MOZEKA

RESULTS AT A GLANCE · CASE STUDIES

Quality systems that work. Results you can measure.

Five anonymised engagements across QC labs, clinical biotech, medical devices, GMP suppliers and generics manufacturing.

2,000+
batches cleared from a global testing backlog in 2 months

3×
faster CCS: 2 weeks against a typical 6, commended by the regulator

225
controlled documents rebuilt into a clear 5-tier QMS

100%
of external audits passed across a 2-year QA retainer

01

CONTAMINATION CONTROL STRATEGY

A risk-first CCS, commended by the regulator at inspection

Grade C/D GMP quality control laboratory testing cell and gene therapy products

THE CHALLENGE

Annex 1 assumes a manufacturer. In a testing lab, contamination harms a result, not a batch. A template CCS would have missed the lab's real risks.

WHAT WE DID

- Built around how a result is harmed (false negative, false positive, invalid run) and 4 contamination sources
- Core strategy plus 5 service annexes: sterility, growth promotion, EM, mycoplasma, endotoxin
- All 15 Annex 1 elements mapped; 10 residual risks named

2 weeks to draft, against up to 6 typically

1 + 5 core strategy plus service annexes

15 / 15 Annex 1 CCS elements mapped

10 residual risks named and controlled

☆ The CCS was singled out for praise in the regulator's inspection summary.

02

REMEDIATION · QC

2,000+ batch testing backlog cleared in 2 months

European generics manufacturer

Challenge: In-process and stability testing gaps found on released product, across more than 2,000 batches worldwide.

WHAT WE DID

- Restructured the QC team and lab to run catch-up testing alongside routine work
- Set up the ongoing testing so it stays compliant

2 months to clear the backlog

3 months to a full state of control

03

QMS ARCHITECTURE

225 documents rebuilt into one controllable QMS

Late-stage clinical biotech running blinded trials

Challenge: A QMS grown around day-to-day needs, with a thin policy layer and forms that had no clear parent procedure.

WHAT WE DID

- Mapped 225 live documents across 12+ functions into a 5-tier hierarchy and 7 QMS domains
- Ongoing QA, including unblinded deviation management

225 documents mapped

0 blinds compromised

04

RETAINED QA SUPPORT

Two years of support, every external audit passed

Established supplier of medical devices and serum to the research market, MHRA-registered

- Post-market surveillance, quality manual review and untangling the QMS
- Staff training, audits and audit support

2 years of retained QA support

100% audits passed; ISO 9001 & 13485 kept

05

MARKET ENTRY

A new supplier, ready for GMP customers

Maker of a new decontamination system entering the life sciences market

- GMP training, core procedures and the validation approach
- Guidance on what GMP customers expect, so the team could sell with confidence

10+ staff trained in GMP

1st life sciences customer won

MOZEKA

Want results like these?

Book a free 30-minute discovery call. We reply within one working day.

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References available on request