

Training and qualification built for cell and gene therapy manufacturing.

GMP training infrastructure, task qualification, inspection readiness, and controlled AI adoption for CGT teams standing up sites, scaling headcount, and moving toward commercial manufacturing.

WHERE CGT TEAMS BRING ME IN

Standing up a new CGT suite or site

Onboarding, curricula, task qualification, and trainer capacity built before hiring outpaces the training system.

Role-task map • Matrix • Onboarding plan

Rapid hiring ahead of scale-up

Intake planned against trainer, evaluator, and supervised-practice capacity, with documented authorization gates.

Capacity plan • Ramp-up roadmap

Records that don't prove readiness

Completion records show who attended. Task-qualification criteria and evidence requirements show who can perform the work.

Qualification criteria • Evidence

Getting ready for an inspection

A training-program review against 21 CFR Part 211, with risk-ranked findings and a 90-day remediation plan.

Training Audit • \$6,500

Bringing AI into GMP quality work

Use cases, work-authorization criteria, human-review checkpoints, and escalation defined before AI touches GMP records.

AI strategy • Work authorization

New processes that need SOPs

Custom SOPs, master SOPs, and work instructions drafted from your processes, source materials, and SME input.

\$325/hr • 2-hour minimum

EXPERIENCE

10+ years in GMP manufacturing, training, and quality operations

WORKED AT

Novartis, Bristol Myers Squibb, Rocket Pharmaceuticals, Lonza, MADE Scientific

CGT TOOLKIT

GMP Training Matrix Architecture for cell therapy, gene therapy, and biologics

IN PRINT

Drapeau's AI Deep Dive, Pharmaceutical Technology; featured on Veeva LearnGxP

Start with a 30-minute discovery call.

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