INTEGRATED DNA TECHNOLOGIES

CGMP OLIGO MANUFACTURING AND SERVICES FOR CRISPR THERAPEUTICS

IDT™
INTEGRATED DNA TECHNOLOGIES

> WWW.IDTDNA.COM

RAPIDLY MOVE FROM THE LAB TO LIFE-CHANGING ADVANCES.

For more than 35 years, Integrated DNA Technologies (IDT) has been enabling genomics laboratories with an oligonucleotide manufacturing process unlike anyone else in the industry, with the most advanced synthesis, modification, purification, and quality control capabilities available. IDT is a global leader in CRISPR genome editing with a complete workflow from design to analysis. Our CRISPR product portfolio includes a comprehensive set of tools, reagents, and services for all your genome editing needs, from discovery to preclinical research to clinical applications. As your trusted partner, we are committed to providing you with the highest quality products and services to help accelerate your research and bring your discoveries to life.

Complete workflow for every developmental stage.

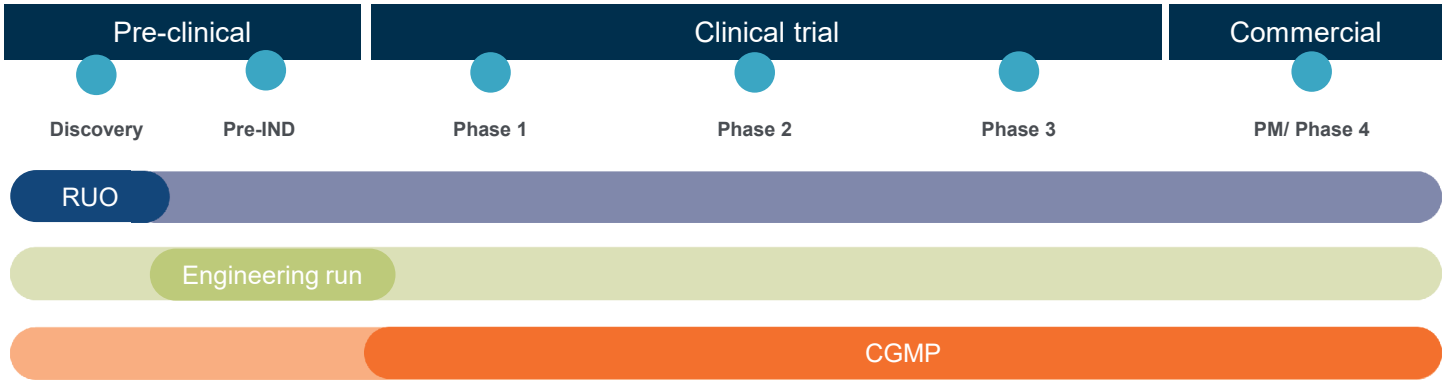
IDT is a leading provider of CRISPR genome editing solution from research use only (RUO) products to Engineering run and full CGMP manufacturing services for guide RNA and homology-directed repair (HDR) donor oligos, taking your work from discovery to therapeutic development with ease.

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

Engineering Run: Synthetic guide RNA produced by the same manufacturing process as CGMP products but with limited quality assurance documentation.

CGMP: Synthetic guide RNA manufactured under CGMP conditions and includes full quality assurance and release documentation.

		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		√	√



State of the art CGMP Therapeutic Oligonucleotide Manufacturing facility.

IDT's 41,000 square-foot GMP manufacturing facility located in Coralville, Iowa is designed to support therapeutic oligonucleotide manufacturing for clinical applications. We are committed to providing you with a transparent and informative experience. Key features of the facility include the following:

Key features include:

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

End-to-end solutions to accelerate your path to the clinic.

IDT has partnered with Aldevron™ to offer a single-vendor solution that provides high-quality, consistent gene editing tools to support your transition from concept to clinic. By working with a single vendor, you can accelerate your therapy development through a streamlined supply chain, reducing risk and cost, while working with our experienced regulatory teams to support your submissions.

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

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.

A trusted partner with a proven record of high-quality and dependable solutions.

Recognizing the crucial significance of time and cost savings along your path to the clinic, our commitment lies in delivering streamlined project plans that establish key milestones and deliverables, ultimately paving the way for a successful transition from research to clinical implementation. We provide tailored quality and documentation solutions that cater to the specific requirements of your program.

Project scoping & approval			Procurement	Production, review, delivery		
DISCOVERY	**PROJECT QUALIFICATION & DESIGN**	**MSA, SOW, CONTRACT, QUALITY AGREEMENT**	**PROCUREMENT**	**SYNTHESIS**	**QUALITY CONTROL REVIEW**	**PROJECT DELIVERY & SUPPORT**
Technical discussion with SME team	NDA	Review key deliverables, timeline & milestones	Raw materials for client project purchased	Synthesis under agreed quality standards	Remote or onsite project review	Release materials
Review timing & budget	Project & product specifications discussed	Signed contract with comprehensive project outline	Project initiation with project management support	Regular updates & tracking of milestones	QC test record review	CoA & documentation delivery
	Technical assessment & consultation	Project scheduling	Detailed project schedule defined		Batch record review & execution	Stability testing
	Desktop and site audits as requested					

Unmatched expertise and service.

IDT stands at the forefront of the genome editing field, leading the way with pioneering contributions and groundbreaking research and development. Alongside our unwavering dedication to innovation, IDT is dedicated to helping our customers take their discoveries from research to clinical applications, bridging the gap between bench and bedside and facilitating the translation of groundbreaking genomic advancements into real-world clinical benefits.

Get in touch.

Talk to our team today to discover how IDT can support your program. Our clinical development leaders are ready to assist your project at each stage. Partner with us during the early stages of your project to meet timely scale-up needs and quality requirements. We are committed to helping you achieve your project goals and meet your timelines. For further details, please visit our website at idtdna.com/CGMPManufacturingConsultation.

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 a 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.

> SEE WHAT MORE WE CAN DO FOR **YOU** AT **WWW.IDTDNA.COM**.

IDT™
INTEGRATED DNA TECHNOLOGIES

NGS • CRISPR • Functional Genomics • Synthetic Biology • PCR & qPCR • Custom Oligos • Contract Manufacturing