

Is bovine serum safe?

Bovine serum has a long (now several decades) and extensive history of safe use in the manufacture of human and veterinary pharmaceutical products and in other applications as well.

To describe all of the precautions taken to achieve and ensure this would require a book. What follows, therefore, is only a very brief overview of the key precautions taken to reduce possible risks to a negligible level – keeping in mind especially its use in pharmaceutical manufacture for the benefit of human and animal health.

The conditions and methods of slaughter, collection, storage, manipulation, processing, treatment, testing and transport of the material are all very carefully controlled to keep to a minimum the risk of the serum being contaminated with living microorganisms or undesirable non-living material. (see also: *How is bovine serum produced and tested?*).

The geographical origin of the material is also very important. Bovine blood is only collected in countries that have a known, well-monitored and documented and acceptable (to regulatory authorities) animal health status. ISIA member companies and regulatory authorities make use of the information published by the World Organisation for Animal Health (the “OIE”) in reaching a decision as to which countries are acceptable. The OIE (an intergovernmental organisation) is responsible for establishing and publishing the animal health status of countries/regions. The diseases monitored by OIE include many diseases that are transmitted from animal to animal (e.g. foot and mouth disease) and also potentially zoonotic diseases (i.e. transmissible from animals to man). The principal source countries/regions for serum are Australia, New Zealand and North, Central and South America.

Disease status of a country is not the sole consideration. With the exception of blood from donor animals in donor herds, blood is obtained from animals at the time of slaughter (see also: *What is bovine serum?*). For this reason source countries must have in place an infrastructure that includes authority-licensed slaughterhouses/abattoirs, acceptable to national and international bodies and dedicated to the processing of healthy animals. The animals must be inspected by qualified, authority recognised experts both before and after slaughter and meat from the animals must be passed as fit for human consumption.

In the case of donor blood the donor herds are very carefully controlled, and the health status of the animals is extensively monitored and documented.

The conditions of processing are also critical. ISIA member companies ensure that the production processes are very carefully controlled and monitored. This includes any processes that may need to be contracted out (e.g. gamma irradiation which can only be done in a specialised and licensed facility).

Quality Assurance systems for the monitoring and evaluation of the equipment, facilities and procedures and competencies and training of staff are in place. Companies will perform periodical self-audits as part of quality assurance. They are also subject to frequent audits by authorities and by customers.

Quality control testing is performed in order to ensure that serum products consistently conform to all relevant rules and regulations and meet customer requirements and specifications. Many of the quality control tests that are performed use protocols that have been developed by, or are recognised by, national or international regulatory bodies. When such recognised test protocols exist they are always followed. The tests that are performed include tests that are specifically designed to detect the presence of a very wide range of bacteria, viruses and other microorganisms.

All of the above is comprehensively documented to ensure that procedures can be seen to have been followed and that relevant test results are available for every step and for every batch of processed serum that is produced. The “traceability” of all of the material that makes up each batch of serum from origin to end product is recognised by ISIA member companies as being an imperative; it provides the necessary assurances that a specified batch of serum cannot have been substituted with another of unknown quality (and thus unknown safety). With this in mind, the ISIA has itself established a very comprehensive traceability policy.