ISIA Traceability

How does it compare to ISO?

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INTERNATIONAL SERUM
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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

What is ISO?

- ISO certification is the internationally recognized standard for QMS.

- ISO 9001 provides a framework and sets principles to
  - ➤ Ensure consistently satisfying customers
  - ➤ While emphasizing process improvement

- ISO 13485 is a set of standards specific to meeting the requirements of Medical Device Manufacturers.

- So why do you need to be traceability audited if you are ISO 13485 certified ?

ISIA vs ISO 13485 Certifications

CATEGORY	ISIA	ISO 13485
Purpose	Certificate for serum traceability	Certificate for QMS compliance
Focus	Animal Serum/Plasma Industry specific	Medical Devices
Frequency	Audit every 3 years - initial certification audit (review 1-year financials / inventory mass balance); subsequent audits every 3 years (review 3 years of financials / inventory mass balance)	Audit every year - initial certification audit followed by two annual surveillance audits; cycle repeats
Batch record review	Review batch records, processes, and documents for serum production	Review batch records and documents
Quality Management System (QMS)	Reviews some aspects of the QMS - depends on integration of business	Reviews all aspects of the QMS
Geographic testing	Required	Not required
Quality Department	Quality unit typically in organization; present when producing finished product; maybe at a lesser extent for raw serum providers only	Requires Quality unit for continuity of QMS and adherence to ISO / regulatory requirements
Sample retention	Sample retention required	Batch / raw material samples maybe retained

ISIA vs ISO 13485 Certifications

CATEGORY	ISIA	ISO 13485
Yield review	Yields strictly monitored; % yield calculations reviewed and verified	Yields may be monitored
Record retention	5 years minimum	Variable
Traceability	Traceability requirement for blood/serum throughout the supply chain- including mass balance	Only requires general traceability for raw materials
Supplier audit requirements	Supplier audits for blood/serum suppliers more detailed - specific questions required	Supplier audits for raw materials are not as detailed as ISIA requirements
Financial mass balance review	Included	Not included
Additional regulatory Requirements	Based on country where member company resides and where product is shipped; ex., EU / USDA / other country regulations	None - minimal USDA or other regulatory involvement
Auditors	ISIA approved auditors trained specifically on the serum industry	Auditors may not have knowledge of the serum industry

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.

Conclusions

- The ISIA Traceability Audit program has been in place for more than 10 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 industry including the table discussed earlier.

- If you have questions feel free to contact the ISIA Staff - Rosie Versteegen, Steve Doelger, Kathryn Pagani-Lee.

Questions?