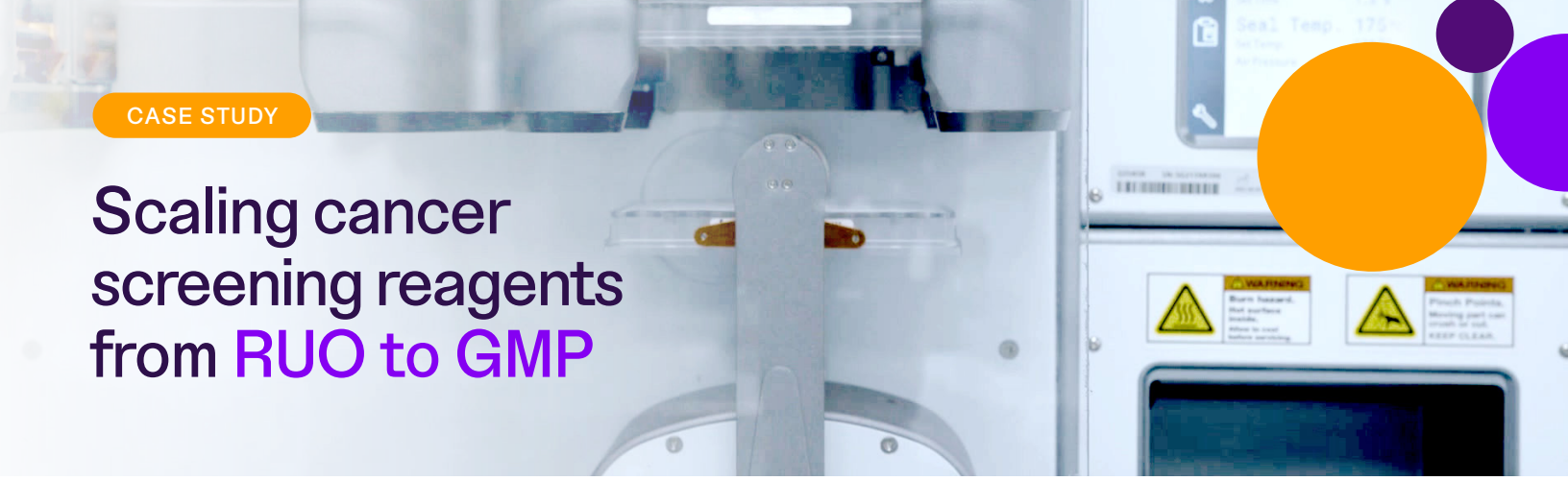


CASE STUDY

Scaling cancer screening reagents from RUO to GMP

A developer of blood-based cancer screening tests needed a reagent partner who could scale with their program. See how we took 23 custom reagents from first hand-filled RUO runs to a validated, automated GMP fill line within a year, with continuous supply throughout.

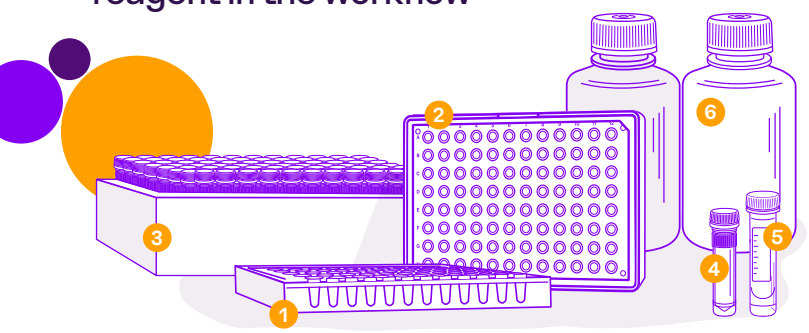
> Today, as their long-term manufacturing partner, we produce all 23 custom components as GMP products, each with its own specifications, release testing, and pack-out. At the center is an automated fill, seal, and label line we engineered, qualified, and validated for them, handling partial fills and multi-reagent plates.

23 custom components
Plates, tubes, and bottles, each released to its own specifications

20–600 µL per well
From low-fill PCR plates to deepwell plates

3 lots per order
Equal quantities to support validation

One partner for every reagent in the workflow



1. **LOW-FILL SKIRTED PCR PLATES:** Fill volumes from 20 to 180 µL per well
2. **HIGH-FILL DEEPWELL PLATES:** Fill volumes from 100 to 600 µL per well
3. **INDIVIDUAL TUBES IN 96-POSITION RACKS:** Labeled on the automated line
4. **2 ML TUBES**
5. **5 ML TUBES**
6. **250 ML BOTTLES:** HDPE and opaque

Research grade to GMP within a year

We took the program from first RUO runs to a GMP-qualified line within a year, then scaled to meet their program's demands. Today, the GMP line we engineered runs at a pace of 50,000 plates a year.

RUO PROCESS DEVELOPMENT

Month 0

We developed the RUO hand-fill process and transferred it into production.

