

YOUR Trusted partner

from Concept
to Commercialization

Contract Manufacturing Solutions

- Biologicals, enzymes, antibodies, and critical raw materials for use in Diagnostics, Medical Device, and Pharmaceutical Manufacturing



Leverage Our Scientific Expertise

Partner with us to expedite your product development and manufacturing

Key Technologies

Molecular Amplification

- Oligos, probes, amidites
- DNA/RNA enzymes
- Molecular-grade buffers, formulations
- Nucleic acid purification

Conjugation

- Large molecules to beads/resins
- Linkage chemistry
- Detection reagents

Bio-organic Reagents

- Detergents
- Resins
- Carbohydrates
- Buffers & solutions
- Material with hazards or complex regulatory requirements

Antibody Production

- Monoclonal and polyclonal antibody production
- Blood typing
- Infectious diseases
- Biomarkers

Detection Chemistry

- Chemiluminescence
- Colorimetric
- Fluorescence

Protein/Enzyme Production

- Recombinant
- Plant and animal sourced
- Animal source free



Our customers

- | | | |
|------------------|--------------------------|-------------------------|
| • Diagnostics | • Biotech | • Academic |
| • Industrial | • Pharma | • Government |
| • Medical Device | • Veterinary Diagnostics | • Clinical Testing Labs |

Our reach

- North America
- Europe
- Asia Pacific

As a leading provider of raw materials for the life science industries and a global leader in contract manufacturing services, we pride ourselves on partnering with both established and emerging life science companies.

Accelerate Your Time to Market

Comprehensive contract manufacturing expertise
with a commitment to quality



Our core capabilities include:

- Custom liquid batching and blending
- Custom dry powder manufacturing
- Product development
- Process development and validation
- Low endotoxin, low bioburden filling
- Bulk and vial lyophilization
- Small- and large-scale filtration
- Small and large scale protein purification and/or conjugation
- Small- and large-scale bioorganic synthesis
- Kit assembly of manufactured products
- Secure global supply chain and sourcing capabilities
- Cell line development, scale up, and manufacturing

Extensive contract manufacturing capabilities for private-labeled:

- Reagents
- Buffers and solutions
- Standards
- Multicomponent kits

Commitment to Quality

Our quality systems are designed to meet stringent regulatory requirements for regulated industries, but are flexible enough for us to customize any specific items for your needs.

Over 40 primary manufacturing sites globally.

Multiple ISO 13485 certified sites.

Registrations/Certifications:

- ISO 9001
- ISO 13485
- 21 CFR 820
- 98/79 EC *In Vitro* Diagnostics Directive
- ISO 14001

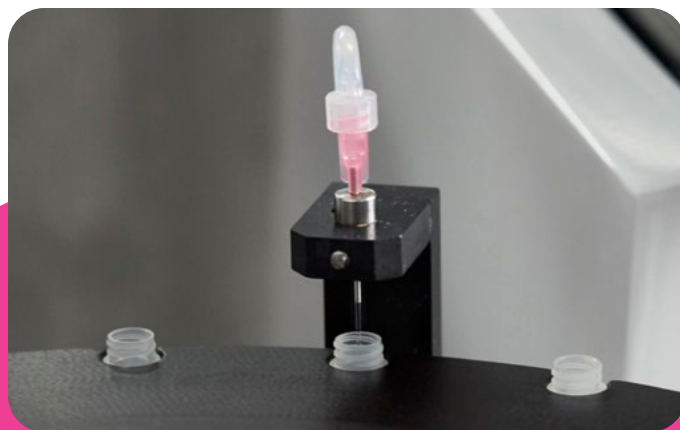


Customized Filling and Packaging Capabilities

Flexibility and options to meet your needs

Key filling capabilities:

- Hazardous materials
- Automated torque and weight checks
- Environmentally-controlled suites
- Molecular biology-grade environments:
 - DNase-free
 - RNase-free
 - Protease-free
 - Phosphatase-free



Powder Fill

- 10 µg to 200 kg+
- Multiple sealing and capping options including foil induction sealing
- Pouching capabilities

Liquid Fill

- High-throughput automated filling capabilities
- Up to 30,000L batch volume for liquid solutions
- Customized fill volumes
- Large lyophilization capacity
- Environmentally-controlled filling

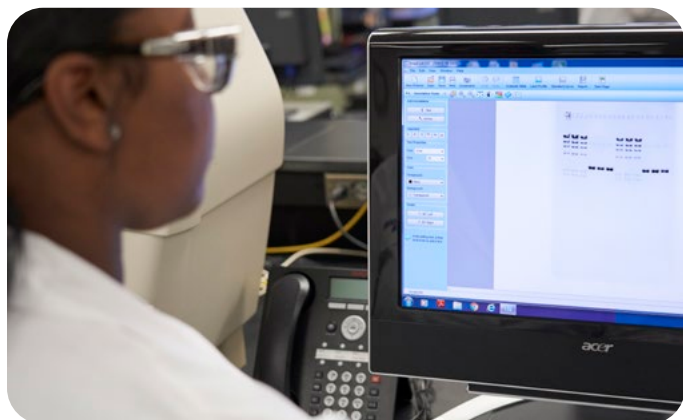
Formats

- Glass and plastic bottles
- Tubes
- Vials
- Boxes and bags
- Cubitainer® products
- Large-volume totes
- Multiwell plates
- Custom labeling including barcoding



Custom QC Testing

Choose assays relevant to your application



State-of-the-art technology for **in process** and **release testing** of your custom product

Our analysis capabilities:

Molecular

- qPCR, PCR, western blotting, Southern blotting, electrophoresis, nuclease contamination, bacterial growth, cell component isolation kits (DNA, RNA, protein)

Concentration

- Absorbance, titration, biuret, Bradford & BCA, specific gravity

Immunological

- ELISA, western blotting, Ouchterlony double diffusion, cell staining, histology, serology

Analytical Chemistry

- Mass Spec, HPLC, GC, NMR, titration, Karl Fischer

Functional

- Plasmid purification, cloning, protein depletion, proximity ligation assays (Duolink®)

Other specialized analyses

- Endotoxins, hematology, enzymatic activity and contamination, cell culture, tablet testing (hardness, friability, and dissolution)
- Test method validation for niche QC needs and ability to partner with external testing labs for esoteric tests
- Functional testing of contract manufactured products on client platform

Your Pathway to Success

Project guidelines and support



Inquiry and Consultation

After receiving your inquiry, you will be contacted by one of our Business Development Specialists



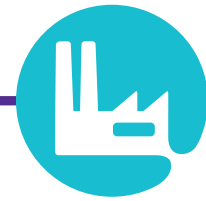
Acceptance

Project specifications are reviewed internally to determine feasibility and costing. A quote for the project is then sent to you.



Creation of Project Team/Implementation

A cross-functional project team is assembled with expertise specific to the project. Small-scale validation batches are produced.



Full-Scale Implementation

We manufacture at scale to your specifications with your custom packaging/labeling for regional or global distribution.

Experienced Project Management to Ensure Success

- Single point of contact for operations and project management
- Expertise in:
 - Supply chain
 - Procurement
 - Quality/regulatory
 - R&D
 - Technology transfer
 - Packaging engineering
- Resources to help you navigate industry guidelines and regulations
- Support through your project's life cycle



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To place an order or receive technical assistance

Order/Customer Service: SigmaAldrich.com/order

Technical Service: SigmaAldrich.com/techservice

Safety-related Information: SigmaAldrich.com/safetycenter

We have built a unique collection of life science brands with
unrivalled experience in supporting your scientific advancements.

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