



# ISIA cGMP/GMP POSITION

NOTHING  
WORKS  
LIKE  
SERUM

INTERNATIONAL SERUM  
INDUSTRY ASSOCIATION  
P.O. BOX 926 | MCHENRY | MD | 21541

A frequently asked question to our membership involves the “cGMP” or “GMP” status of serum and other animal derived products. The International Serum Industry Association (ISIA) position is as follows:

Current Good Manufacturing Practice (cGMP) or Good Manufacturing Practice (GMP) ensures products are consistently produced and controlled according to quality standards. The process is designed to minimize the potential risk to a patient involved in any pharmaceutical production that cannot be eliminated through testing of the final product. cGMP/GMP in the manufacturing process can only be applied to a pharmaceutical or an active pharmaceutical ingredient.

Fetal Bovine Serum (FBS) is not a pharmaceutical nor is it an active pharmaceutical ingredient. It is on this basis that the ISIA considers that processed FBS cannot be said to be cGMP/GMP compliant or be called a cGMP/GMP grade product.

Many members of the ISIA manufacture products that are produced in facilities that comply with relevant portions of the US FDA Quality System Regulation 21 CFR 820, current Good Manufacturing Practices, or ISO 13485:2016 and ISO 9001:2015 standards, or in facilities registered to manufacture under GMP or which hold FDA registration. This does not mean that the FBS manufactured in these facilities may be labelled as cGMP/GMP. It can be said to be manufactured within a facility that holds a specific registration.

Customers are responsible to determine if these serum products are suitable for use in their specific application.

Rosemary J. Versteegen Ph.D.  
ISIA CEO



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