RUO PRODUCTION AND GMP DEVELOPMENT

Month 3

We began custom-engineering the automated GMP fill line while hand-filled RUO supply continued.

GMP EQUIPMENT QUALIFICATION

Month 8

We installed and qualified the dedicated, custom-engineered fill line in our ISO 7 cleanroom and released it for GMP performance qualification.

GMP PERFORMANCE QUALIFICATION

Months 9–12

We manufactured every plate component in triplicate lots to qualify the line for GMP.

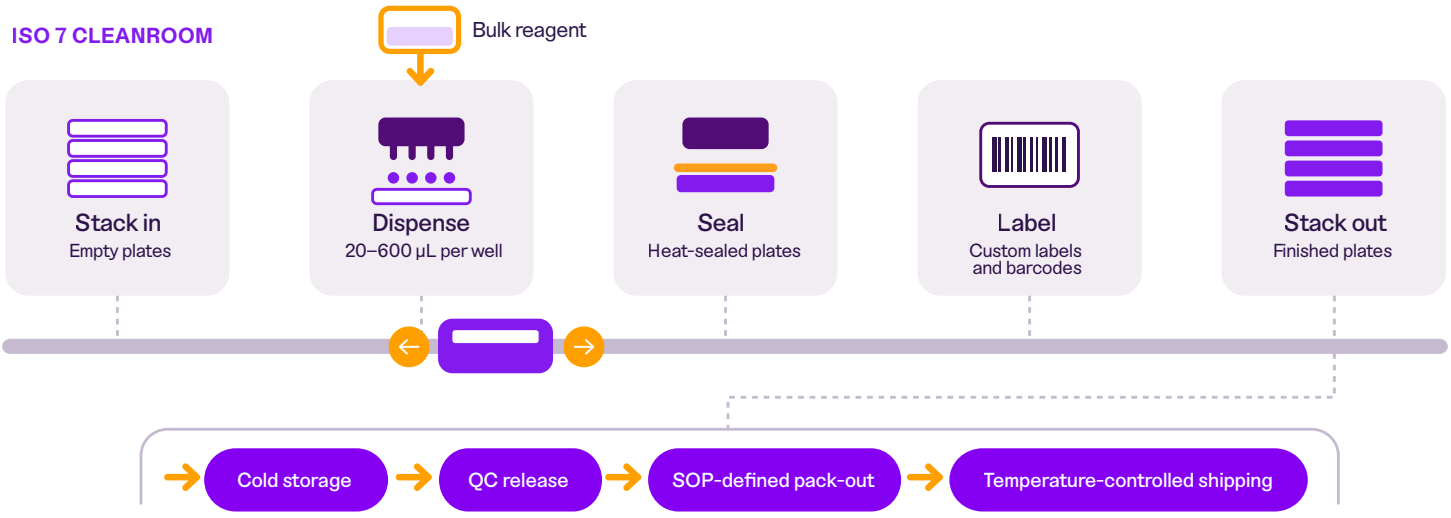
GMP PRODUCTION

Month 13

The full portfolio entered routine GMP production.

teknova

A dedicated, custom-engineered GMP fill line in our ISO 7 cleanroom



Specialized materials, methods, and equipment

Proprietary raw materials

We plan production around customer-supplied materials and fill proprietary reagents under GMP controls.

Assay-specific QC methods

PCR-based QC methods built to the assay's release specifications, with linked lot release.

Dedicated QC instrument

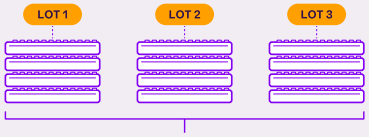
Release testing runs on a dedicated, customer-owned instrument we maintain.

Custom labels and barcodes

Every plate carries custom labels, barcodes, and lot numbers their automation reads.

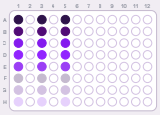
Every order, in triplicate

Each order covers the full portfolio, manufactured as triplicate lots of equal quantity to support validation and shipped together as a single order.



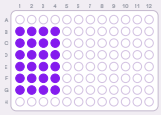
CUSTOM PLATE LAYOUTS

Multi-reagent DNA standards plate



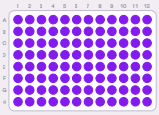
Each row holds a different DNA standard, released with its matching bottle on one QC test.

Partial fill



We fill a defined 24-well block in rows B–G, columns 1–4, matched to the assay plate map.

Full plate



All 96 wells filled, the format behind most of the plates in the program.

Every lot is manufactured within our ISO 13485 certified QMS

ISO 7 AND ISO 8 CLEANROOMS

Every cleanroom is animal-origin-free and endotoxin-controlled.

ISO 13485 CERTIFIED QMS

We manage change control, deviations, CAPAs, and internal audits in our MasterControl eQMS.

Send us your kitting challenge

Bring us a single component or a full kit, for your own labs or for kits you sell. We can manufacture every component tailored to your assay, from first RUO runs through GMP qualification and routine production.

SCAN TO START YOUR KIT

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