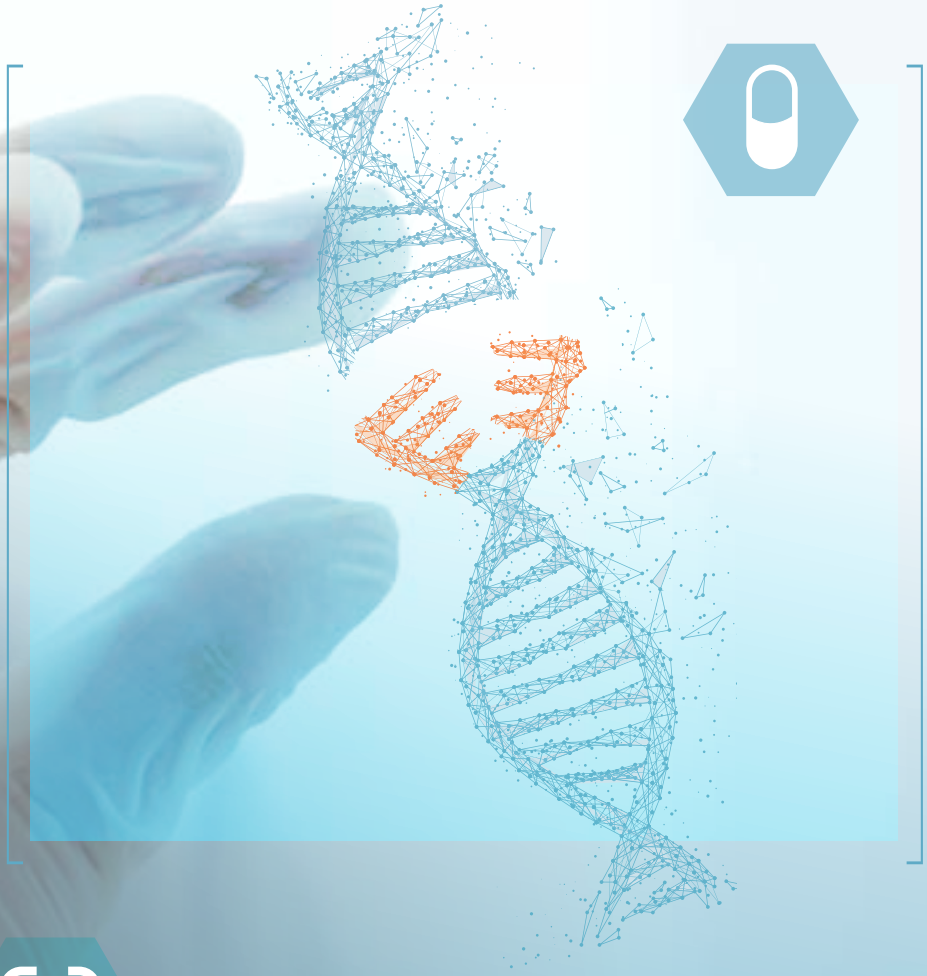
Integrated DNA Technologies
cGMP Manufacturing



IDT™
INTEGRATED DNA TECHNOLOGIES

> WWW.IDTDNA.COM

ENABLING RESEARCHERS TO 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 of your genome editing needs, including discovery, preclinical research, and clinical applications. As your trusted partner, we're committed to providing you with the highest quality products and services to help accelerate your research and bring your discoveries to life.

