



Girindus is a recognized leader in the development and manufacture of cGMP oligonucleotides for therapeutic use. Our FDA-inspected production site in Cincinnati, Ohio, provides capacities to supply oligonucleotides from early development to commercial quantities.

Solid Phase Technology

Our significant investments in Solid Phase technology enable us to provide our customers with a long-term, reliable supply. Using phase-appropriate and dedicated production trains, we conduct cGMP manufacturing to support the entire drug development process from pre-clinical through clinical phases and on to market.

The continuing expansion of our Solid Phase capabilities allows for simultaneous production of multiple commercial oligonucleotides in order to meet our customers' rapidly growing demands.

Development & Manufacturing Excellence

At Girindus, we support our customers' manufacturing needs through a comprehensive array of analytical capabilities and services, including analytical method development, product and impurity characterization, and finished product release testing. We offer comprehensive process validation packages to ensure you have all necessary CMC data to support your NDA.

Our synthesis and engineering experts are known for their long-time experience in the manufacture, purification and analysis of various oligonucleotides, including modified DNA and RNA, duplexes, aptamers and chimeras.



Development

- Process development and scale up
- Process validation
- CMC documentation
- Radiolabeling of oligonucleotides (^{14}C , ^3H)

Analytics

- Full range of QC release testing specific for oligonucleotides
- Analytical method development and validation
- Stability studies
- Impurity profile analysis
- Endotoxin testing
- Thermal properties by DSC
- FT-IR
- Raman spectroscopy
- Tm analysis
- Extinction coefficient
- NMR

Manufacturing

- Small- and large-scale synthesizers in segregated cGMP facilities
- Lab- and industrial-scale purification systems
- Classified clean rooms for purification and isolation
- Ultra filtration and lyophilization
- AKTA 100, OP 400 and TechniKrom Synthesizers
- FDA inspected