

Custom Manufacturing Services: Exactly What You Need, Delivered Where and When You Need It

Promega Corporation
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Challenge: Finding a manufacturer, OEM or custom order supplier that can reliably provide high-quality reagents and assay components at the volume and frequency required to meet your growing needs.

Solution: Promega offers customizable options on a wide range of reagents. We can partner with you to collaboratively develop a solution to meet your specific needs.

Benefits:

- Quality assurance
- Flexible manufacturing capacity scalable to your needs
- Customizable formulation, storage and packaging
- Global distribution and delivery options

Custom manufacturing options range from simple changes in dispensed size to uniquely designed products specifically created for individual clients.

Key Considerations for Custom Manufacturing

Finding the right custom manufacturing partner can be challenging. There are many options to choose from, and many decisions to be made in order to match your particular needs to the capabilities of any potential supplier. It is important to identify a manufacturer who is equipped to meet both your current and future needs, who can consistently deliver a quality product on time to your specifications and who understands and applies quality and regulatory requirements in accordance with internationally recognized standards.

When seeking a manufacturing partner in the life sciences industry, the key considerations to bear in mind are:

- Scientific expertise that matches your product requirements
- Consultation and technical support to help make the design decisions you need
- Manufacturing capabilities that meet your current and future production needs
- Ability to meet quality standards and comply with regulatory requirements
- Logistical support and delivery capabilities

Gaining an understanding of the capabilities of any potential supplier in these five areas is essential to making an informed decision and finding a qualified partner to meet your needs.

Promega offers extensive manufacturing capabilities on an expansive range of products. The custom order team has many years of experience developing reagents for specific customer needs. Whether you require a single adjustment in product volume, a change in packaging, a unique kit configuration or a change in formulation, we can deliver exactly what you need. In addition to bulk and custom orders, we provide a range of manufacturing services including cGMP-compliant manufacturing capabilities.

This White Paper provides information on how Promega's Scientific Expertise, Consultative Technical Support, Manufacturing Capabilities, Quality Standards and Logistical Support network are applied to meet your custom manufacturing needs.

Scientific Expertise to Meet Unique Specifications

Promega is a global leader in the life sciences industry, with a portfolio of over 3,500 products and a 40-year track record of supplying high-quality reagents to academic institutions, forensic laboratories and the biotechnology and pharmaceutical industries. We also provide assay components to diagnostics companies, core labs and clinical laboratories. Our broad scientific expertise in nucleic acid purification

and amplification, protein analysis, cell biology and genetic identity is applied to the manufacture of numerous products. This wide-ranging expertise is made available to our clients as we work with them to design and manufacture products according to their specifications.

A lead scientist and dedicated team are assigned to manage your custom order from inquiry through shipment to ensure accuracy, personal service and highest quality. Subject matter experts are interjected into the process to consult on novel product development from custom formulation to creation of unique products. Other team members have expertise in project management, resource planning, materials, quality assurance and logistics. It is our goal to maintain a high degree of flexibility and innovation to enable us to customize products and processes as needed to satisfy your requirements.

Consultation Services and Technical Support

We offer a personal service to ensure that our experts are accessible to support clients during project planning and implementation. Promega scientists provide technical consultation on custom product design to help you during the planning and manufacturing process. We can help accelerate project development by proving out specifications, providing technical expertise to assist with design decisions and offering advice based on previous manufacturing experience.

Manufacturing Capabilities: Built for Flexibility, Based on Quality

Flexibility

With more than 450,000 square feet of manufacturing space across the United States, in China and in South Korea, Promega has made dedicated investments in the development and maintenance of state-of-the-art, high-quality manufacturing facilities. We are committed to excellence in manufacturing, compliance to the highest quality standards and expansion to meet your growing needs. Promega's capabilities include:

- Flexible manufacturing and dispensing lines
- Manufacturing within environmentally controlled spaces
- Separation of pre- and post-amplification processes
- Formulation and dispensing to requested volume specifications, including semi-automated filling for low-volume units

- Automated packaging of ambient kits—vision system to perform 100% inspection of kit components and label content
- State-of-the-art bioprocessing facilities
- Packaging options to suit your specifications

Promega manufacturing expertise covers techniques relevant to the life sciences and clinical diagnostic areas, including protein engineering, cell biology and nucleic acid purification and amplification. We have the flexibility and capacity to manufacture a range of batch sizes and experience perfecting the techniques required to ensure consistency in product quality batch after batch and time after time.

Quality

Promega first certified to international standards for quality management systems in 1998, and that commitment continues today. An organization achieving ISO certification has demonstrated to a third party that the organization meets all requirements of the standard and has implemented a quality system capable of developing, manufacturing, testing and delivering high-quality products around the world. ISO certification exemplifies our commitment to our clients, our business and all those who rely on and benefit from the use of our products.

