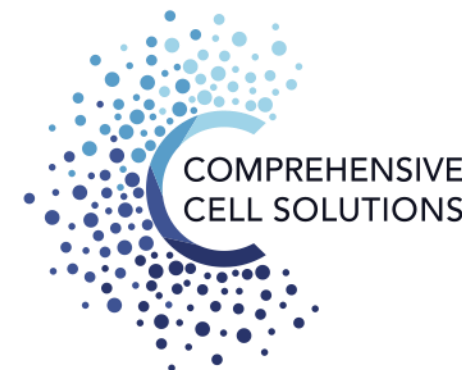


cGMP Manufacturing Example: CAR T Products



Activation - Gene modification - Expansion

Lentivirus, Retrovirus
Plasmid, RNA, LNPs

CD3/CD28 beads
T cell agonists
Cytokines
Irradiated feeder cells

Customized media
G-Rex® bioreactor
GMP-in-a-Box
PermaLife™ bags

Harvest - Volume reduction - Wash

COBE® cell processor
Tangential flow filtration
Lovo® closed cell processor
Centrifugation

Formulate - Fill/Finish - Cryo

CS-5, CS-10
Custom formulation
Automation
Final product fill/Unique product number
Bio-archive/Shipping

QC - Regulatory

Thaw: post-thaw viability
Safety: Rec virus, integration sites
Purity: FLOW, genomics
Potency: Lysis, cytokines, biomarkers

3000 sq ft GTP lab space
Two ISO 7 clean rooms
Three shifts staffed by
skilled technologists

Our
complete
vein-to-vein
solution

Patient

T cell isolation

CliniMACS® cell separation
Sony MA900 cell sorter
BD FACSAria™ Fusion flow cytometer
Ficoll® density gradient

Cryopreservation - Storage

Controlled rate freezers
CS-5, CS-10
Custom formulation
LN₂ tanks

Apheresis

Spectra Optia®
Network of collection sites
Traveling nurses