CGMP Oligo Manufacturing & Services for CRISPR Therapeutics

Your trusted CMO partner for CGMP gRNA manufacturing, CGMP Cas enzyme offerings, off-target analysis services, and regulatory support.

CGMP gRNAs manufactured in IDT's state-of-the-art Therapeutic Oligonucleotide Manufacturing Facility

CGMP Cas Nucleases from Aldevron® and sold by IDT to accelerate therapeutic development milestones with a single-vendor solution

CRISPR analysis tools and services, featuring the award-winning rhAmpSeq CRISPR Analysis System and off-target analysis services

Regulatory services and support aligned with IND or CTA submissions and clinical development phases

CGMP Oligonucleotide Manufacturing Facility to accelerate advanced therapies

IDT's CGMP manufacturing facility is located in Coralville, Iowa and complies with the highest industry standards including:

- Compliance with ICH Q7
- ISO 8 cleanrooms
- HEPA-filtered, single pass airflow to reduce risk of cross-contamination
- Continuous monitoring for temperature, relative humidity, and differential pressure

Complete workflow for every development stage

RUO (Research Use Only): Our comprehensive workflow provides a seamless experience from construct design through to editing analysis, ensuring the highest quality results at every step of your discovery journey.

Engineering Run (ENG): Synthetic gRNA manufactured in the same facility as CGMP but with draft QC SOPs and draft Batch Records. Confirms performance of all processes prior to CGMP manufacturing.

CGMP: Synthetic gRNA manufactured under phase appropriate CGMP conditions, in accordance with ICH Q7, and applicable portions of 21 CFR 11, 210, and 211, including fully reviewed QC documentation and batch records by IDT QA.

		Research (RUO)	Engineering Run	CGMP
Quality Management System	ISO 9001:2015	✓		
	ICH Q7 for Pre-Clinical and Early Phase Clinical Trials			✓
QC Testing	Basic Characterization (Yield, Identity by ESI-MS)	✓	✓	✓
	Qualified QC Methods (Purity, Process-Related Impurities, Endotoxin, Bioburden, Appearance)		Draft SOPs	✓
Certificate of Analysis and Batch Record	CGMP Compliance Statement			✓
	Certificate of Test		✓	✓
	Certificate of Origin, including TSE/BSE		✓	✓
	QA Reviewed and Released Batch Record		Draft BR (Optional)	✓
Manufacturing Environment	Environmental Monitoring		✓	✓
	Temperature and Humidity Control		✓	✓
	Cleaning Validation			✓
	Dedicated Suite During Manufacturing			✓
	Cytiva Synthesis and HPLC Purification Systems	Mid & Large Scale Only	✓	✓
IDT's Recommended Application*	Discovery/Early-Stage R&D	✓		
	Pivotal Toxicology Studies, Suitable reference Standard, Pre-Clinical		✓	
	Clinical, Therapeutic, CGMP			✓
	Regulatory Support		✓	✓

Off-target analysis tools and services to ensure safety

IDT offers unparalleled off-target editing analytical services for CRISPR projects, combining best-in-class technologies like GUIDE-seq and the rhAmpSeq™ CRISPR Analysis System. This integrated solution streamlines the therapeutic development process, providing dedicated expert guidance on off-target editing events to optimize gRNA design and specificity for clinical applications.

Regulatory support to enable IND or CTA submissions and beyond

IDT offers unparalleled regulatory support by delivering detailed documentation and expert guidance tailored to each phase of your clinical program. We provide comprehensive services and expert support for eCTD Modules 2 and 3, as well as Quality and CMC for Drug Substance and Drug Substance Intermediates. Our offerings are designed to guide and support you throughout your clinical development journey, ensuring seamless progress and regulatory compliance at every stage.

Enabling scientists to rapidly move to the clinic

For more than 35 years, Integrated DNA Technologies (IDT) has been enabling the industry with an oligonucleotide manufacturing process unlike anyone else, with the most advanced synthesis, modification, purification, and quality control capabilities available. As your trusted partner and a global leader in CRISPR genome editing, we are committed to providing you with the highest quality products and services to help accelerate your project and bring your discoveries to life.

For more information or to request a consultation, visit **idtdna.com/cGMPManufacturingConsultation**

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CGMP refers to products manufactured under ICHQ7; IDT engineering runs and CGMP gRNA are for development and investigational use only. The performance characteristics of this product have not been established. This product is not intended to be used as final drug product. The purchaser is solely responsible for all decisions regarding the intended use of the product and any associated legal or regulatory obligations. Doc ID: CGMP25-3330_001 04/25