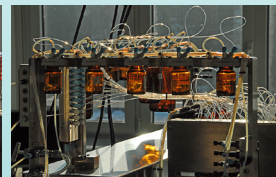
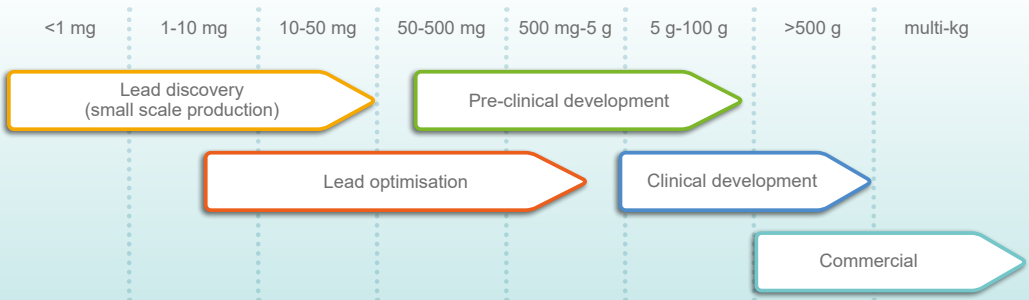


Our development and manufacturing capabilities supporting early to late phase clinical programs.

Axolabs expertise in process research and process development translates into GMP manufacturing of therapeutic oligonucleotides.

- Conduct process development for the improvement of product quality, cost of goods, and cycle time.
- Create new process definitions for oligonucleotide production, optimise chemistries, and develop models for scale-up, conduct ligand conjugations (in solution or on solid support).
- Highly experienced in developing methods and providing GMP analytical data to optimise manufacturing processes and support CMC dossiers for IND and IMPD submissions.
- cGMP production supporting early to late-stage clinical programs.



Our capabilities include:

Custom tailored process characterisation and optimisation based on ICH Q8-Q11

Manufacturing processes are designed and optimised with a forward-looking focus on product quality, process efficiency, process robustness, and product yield. The approach to each process is in full alignment with customer expectations and ICH guidelines Q8, Q9, Q10 and Q11, following a risk-based Quality by Design (QbD) approach using statistical Design of Experiment (DoE) tools.

cGMP Production capabilities

- A small-scale production train, based on an Äkta Oligopilot™ 100 (10mmol scale).
- Three medium-scale production trains (40mmol and 2x60mmol scales) based on an OP400 and two upgraded Oligopilot™ 400+ synthesizers in controlled laboratories or classified cleanrooms with isolated sub-suites. ÄKTA Process™ purifier with medium to large sized TFF and lyophilizer.

- Pilot scale trains: two (2x) 120 mmol scale synthesizer. Each Pilot train comes associated with appropriately sized Downstream- and Lyophilization suites.

Beyond, Axolabs has invested in a capacity expansion for large-scale production of oligonucleotides at the Petaluma and Berlin sites, implementing:

- First Process scale: production train with a synthesis scale of 300mmol, supplemented with appropriately sized Downstream- and Lyophilization instrumentation.
- Second Process scale: production train with a maximum synthesis scale of 1.8 mole, supplemented with appropriately sized Downstream- and Lyophilization instrumentation.

Axolabs, a full spectrum service provider supporting your needs in synthetic RNA Therapeutics

CONTACT

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Nucleic Acid Therapeutics by LGC