

CUSTOM PRODUCT DEVELOPMENT & MANUFACTURING

Golden West Biologicals, Inc.[®] (GWB) specializes in custom product development and manufacturing services for the in-vitro diagnostic industry. GWB collaborates with customers to determine project goals, specifications and intended product use. This interaction ensures that the product developed is suitable for the intended application. GWB's custom manufacturing services also include processing according to customer supplied methods and protocols. Our trained and experienced staff work with customers from selection of raw materials, custom processing & formulation to the determination of quality control requirements and acceptance criteria for product analysis, stability and inspection. GWB's quality management system ensures product integrity and consistency on a lot-to-lot basis and product reproducibility is ensured through established procedures. GWB guarantees confidentiality of all customer communications, procedures, processes and all other relevant information. With over 20 years of experience GWB develops and manufactures the Products of Reference.



Golden West Biologicals, Inc.[®] - The Products of Reference
www.goldenwestbio.com
888-690-0963

Available Capabilities and Processes

Affinity Purification	Removes specifically targeted analytes without the use of activated charcoal, when charcoal may interfere with an application.
Aseptic Liquid Filling	Aseptic liquid filling is a process utilizing a set of specific practices and procedures to result in a sterile product. Aseptic filling is performed using autoclaved or sterilized equipment in an ISO 14644 class 7 (class 10,000) clean room under an ISO 14644 class 5 (class 100) laminar flow hood into sterile packaging. Laminar flow hoods provide clean air flow to the working area.
Bacteriostatic Agents, Preservatives and Anti-Microbials	Sodium Azide, Gentamicin, and Ciproflaxin are examples of commonly used bacteriostatic agents or anti-microbials. These or other customer directed additives are only added upon customer request.
Centrifugation	Centrifugation is a process using centrifugal force that separates the more dense components from less dense components. This process is commonly used in fractionation, purification, and stripping of products.
Charcoal Treatment	Charcoal treatment is a process used to remove hormones and steroids from plasma, serum, urine and saliva. The active binding sites on the charcoal bind with hormones and steroids. This process reduces hormones and steroids. The process can be performed one to four times.
Clarification or Depth Filtration	Clarification or depth filtration removes contaminants that affect downstream product quality that may reduce the effectiveness or life of membrane filters. This process leads to the reduction of lipids and enhances the optical clarity of products.
Concentration	Concentration is the process that usually follows diafiltration or dialysis. During the concentration process particles smaller than the membrane pore size pass through the membrane, while particles that are larger than the pore size are retained and thereby concentrating the material.
Custom Packaging and Labeling	Products can be packaged and labeled to customer defined specifications.
Defibrination	Removal of fibrin from plasma. Defibrination is done through a process using thrombin and/or calcium chloride. Defibrinated plasma is more cost effective than human off the clot serum.
Delipidization	Removal of lipids from plasma and serum improves clarity, stability and can reduce matrix effects in certain applications. Lipids are commonly removed using a silica process. Lipids can also be removed through use of other chemicals or other processes such as dextran or fractionation.
Diafiltration/Dialysis	The process of dialysis and concentrating is referred to as diafiltration. During this process the material is dialyzed to separate proteins from buffer components for buffer exchange, desalting, or concentration.
Formulation	The process of developing the correct process to meet predetermined GWB or customer set specifications.

Freeze/Thaw	This process is used to improve clarity, optical density and stability. May also be used to remove some lipids instead of completely delipidizing a product.
Heat Inactivation	Process where plasma or serum products are exposed to temperatures usually in the 56°C to the 60°C range for a period of 30 minutes to 1 hour. Customers can define temperature ranges and duration of time. This process is utilized to destroy complements, reduce enzymes and reduces infectivity of viruses.
Lyophilization	Process also known as freeze drying which extracts the water from materials so that they remain stable and are easier to store at refrigerated or ambient temperatures. Bulk and vial lyophilization available.
Membrane Filtration	Membrane filtration is a process that removes particles and microbial organisms. Membrane filtration can be done using a variety of low protein binding membranes and pore sizes down to 0.04µm. 0.2µm is used to remove microbials present in material and 0.1µm and 0.04µm are used in tissue culture applications. The most commonly used media is polyethersulfone. Glass fiber, polypropylene and nylon can be used. Glass fiber can cause interference with some urine, plasma and serum applications.
Microbial Testing	Microbial testing is performed on lots to ensure that product does not have microbial or bacterial contamination that is above a specification determined by in-house or customer specifications. Typical specification is <100 cfu/ml for diagnostic applications and typical results are <1 cfu/ml.
MSG (Mass Spect Gold®) Process	Proprietary process that effectively removes hormones, steroids, Vitamin D and other analytes. This process provides ultra-low analyte products for ultrasensitive requirements.
On-Site Laboratory Analysis	GWB's on-site lab has the ability to perform general chemistry, hormone and steroid tests on-site which facilitates processing and formulation due to the availability of the test results in real time. GWB also screens raw materials for in-house and customer defined raw material specifications.
pH Treatment	This process reduces enzymes and proteases in plasma or serum and eliminates precipitates in urine.
Protein Fractionation	Process to extract protein fractions from plasma or serum. The following processes are used: Cohn fractionations and Ammonium Sulfate.
Protein Purification	Process to remove specifically targeted analytes. The following processes may be used: denaturation, ion exchange or size exclusion chromatography.
Raw Material Selection	GWB offers the following material: source plasma, fresh frozen plasma, liquid plasma, off the clot and whole blood. Material can be selected by gender, screened for specific analytes, or other customer defined selection criteria to create a pool.
Resin Treatment	Process to reduce thyroid hormones in plasma or serum.
Temperature Controlled Processing	Materials are processed in a temperature controlled environment and process parameters are maintained to ensure lot-to-lot consistency and integrity of products.

Why Choose Custom Product Development & Manufacturing by Golden West Biologicals, Inc.®?

GWB believes the diagnostic industry deserves more than what has become accepted as the standard. GWB provides products that set standards and redefine quality. GWB works with customers to provide innovative solutions to the challenges that our customers and industry face. By working with customers and providing solutions, we assure meeting project goals both on schedule and within budget.

Quality

- ISO 9001:2008 Certified
- cGMP Compliant
- Forward and backward traceability from donor through final distribution
- Each serum and plasma donor unit is tested negative for HIV 1/2-ab, HBsAg, HCV-ab, HCV (NAT), HIV-1 (NAT), and RPR
- Each donor of saliva and urine is tested negative for HIV 1/2-ab, HBsAg, HCV-ab, HCV (NAT), HIV-1 (NAT), and RPR
- Analyzed and inspected for conformance to customer specifications

Consistency

- 20+ years of experience providing consistent products
- Highly skilled and trained professionals
- Raw material selection process
- Validated processes
- Quality control, inspection and testing ensure consistent products
- Low variance between lots

**For more information or to place an order, please contact a
GWB account representative at 888-690-0963**