

H. Cengiz Akyüz

Independent GMP & Technical Consultant · Istanbul, Türkiye

I help sterile pharmaceutical manufacturers get from where they are to EU GMP — a gap assessment against Part I and Annex 1, a remediation roadmap costed in money and months, and support through to the inspection.

WHAT I DO

- EU GMP and Annex 1 gap assessment (sterile)
- Inspection readiness and mock inspection
- Quality system establishment — ICH Q10, SOP architecture
- Validation: process, cleaning, media fills, qualification
- Plant set-up and technical feasibility studies
- Data integrity, 21 CFR Part 11 / Annex 11 assessment

WHERE THIS COMES FROM

Twenty-one years in pharmaceutical manufacturing and quality assurance, seventeen of them on the production floor: solid dose, semi-solids, syrups, sterile liquids and ointments; six years of freeze-dried cytotoxics and antibiotics; five years of penicillin powder filling in segregated sterile suites. At peak, 45 products and 2.1 million boxes a month.

As **Senior QA Manager** at a veterinary sterile facility I built the quality system from zero — ICH Q10 structure, full GMP documentation, media fills, cleaning and process validation — and led the regulatory inspections through which the plant received its GMP certificates. Earlier: greenfield plant set-up, GDP warehouse qualification, technology transfer with foreign engineering teams. Independent since 2016, including the technical feasibility study for a large volume parenteral plant — 500 mL polypropylene bag serum, 30 million bags a year.

I am also the developer of a 28-module pharmaceutical eQMS built against ICH Q10, EU GMP, PIC/S and 21 CFR Part 11. When I assess your computerised systems, I have built one — not only used one.

HOW ENGAGEMENTS WORK

1 • Scoping call	No charge. Enough to establish whether there is a problem worth paying to define.
2 • Assessment	Fixed scope, fixed price. Documentation review, facility walkthrough, operator-level interviews and record sampling. Findings classified by patient risk.
3 • Roadmap	Phased remediation plan costed in money and months, with an honest answer on whether your target inspection date is achievable.

Independent of any equipment supplier, engineering contractor or turnkey EPC provider. No commission on anything you buy. Mutual NDA before any site access.

Remote and on site · Türkiye, Europe, MENA, Central Asia · English and Turkish

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