

ISIA Traceability Certification



NOTHING
WORKS
LIKE
SERUM

INTERNATIONAL SERUM
INDUSTRY ASSOCIATION

International Serum Industry Association

- International Association of serum producers, suppliers and customers, founded in 2006
- Members estimated to supply more than 90% of all animal serum used globally
- Members are also major suppliers of all animal derived products
- Protein, Antibodies, Enzymes, etc.
- Expanded mandate includes all animal derived products
- Currently 52 members ~ complete listing at www.serumindustry.org
- Includes many major suppliers
- Several large Pharma companies





Current as of 07.13.2023

ISIA Membership Make-up

- Current membership is made of the following:
 - Eighteen of the current ISIA membership are **Traceability Certified**;
 - The number of sites and the volume of sera audited is great as most of these certified companies have multiple sites
 - An additional eighteen ISIA members are **Regular Members** of the association, but are not ISIA traceability certified at present
 - There are also nine ISIA members that are considered **Associate Members**. These companies have access to the ISIA website (International Serum Industry Association | Traceability, Bovine Serum, FBS), but do not have access to the Member or Auditor Resources sections of this website, nor do they have voting rights. They can attend the annual ISIA meeting for a fee.



Industry Background

- The Biotechnology industry is a multibillion-dollar business affecting healthcare worldwide, and relies extensively on the use of serum and animal derived products as essential raw materials
- Animal serum is used extensively in
 - Life science research
 - Production of human and animal vaccines
 - Production of biopharmaceuticals
 - Production of diagnostic products
- In the applications above, material produced using serum raises concerns about adventitious agents being present



Why Traceability Matters

- Of all the types of bovine serum, fetal bovine serum(FBS) works the best in many cell culture applications
- Total liters of FBS available is estimated at 900,000L+ per annum
 - Other animal sera are in millions of liters per annum
- As a result of availability, FBS is much more expensive than other types of serum
- Customers need to be able to trust that they are getting what they pay for
- Since all finished FBS looks alike, there has been a financial incentive to switch origin and/or age of serum
- The cost of FBS to the customer is dependent on the country of origin
 - FBS works the same way regardless of the origin



How to Manage Traceability

- Oritain provides origin testing to determine geography
- Testing is also available to determine the age of the source animal for the serum
- ISIA Traceability Certification



Traceability Certification Program



What is the Program?

- ISIA Traceability Certification is available only to members of the Association
- Certification requires successful completion of a third-party audit to the ISIA policy and audit checklist; includes sampling / Oritain testing
- A company may combine this third-party audit with another quality systems audits such as ISO 13485
- Certification is granted for maximum of three years or until ISO re-audit
- No historic claims



Program Overview – Traceability Certification

- Preparation
- During the Audit
- Post Audit



Traceability Certification ~ Preparation

- Notify ISIA ~ info@serumindustry.org
- Waiver
- Audit Scope
- Auditor Approval
- Audit Plan
- Notice to Proceed



Traceability Certification ~ Audit Plan

- Discussed with the auditor
- Submitted to ISIA for approval
- Approved prior to start of the audit
- Cover all serum types and stages
- BSA does not have to be included



Traceability Certification ~ During the Audit

- Covers all animal serum types
- Initial audit covers 1 year of data
- Certification lasts for 3 years
- Complete checklist

Type of serum/plasma	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Species	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Shipping date	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Number of boxes	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Unique batch number	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Number of jugs with a list of all the unique jug numbers	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Volume of each jug	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Country of origin	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
Name of company	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A



Traceability Certification ~ During the Audit (checklist)

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



Traceability Certification ~ During the Audit (checklist)

- Checklist
- Labeling – country of collection required for raw and finished serum
- Mass balance
- Oritain samples



Traceability Certification ~ During the Audit (checklist)

- Recertification every 3 years
- Regions no longer accepted on the label
 - Country of collection required on label
 - Even when multiple countries are used in a batch – effective 01JAN2023



Traceability Certification ~ Post Audit

- Audit report
- Nonconformance plan (if applicable)
- Certification issued
- Seal use
 - Application
 - Examples
 - Approval



Virtual Audits

- ISIA offers virtual audits for companies who need recertification



Benefits of Certification

- End users and regulator support
- Independent third-party audit
- Common ground – we all work towards harmonization of the industry to ensure the products we provide are what they



Questions?

