# End-to-end support for your parenteral oligonucleotide

Quality & reliability at every step from lab to launch

With over a decade of experience in oligo fill-finish, Vetter offers specialized services for every stage of your product's lifecycle. Whether you're preparing for First-in-human, ramping up to commercial launch, or scaling to new markets, we'll support you with the highest possible quality standards, in-depth knowledge, and expert project execution.



**Technical batches**Active





Process qualification (PQ) batches

Oligo-specific analytical testing: Lab qualification  $\delta$  method transfers

#### **Development:** Scalable support for oligo trials

### Lifecycle phases:

Phase 1-3

**Batch sizes:** Typically ≤6,000 units

#### Fill volumes:

- Vials: 0.3-28.9 mL (2R, 6R, or 10R)
- Syringes: 1.0 mL

#### **API formulations**: Liquid & lyophilized

#### **API quantities:**

- Small batches (early clinical)
- Commercial ramp-up batches

**Quality:** Quality by design compliant with ICH Q8 & FDA guidance

#### Storage:

- Liquid
- Frozen (-20°C and -80°C)
- · Lyophilized

#### **Testing:**

- Small- & at-scale
- Development, in-process, release, stability

70+

clinical oligo products supported since 2010

- Mass spectroscopy (in implementation)
- Hyperchromicity-UPLC/HPLC

#### Commercialization: Oligo expertise from approval to market

Lifecycle phases: Phase 3 & commercial

**Supported formats:** Vials, syringes, dual-chamber syringes, cartridges

API formulations: Liquid & lyophilized

#### **API quantities:**

- Ramp-up batches
- Large commercial batches

**Quality:** Highest possible quality standards for all processes  $\delta$  analytics

#### Testing:

- IPC, release & stability
- · Mass spectroscopy (in implementation)
- Hyperchromicity-UPLC/HPLC

## Rely on us.









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