The Promega Madison, USA, facility maintains certification to ISO 9001 and ISO 13485, the standard for the manufacture of medical devices. We also maintain certification in ISO 18385, which focuses on minimizing the risks of human DNA contamination in products.

Currently 15 Promega facilities around the world have certified to ISO standards.

You can have confidence in our ability to manufacture products and assay components reproducibly and to provide the required quality documentation. These requirements include:

- Detailed manufacture and QC documentation
- Production and process controls
- Product Certificate of Analysis
- Traceable product batch records
- Product stability programs
- Product change control and notification procedures
- Supplier evaluation and qualification program
- Equipment maintenance and calibration program
- Nonconforming product and complaint-handling procedures
- Design control



Example Manufacturing Capabilities

Fermentation:

- Volumes from 20–2,500 liters.
- Automated monitoring and control with batch data trending and history.
- Experience in high-cell-density fed-batch and batch fermentations with recombinant *E. coli*, *Pichia* and many native strains.
- High-speed tubular bowl, bucket-type and tangential flow cell harvest capabilities.

Protein Purification:

- Capacity to purify milligram to kilogram quantities of protein.
- Extensive experience purifying proteins from recombinant *E. coli*, *Pichia pastoris*, Hybridomas and many native sources.
- Expertise to provide a wide range of development and manufacturing support for cGMP protein production and testing.
- Knowledge of protein manufacturing scale-up issues and solutions.

Amplification and Human Identity:

- Separate and dedicated pre-amplification and post-amplification areas to protect products.
- All pre-amplification reagents are manufactured and dispensed by fully gowned staff within environmentally controlled spaces.
- Automated dispensing to reduce/eliminate potential human-to-product contamination.

Nucleic Acid Chemistry:

- 20 years of experience producing high-purity, dye-labeled oligonucleotides.
- Production capacity in excess of 500 liters/year of 100mM dNTPs. State-of-the-art bioprocess equipment and processes generate consistently high-quality (>99% pure) dNTPs.
- Over 25 years of experience manufacturing DNA and RNA products. Proprietary chemistry and nucleic acid purification processes, bioprocessing facilities and equipment produce consistent, high-quality products.
- Lysates for transcription/translation systems require extreme care during production to ensure performance. Our staff are experts in manufacturing and dispensing these sensitive products.

Bioluminescence:

- Our experienced team has an average tenure of over 10 years manufacturing and testing ATP detection and reporter assay reagents. We can manufacture bulk reagents in volumes from 0.5ml to 650 liters. Luciferase-based substrates can be lyophilized in batches up to 21,500 units.



Promega capabilities include the ability to manufacture assay components under cGMP requirements.

Logistics: Ensuring On-Time Delivery to Any Location

Once you have found a supplier with the required expertise, manufacturing capabilities and quality controls, you also need to know that the chosen manufacturer has the required logistic support and supply chain in place to meet your delivery requirements.

Promega has branches in 16 countries and more than 50 global distributors. Our main distribution center in Madison, WI, services our global branches and distributors. Likewise, our distribution centers in Germany and Singapore service direct customers in Europe and Pacific Asia, respectively. In addition, we have logistics operations in South Korea, Japan, China, Australia, United Kingdom and Brazil.

Our fully controlled, reliable end-to-end supply chain—from inventory management to warehousing, order processing and distribution—ensures accurate and timely product delivery. Modern warehousing and storage facilities and equipment, together with skilled logistics staff, ensure products are maintained at the correct temperature during storage and shipping. We are IATA-certified and provide flexible shipping options depending on your needs. In addition, we provide environmentally friendly packaging options.

Summary

Promega offers a range of custom manufacturing services, from simple changes in dispensed size to uniquely designed products specifically created for individual clients. Our extensive and growing manufacturing capabilities include the ability to manufacture assay components under cGMP requirements and offer broad flexibility in dispensing, formulation and batch sizes to meet your needs. Our scientific expertise covers a broad array of disciplines in molecular and cell biology, and our manufacturing capabilities cover an equally broad range of processes. We seek to work alongside you to share that expertise and generate innovative, high-quality products to your desired specifications. Our commitment to quality is underscored by our ISO certification and our continued investment in state-of-the-art manufacturing facilities that ensure compliance with internationally recognized quality standards.

Questions?

Below are some common questions posed by our custom manufacturing clients over the years. The answer to all of these questions is yes, but this is not an exhaustive list. If you have questions that are not answered in this paper, please contact us to discuss your specific need.

- Do you have packaging expertise?
- Can you package product under our label?
- Can you perform unique QC tests to our specifications?
- Can you provide 3 different lots of material to us for testing?
- Can I talk to the scientists involved in the project?
- Will you help us optimize reactions?
- Can you meet our needs today and grow with us?
- Can you help us plan batch size, stability testing and product configuration?
- Can you help with product inventory management?

Promega's Answer is Yes

To request information or arrange to visit Promega, please contact us at:

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