

# Your Expert Source for Oligonucleotides, from Pre-Clinical to Commercial



#### **OLIGO SERVICES**

- » cGMP API production through development and commercialization
- >> Pre-clinical production, from µmols to mmols, with OliGrow
- » Analytical services: method development and validation through regulatory support
- Stability studies, on-site stability storage for drug substances and drug products
- » Streamlined process development with the OliGo: Faster, Smarter, Better™ program
- Specialized equipment for oligonucleotide modifications
- » CMC, IND, BLA, NDA, and IMPD technical support

Nitto Avecia, a market leader with more than 20 years' experience, brings you unparalleled oligonucleotide manufacturing and related services to support your oligo programs throughout their lifecycle. Having produced more than 1,000 oligonucleotides of every type, Nitto Avecia stands ready to handle your process development, analytical, or manufacturing challenge. Two FDA-inspected cGMP facilities ensure you receive a reliable supply of quality oligo APIs, whether antisense, siRNA, aptamers, immunostimulants, or miRNA, at any scale.

#### **REASONS TO CHOOSE NITTO AVECIA**





# Nitto Avecia



#### THE RIGHT PARTNER FOR YOU

Nitto Avecia's leadership and expertise, developed over two decades, provide you with the support and guidance required to carry out even your most demanding oligonucleotide development and manufacturing programs. Known for transparency and accountability, we apply our extensive knowledge to guide your oligonucleotide program, from pre-clinical to launched product markets. We serve clients worldwide, meeting the international requirements of ICH Q7 through ICH Q11 and maintaining an outstanding quality record through customer and FDA audits.

As part of Nitto, Japan's leading diversified materials manufacturer, Nitto Avecia continues to expand and improve our services for DNA-and RNA-based therapeutics.

**NEXT STEPS:** Contact Nitto Avecia at OligoInfo@Avecia.com or 508-532-2500 to discuss how we can put our expertise to work for you.

#### **KEY OPERATIONAL ASSETS**

#### Synthesis (scale range up to 1600 mmol)

- » 8 AKTA OligoPilot 100
- » 3 OligoPilot 400
- » mid-scale synthesizer up to 120 mmol
- » mid-scale synthesizer up to 300 mmol
- » large-scale synthesizer up to 900 mmol
- » large-scale synthesizer up to 1600 mmol

### Chromatography (scale range up to 1600 mmol)

- » 2 small-scale high-pressure systems
- » 6 small-scale low-pressure systems
- » 2 mid-scale high-pressure systems
- » 2 mid-scale low-pressure systems
- » 2 large-scale high-pressure systems
- » 1 large-scale low-pressure system

## Ultra-filtration (scale range up to 8 mol)

- >> 2 small-scale automated UF skids
- » 3 large-scale automated UF skids
- » multiple flexible-scale manual UF apparatus
- >> 2 Large-scale evaporation system to facility lot sizes up to 8 mol

# Freeze-drying (scale range up to 8 mol)

- » 3 small-scale systems
- » 5 mid-scale systems
- » 3 large-scale systems