

NEWS

on diagnostics

2024 cGMP Oligos Special Edition



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Manufacturing Overview

Welcome to this special edition of News on Diagnostics for 2024. Custom cGMP Oligos are essential for commercialising Molecular Diagnostics (MDx), creating Laboratory Developed Tests (LDTs), and conducting preclinical research, especially when an extraordinary level of quality is required to comply with strict regulatory or study standards. Choosing Custom cGMP Oligos ensures that the final kit, assay, or modality meets the necessary quality and regulatory requirements, providing confidence in the reliability and accuracy of the results.

Regulatory Compliance

cGMP oligos, also known as current Good Manufacturing Practice oligonucleotides, are synthetic DNA molecules manufactured in compliance with cGMP regulations. These regulations are designed to ensure that pharmaceutical and biotechnological products are consistently produced and controlled according to quality standards suitable for their intended use. In the context of oligonucleotides, cGMP compliance is essential for ensuring the quality, purity, and consistency of these molecules, especially when they are intended for use in clinical applications, diagnostic assays, or therapeutic research.

cGMP oligos are produced under strict quality control measures to meet the regulatory requirements for safety, efficacy, and traceability. The adherence to cGMP standards in their manufacturing processes is critical to ensure the reliability and reproducibility of results in research, diagnostics, and clinical settings.





cGMP Oligos

cGMP oligos are oligonucleotides manufactured under current Good Manufacturing Practice (cGMP) standards. These rigorous standards ensure high-quality production by minimising the risk of contamination, mix-ups, deviations, and other errors.

Risk Mitigation: Manufacturing oligos under cGMP minimises the probability of errors, making them suitable for molecular diagnostics, laboratory developed tests (LDTs), and preclinical research. Learn more about our Quality Management System (QMS) for commercial oligos [here](#)!

Commercial Use: Merck offers Custom cGMP Oligos, which are oligonucleotides manufactured under current Good Manufacturing Practice (cGMP) standards. These high-quality oligos are tailored for diagnostic and preclinical markets. Here are the key points:

Manufacturing Suite:

- Merck's suite includes three laboratories: Synthesis, Purification, and Quality Control.
- The oligos are manufactured in accordance with US GMP (21 CFR 820).
- Filled in a classified cleanroom (ISO 14644-1:2015 Class 8).
- The site maintains an ISO 13485 Quality Management System certificate.

Benefits of Custom cGMP Oligos:

- Controlled and validated processes ensure batch-to-batch consistency and reproducible results.
- Extensive materials traceability enhances quality and risk mitigation.
- These oligos meet stringent requirements for Molecular Diagnostics (MDx), Laboratory Developed Tests (LDTs), and preclinical research.

Key Considerations:

When selecting a vendor, ensure:

- **Quality:** Superior raw materials prevent lost business or useless study data.
- **Documentation:** Certificates of Analysis (CoA) and batch records provide evidence.
- **Turnaround Time:** Quick delivery keeps operations on track.
- **Manufacturing Capacity:** Merck can scale with your needs.
- **Supply Chain Support:** Customer and technical service teams assist you.
- Merck's commitment to cGMP ensures reliable oligos for critical applications.

It's clear that forming partnerships with customers is a priority for our Commercial Oligos offering, especially for successful Custom cGMP Oligos manufacturing campaigns. By emphasizing flexibility in the partnership process, Merck aims to accommodate individual customer needs and preferences. This customer-centric approach reflects a commitment to providing tailored solutions and expediting the process based on the specific requirements of each customer.

From early-stage research through commercial launch, we provide project expertise to ensure your success.

The Process

1. Sign non-disclosure (if required)
2. Assign project manager.
3. Assess your specifications.
4. Visit site, meet team & conduct audit.
5. Commence development & manufacturing specifications.
6. Deliver as quickly as possible.

Find out more about our [Partnership Process](#)

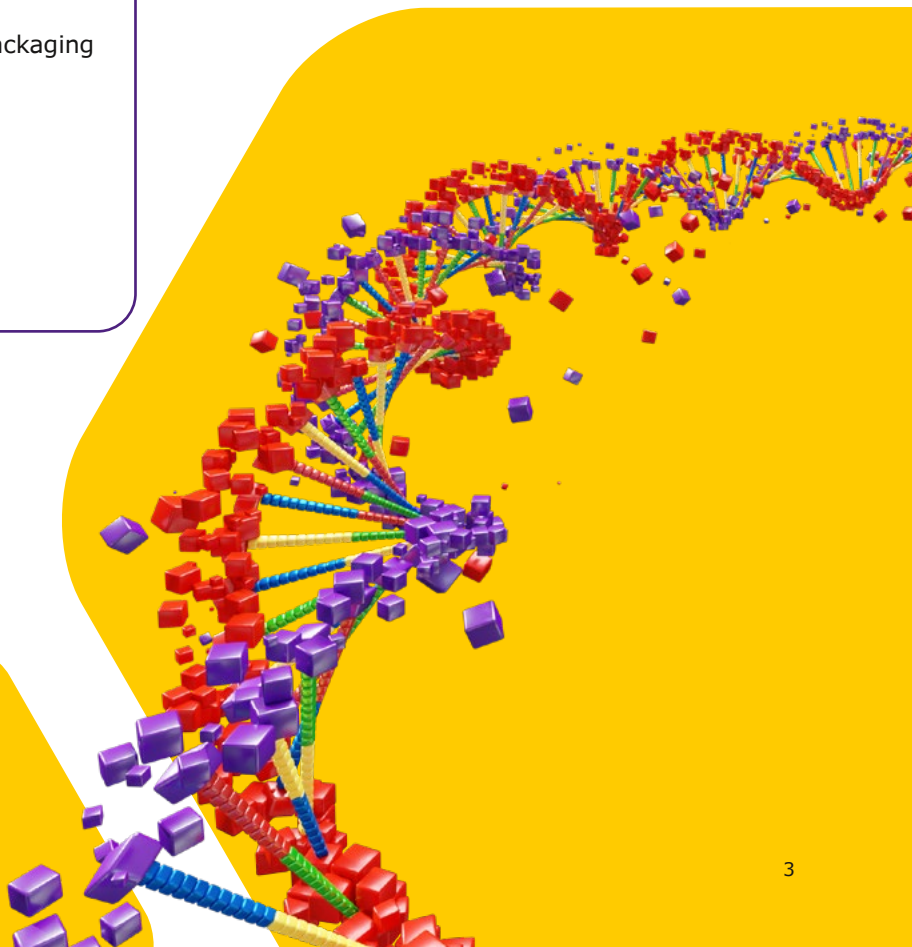


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- High-quality standard and specialized products for the complete workflow
- Flexible and customizable production and packaging options





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In this series of informal discussions with research and development scientists we aim to illuminate some of the not so obvious tips, trick, and insider information on developing novel IVD molecular assays.



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Custom Oligos for Commercial Use

We offer custom DNA Primers, qPCR Probes, and Next-Gen Sequencing Oligos for

- Life Science Research Tools
- Molecular Diagnostics
- Laboratory Developed Tests

We can also perform component or complete kit manufacturing, including custom formulations, packaging, and private labeling. Learn about our manufacturing capabilities or request a consultation to determine which type of product best fits your needs at SigmaAldrich.com/compliantoligos



DID YOU KNOW...

Merck is committed to a greener way of doing business?
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