

Corning® Custom Media and Sterile Solutions

CORNING

Introduction

Let Corning support your product pipeline from discovery to commercial production. We adhere to cGMP standards throughout our manufacturing process and are a certified ISO 13485 facility. Our custom sterile solutions support your research, development, and production needs in the following fields and more:

- ▶ Mammalian cell culture, insect cell culture, and microbial biopharmaceutical manufacturing
- ▶ Monoclonal antibody production
- ▶ Cell culture process development
- ▶ Tissue and cell culture manufacturing
- ▶ Drug discovery and high throughput screening (HTS)
- ▶ Viral vaccine manufacturing

Custom Media Services

We are proficient in customizing and producing tailored media and reagents for research and biopharmaceutical professionals. We offer solutions with a full range of capabilities to meet custom formulation, packaging and regulatory solutions for the ever-expanding customer specific cGMP requirements.

Our cGMP capabilities include:

- ▶ Liquid and powder manufacturing
 - Single batch aseptically processed liquid products up to 8000L
 - Single batch powder lots up to 1000 kgs
- ▶ Dedicated animal-derived-component-free product manufacturing suites
- ▶ Custom packaging sizes for liquid products ranging from 10 mL bottles to 500L bioprocess containers using PET and other plastic bottles and flexible containers
- ▶ Custom packaging sizes for powder products including capabilities of bulk or individual packing

Custom Pilot Batches

Pilot batches are ideal to use for development and testing purposes prior to cGMP scale-up.

- ▶ Economical
- ▶ Rapid Delivery
- ▶ Small Scale
- ▶ Use controlled raw materials and bulk WFI



A summary of quality control tests performed on liquid pilot batches is available for:

- › Sterility
- › Endotoxin
- › Appearance
- › pH
- › Osmolality
- › Conductivity

Available quality control tests for powder pilot batches include:

- › Solubility
- › Moisture
- › pH
- › Osmolality

	Liquid Media (1x)	Dry Powder Media (DPM)
Lot Size	1 L to 100 L	1 kg to 1000 kg batches
Packaging	Standard bottles	Standard plastic containers
Container Sizes	50 mL, 100 mL, 500 mL, 1 L bottles	1 kg, 2 kg, 5 kg

Our standard product offerings include:

- › Classical media and serum-free formulations
- › Molecular biology solutions
- › Sterility challenge media (tryptic soy broth) for use in biopharmaceutical production validation
- › Animal sera - multiple species
 - USDA approved source (regular and heat-inactivated)
 - U.S. source (regular and heat-inactivated)
- › Human AB sera
- › Supplements
- › Microbiology reagents
- › Insect cell culture formulations

Extensive and diverse custom product offerings include:

- › Classical and serum-free formulations
- › Downstream purification buffers
- › Cell and tissue processing solutions
- › Diluents and controls
- › Tris, salt, and saline solutions
- › Customer specific formulations

High Quality Water

- › WFI-quality water
 - USP and/or EP certified
 - 100 mL bottles to 200L drums
- › Purified water
 - Meets current USP requirements
- › Molecular grade
 - RNase, DNase and protease free
- › Cell culture tested for assessment of cytotoxicity

Corning Flexible Packaging Systems

Corning single-use bags offer convenient, high-quality solutions to meet research and biopharmaceutical production needs.

- › Media storage and delivery
 - Bioreactor and fermentation
- › Product seeding, expanding, harvesting, and recovery
 - including rocker bags
- › Downstream purification and filtration
- › Waste containment
- › Final product fill
- › Cryopreservation

The full line of single-use bags are engineered as expedient, practical, and cost-effective alternatives to rigid-walled containers.

Corning flexible packaging products:

- › Available in standard sizes ranging from 1L to 200L
- › Gamma irradiated to a Sterility Assurance Level of 10^{-6}
- › Eliminate costs associated with washing, sterilization, and SIP/CIP validations
- › Eliminate the risks associated with cross contamination
- › Require minimal set-up time
- › Biocompatible product contact surface

Features and Benefits

- › Bag construction assures stability of contents by providing a superior effective gas and moisture barrier equivalent to Type I glass used for long term storage of sterile media.
- › Animal-free – no animal by-products are used in the finished container or during film production.

Customization

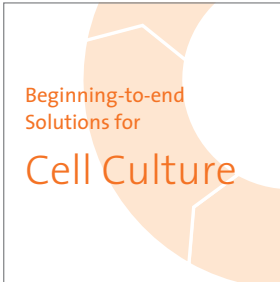
Single-use bags and collection containers can be custom fabricated to meet your unique application requirements with a wide variety of bag sizes and tubing/connector configurations available, including:

- › Custom sizes range from 50 mL to 2000L, in 2D and 3D configurations.
- › Manifold systems
- › Tubing and transfer assemblies
- › Tank liners from 50L to 1090L

Trust Corning flexible packaging systems for storage and delivery of your important products: versatile solutions with industry-leading quality.

Corning is uniquely positioned in the industry to offer a variety of custom products. For more information, contact us at MTProdDev@corning.com or visit: www.corning.com/lifesciences/media

Warranty/Disclaimer: Unless otherwise specified, all products are for research use only. Not intended for use in diagnostic or therapeutic procedures. Not for use in humans. Corning Life Sciences makes no claims regarding the performance of these products for clinical or diagnostic applications.



www.corning.com/lifesciences/solutions

At Corning, cells are in our culture. In our continuous efforts to improve efficiencies and develop new tools and technologies for life science researchers, we have scientists working in Corning R&D labs across the globe, doing what you do every day. From seeding starter cultures to expanding cells for assays, our technical experts understand your challenges and your increased need for more reliable cells and cellular material.

It is this expertise, plus a 160-year history of Corning innovation and manufacturing excellence, that puts us in a unique position to offer a beginning-to-end portfolio of high-quality, reliable cell culture consumables.

For additional product or technical information, please visit www.corning.com/lifesciences/media or call 1.800.235.5476.

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