

Traceability Certification

Frequently Asked Questions



NOTHING
WORKS
LIKE
SERUM

INTERNATIONAL SERUM
INDUSTRY ASSOCIATION

What is ISIA Traceability?

- The ISIA Traceability Policy is an international set of standards to ensure traceability of animal serum products.
- The emphasis of the ISIA Traceability Program is on systems and controls to ensure quality and traceability of a product from the abattoir to the end user.
- The Program has been in place since 2009.
- List of certified companies available – www.serumindustry.org



What is audited?

- A sound traceability audit is based on key aspects of the
 - Supply chain
 - Overall traceability
 - Truth in source
 - Quality of the serum products being audited
- Certain aspects of a Quality Management System (QMS) are required so that the system can provide evidence to support these criteria at each step of the collection and manufacturing process.
 - Quality overview
 - Supplier audits
 - Document control
 - Training
 - Identification
 - Segregation
 - Records



Who can be certified?

- Raw serum suppliers
- Filtration companies
- Contract manufacturers
- If your label goes on the bottle at any stage
- Warehousing companies



How does the program work?

A	Contact Information
B	Company Overview
C	Raw Materials
D	Blood Collection
E	Blood Transfer
F	Primary Processing
G	Product Transfer – Primary to Final
H	Secondary Processing
I	Product Transfer – to Other Locations
J	Finished Material
K	Shipping
L	Contract Manufacturing Companies
M	Obtain Samples
N	Bovine Serum Albumin



What species are included in the program?

- All species!!



Is certification for unfiltered or finished material?

- Both
- Material can be certified at either stage



What about purchasing material from a non-certified company?

- If a traceability certified member purchases blood or raw serum from a non-traceability certified company, the material can be considered traceability certified only if
 - Independent Quality department has audited, **including traceability**, and approved the source of raw material OR
 - Independent Quality department has provided a checklist for trained personnel, **including traceability**, to evaluate the supplier and the completed checklist is approved and reviewed by Quality.



Why should my company become certified?

- Industry health
- Government support
- Harmonization of standards
 - Paperwork
 - Traceability
 - Worldwide acceptance



How much does it cost?

- Price is dependent on size
- Smaller company with 2 locations ~\$5500
- Larger companies and more locations = more money



What if I am ISO 13485 certified?

- Accommodations have been made in the Audit Checklist, removing some sections for companies that are ISO 13485 Certified.
- However, if evidence is present showing these requirements are not met, this will be noted in the report and could lead to a nonconformance.



What is the first step to certification?

- Notify ISIA ~ Email info@serumindustry.org
- Paperwork
- Audit Scope and Plan
- Auditor Approval



Conclusions

- The ISIA Traceability Audit program has been in place for more than 14 years.
- It has changed dramatically and will continue to adapt to the needs of the serum industry.
- The ISIA website contains up-to-date information on the program.
- If you have questions feel free to contact the ISIA Staff ~ Rosie Versteegen, Steve Doelger, Kathryn Pagani-Lee at info@serumindustry.org.



Questions?

