

# ISIA Traceability Certification



**INTERNATIONAL SERUM  
INDUSTRY ASSOCIATION**



# Why Traceability Matters

- **Customers and regulators continue to be concerned about the potential for adventitious agent contamination of animal derived materials used in biopharmaceutical and vaccine production**
- **Certain geographic regions are preferred for these applications based on disease profile and infrastructure**
  - **New Zealand**
  - **Australia**
  - **USA**
  - **Canada**



# Why Traceability Matters

- The recent recall of PAA produced misbranded and adulterated material has made customers and regulators are even more concerned about the origin and integrity of materials
- Traceability has become a mantra at meetings where vaccine and biopharmaceutical manufacturing are discussed
- Many companies have dedicated sourcing and audit programs to ensure Traceability



# A Brief History

- Since its inception ISIA has identified Traceability as a key issue for the Industry and its customers
- The ISIA Traceability Certification Program has been evolving since 2009
- Currently 70% of companies who have been ISIA members for at least two years are certified or in the process of becoming certified
- See the ISIA website for a complete list of certified companies



# What is the Program?

- ISIA Traceability Certification is available only to members of the Association
- Member companies may combine this audit with another quality systems audits such as FDA or ISO 9000 and the audit is performed at the company's expense



- Traceability Certification requires successful completion of a third party audit based on the ISIA audit checklist by an ISIA approved auditor to an ISIA approved audit plan
- Traceability Certification is granted for a maximum of three years, or until the expiration of ISO certification
- ISIA reserves the right to randomly audit to ensure program effectiveness



# What is the Program?

- All of a company must be audited
  - An approved sampling plan must be used for companies with multiple facilities
- All serum and plasma must be audited
  - Not just FBS
- For an initial audit at least one year's worth of information must be reviewed
  - This can include a random selection of all batches manufactured, their documentation and related cost accounting to create a true mass balance of materials over the time period
  - 3 years of data required for recertification
- Since July 1, 2014 a company must be certified, or in special cases actively planning to be so, to hold a seat on the ISIA Board of Directors



# Traceability Certification



- **The right to the use of the ISIA Seal and the ability to claim certification is granted solely to those companies that have fulfilled the criteria stated above and cannot be transferred under any circumstances.**
- **Purchase of material from a certified company, or processing of material by a certified company, confers no right to claim or infer traceability certification.**

**Want ISIA Traceability Certification?  
Apply for Membership Now!**

