists (Equipment, Facilities, Utilities, Cleaning & CSV). Oversight of IQ/OQ/PQ activities, Validation Master Plans, MACO calculations, data integrity, Annex 11 compliance, and regulatory inspections (EU GMP, FDA, HPRA).
- QA Validation Specialist – Laboratory / CSV (Contract). Validation of LIMS and Empower systems, full CSV lifecycle (URS through PQ), audit readiness, and data integrity support.

Quality Systems & Operations

- Document Controllers. EDMS implementation, GMP document control (SOPs, batch records, validation documentation), archival, audit readiness, and QMS support.
- IPQA (In-Process QA) Specialists. Batch record review, line clearance, in-process checks, sampling, deviation investigations, process audits, and direct production floor support.

Outcome & Value Delivered

Through this engagement, Test Triangle enabled Amneal Pharmaceuticals to:

- Scale Quality and Production teams in line with a growing inhalation product pipeline.
- Maintain regulatory compliance during major facility and system upgrades.
- Secure both short-term contract expertise and long-term permanent talent.
- Ensure continuity and stability during validation-heavy and inspection-critical phases.

The successful retention of previously placed candidates and long-term contract extensions further demonstrated the effectiveness of Test Triangle's tailored, relationship-driven recruitment approach.

Quality Control & Laboratory

- Quality Control Analysts. Routine and non-routine testing, environmental monitoring, cleanroom support, GLP/GMP compliance, and cross-functional collaboration.
- Microbiologists. Contamination control, environmental monitoring, water systems (PW/WFI), microbiology validation, laboratory setup, audit support, and training.

Production & Manufacturing Support

In addition to Quality roles, Test Triangle also supported Production / Manufacturing requirements, sourcing candidates with:

- Hands-on pharmaceutical manufacturing experience.
- Strong cleanroom and GMP compliance background.
- Exposure to batch manufacturing, production line operations, and documentation.
- Ability to support regulated production environments during scale-up and routine operations.

Why Pharmaceutical Companies Choose Test Triangle

Pharma and life sciences organisations partner with Test Triangle when they need:

- Access to scarce GMP and validation talent.
- Recruiters who understand quality, regulatory, and manufacturing realities.
- Support during scale-up, transformation, and inspection-critical periods.
- A trusted partner committed to compliance-driven hiring.

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