

Synthego

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Location:

3696 Haven Ave Suite A and Suite C, Redwood City, CA 94063 (Factory 1)
955 Charter Street, Redwood City, CA 94063 (Factory 2)

Manufacturing facilities footprint & capacity:

RUO and INDe: 40,000+ sq ft facility. We accommodate most scales (starting with < 50 nmol for the RUO), where Synthego has produced over 1 million gRNAs since start of commercial operation. For INDe capacity, 10g+ annual capacity

GMP: 18,000+ sq ft facility with 100g+ annual capacity

Modalities/tech platforms supported:

Synthego's synthetic sgRNA is manufactured via a proprietary methodology created and utilized by Synthego to produce RUO, INDe, and GMP sgRNAs for a variety of nucleases including but not limited to SpCas9, Cas12a, Cas12b, and MAD7 with the sgRNA length covering from 40-120 mer.

RUO sgRNAs - high quality, research-grade synthetic sgRNA with scale of 1.5-1000 nmol; additional HPLC purification is available

INDe sgRNAs - custom sgRNAs manufactured under non-clinical GLP guidelines with current scale of .

GMP sgRNAs - custom sgRNAs manufactured under GMP guidelines with current scale of 200 mg to 2 g batch sizes.

The current scales Synthego provides in GMP manufacturing are 200 mg to 2g batch size.

Synthego partners with SeQure Dx to offer comprehensive off-target editing services for RUO, INDe, and GMP sgRNAs. Off-target editing analysis includes orthogonal off target nomination and confirmation analyses and is customizable based on customer need. The off-target editing analysis meets the current regulatory guidelines for CRISPR-based therapies and can be used for IND submissions.

Process & analytical development capabilities:

Synthego mainly utilizes platform production processes and analytical methods to support clients. However, Synthego can support process & analytical development case by case for INDe and GMP sgRNAs.

GMP manufacturing capabilities:

Synthego's synthetic sgRNA is manufactured via a proprietary methodology created and

utilized by Synthego to produce INDe or GMP sgRNAs , for example, for SpCas9, Cas12a, Case 12b, and MAD7 with the sgRNA length covering from 40-120 mer. The current scales Synthego provides in GMP manufacturing are 200 mg to 2g batch size.

Analytical capabilities:

For research-grade synthetic sgRNAs, Synthego provides intensive QC analysis and reports using mass spectrometry (all) and HPLC analytical report (for HPLC purified only).

Synthego offers a range of QC release test panels that adhere to regulatory agency requirements and guidelines, and can be tailored to meet individual client requirements for INDe and GMP sgRNAs.

Synthego provides ICH-compliant stability storage conditions and a skilled QC team dedicated to meeting GMP stability requirements.

Track record:

Synthego has synthesized +1million research-grade sgRNAs for a variety of customers including pharma, small biotech, and academic/non-profit. Synthego's RUO synthetic sgRNAs have been utilized in a variety of applications for basic research and early discovery work and have been cited in +1500 publications.

Synthego has completed more than 100 INDe and GMP sgRNA campaigns since May 2020. Synthego has about 40+ distinct clients from CRISPR therapeutic companies and academics where 80% of the clients is based on CRISPR therapeutic companies. We have have directly supported 17 IND submissions, of which 8 have been approved.

Facility certifications:

GMP: ISO9001:2015 bsi certificate

Regulatory inspections & corrective actions:

N/A - have not had any Regulatory Inspections

Value proposition:

Synthego is a leading innovator of CRISPR editing tools, focused on best-in-class synthetic sgRNA manufacturing designed for each phase of CRISPR-based therapeutic development. Through its state-of-the-art GMP facility, Synthego is uniquely positioned to meet the demands of the rapidly evolving regulatory landscape by strategically aligning products and manufacturing processes with the most current regulatory guidelines, ensuring they provide compliant and safe technologies for clinical applications. With RUO, INDe, and GMP-grade sgRNAs, Synthego supports every phase of CRISPR research from from basic research and discovery to clinical trials.