



TCI
CONSULTANCY

Life Science · Gene & Cell Therapy Advisors

Capabilities Statement

Gene & Cell Therapy Advisory
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Many AAV manufacturing problems are designed in long before they show up in a production run. TCI Consultancy gives gene and cell therapy developers independent, senior-level advice on the decisions that determine whether a program moves cleanly from research to the clinic.

CORE SERVICES

Vector Design

AAV transgene, helper and RepCap plasmid design optimized for efficacy and manufacturability.

CMC Strategy & Oversight

Plasmid supply strategy, CRO/CDMO selection and oversight from research grade through GMP, including cell banks.

Assay Development

Cell-based potency assays, qPCR and NGS sequence verification of plasmids and AAV particles.

Sequence Analysis

Construct review and risk identification before you commit to synthesis or production.

Quality & Regulatory Documentation

SOPs and quality documents, plus authoring and review of DNA/plasmid sections for IND and BLA filings, including BLA Type D submissions.

HOW WE WORK

Purely advisory: no lab services and no products to sell, so recommendations are driven only by your program's success. Engagements range from focused design reviews to ongoing CMC support and fractional subject-matter expertise for filings.

EDUCATION

- PhD, Molecular Biology – University of Reading
- BSc (Hons), Biochemistry & Genetics – University of Nottingham

CREDENTIALS

- 20+ years in gene cloning, vector construction and gene therapy; **2,000+ constructs** built
- Built Vertex's AAV vector construction, plasmid production and potency assay groups from inception
- Developed a cell-based potency assay for AAV-delivered CRISPR gene editing, transferred to a CMO for release testing
- Subject-matter expert for DNA/plasmid sections of IND/BLA documentation
- Extensive CRO oversight across research-grade and GMP production

EXPERIENCE

- **Vertex Pharmaceuticals** – Director, Vector Construction
- **Agilent Technologies** – Scientific Program Director, R&D
- **Allergan** – Senior Scientist, Bioanalytical Method Development
- **Invitrogen** – Senior Scientist

INNOVATION

- Inventor, SureVector DNA assembly system (US 10,662,424 B2)
- Inventor, enterokinase production in yeast (US 8,557,558 B2)
- 18 peer-reviewed publications

Peter Sheffield, PhD

Founder & Principal Consultant, TCI Consultancy

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