



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?

| Α | Contact Information |
|------------------|---|
| В | Company Overview |
| С | Raw Materials |
| D | Blood Collection |
| E | Blood Transfer |
| F | Primary Processing |
| G | Product Transfer – Primary to Final |
| н | Secondary Processing |
| | - coonday i rocconing |
| | Product Transfer – to Other Locations |
| | |
| 1 | Product Transfer – to Other Locations |
| I J | Product Transfer – to Other Locations Finished Material |
| J K | Product Transfer – to Other Locations Finished Material Shipping |
| I J K L | Product Transfer – to Other Locations Finished Material Shipping Contract Manufacturing Companies |

What species are included in the program?

• All species!!



Is certification for unfiltered or finished material?

- Both
- Material can be certified at either stage

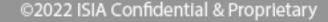


What about purchasing material from a non-certified company?

- 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 ISO13485 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?