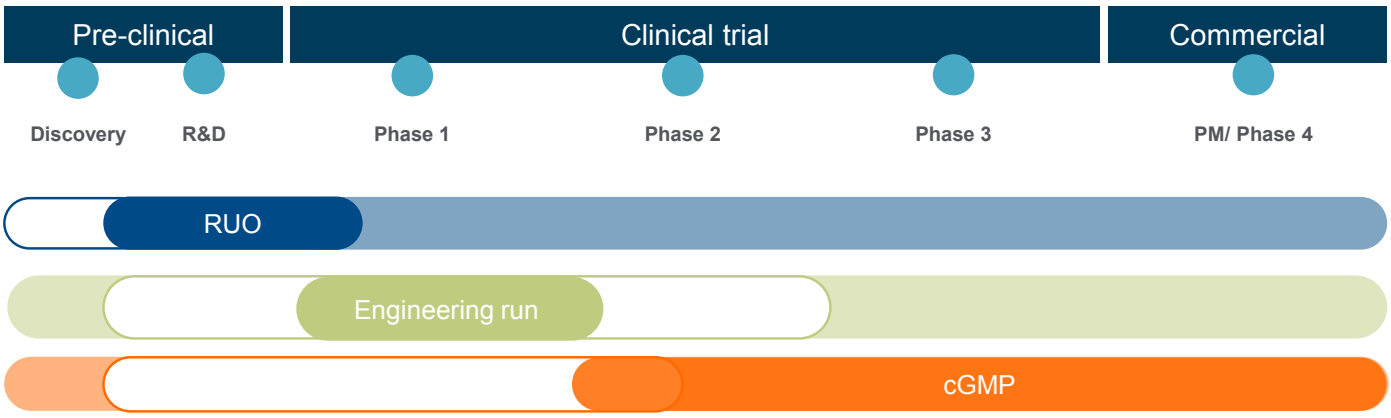
Complete workflow for every developmental stage.

IDT has been a leading provider of research use only (RUO) products for CRISPR genome editing. We're excited to expand our product portfolio with the addition of Engineering run and full cGMP manufacturing services for guide RNAs 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 and HDR donor oligos produced by the same manufacturing process as cGMP products but with limited quality assurance documentation.

cGMP: Synthetic guide RNA and HDR donor oligos manufactured under cGMP conditions and includes full quality assurance documentation.



		Research (RUO)	Engineering Run	cGMP
Compliance	ISO 9001-2015	√		
	ICH Q7 for Pre-clinical and early phase clinical trial material		√	√
Quality Control	Basic characterization tests*	√	√	√
	Qualified Testing Methods		√	√
	Quality Control Testing •		√	√
	Out-of-Specification Investigation		√	√
	Customized Part Number with Customized Final Specifications		√	√
Certificates	Certificate of Testing		√	√
	Certificate of Origin (TSE/BSE Certificate)		√	√
Batch Record	Tracable		√	√
	Custom		†	√
	QA Review and Release		√	√
Raw Materials	Traceable	√	√	√
	Inspection and Release #	√	√	√
Environment	Temperature and Humidity Controls		√	√
	ISO Class 8 Clean Rooms		√	√
	Environmental Monitoring		√	√
	Dedicated Laboratory Suite During Manufacturing			√
Additionals	Regulatory support		√	√

* = ESI-MS and OD to confirm identity and yield

• Standard Quality Control Testing includes: Concentration, Appearance, Elemental Impurities per <USP 233>, Residual Solvents per <USP 467>, Endotoxin per <USP 85> and Bioburden per <USP 61/62>

= Inspection of release for RUO will follow ISO 9001 standard and ICH Q7 process for Engineering run and cGMP manufacturing

† = IDT Controlled

State of the art cGMP Therapeutic Oligonucleotide Manufacturing facility.

In October of 2023, IDT opened a new, 41,000 square-foot cGMP manufacturing facility. With this addition, we now offer a complete solution for all your genome editing needs, from research to clinical applications. Onsite tours of our cGMP manufacturing facility are available for prospective customers. We are committed to providing you with a transparent and informative experience.

Key features of IDT's Therapeutic Oligonucleotide Manufacturing 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

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

DISCOVERY

Technical discussion with SME team

Review timing & budget

PROJECT QUALIFICATION & DESIGN

NDA

Project & product specifications discussed

Technical assessment & consultation

Desktop and site audits as requested

SOW, CONTRACT, QUALITY AGREEMENT

Review key deliverables, timeline & milestones

Signed contract with comprehensive project outline

Project scheduling

Production, review, delivery

SYNTHESIS

Synthesis under agreed quality standards

Stability testing (if requested)

Regular updates & tracking of milestones

QUALITY CONTROL REVIEW

Remote or onsite project review

QC test record review

Batch record review & execution

PROJECT DELIVERY & SUPPORT

Release materials

CoA & documentation delivery

Stability testing

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 (R&D). Alongside our unwavering dedication to R&D, 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 provide assistance for 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