

ISIA

Why Your Company Should Join!



NOTHING
WORKS
LIKE
SERUM

INTERNATIONAL SERUM
INDUSTRY ASSOCIATION

The International Serum Industry Association - ISIA

- **Founded in 2006**
- **54 Members, representing producers, suppliers and users of animal serum and derived products**
- **Over 90% of animal serum used globally is supplied by ISIA members**
- **The ISIA provides value to members by supporting industry, the end users and helping regulatory decision-makers understand the complexity of these markets**



ISIA - Our Mission

Ethics

ISIA shall establish, promote and assure compliance with uncompromised standards of excellence and ethics in the business practices of the global animal serum and animal derived products supply industry.

Safety and Use

Our primary focus will be on safety and safe use of serum and animal derived products through proper origin traceability, truth in labelling, and appropriate standardization and oversight.

Education

We will work to educate stakeholders on the scientific foundation of the safe use of serum and animal derived products.



Our Members



Industry Background

- **Animal serum is used extensively in**



- Life science research
- Production of human and animal vaccines
- Production of biopharmaceuticals
- Production of diagnostic products

- **Total liters of FBS is in excess of 600,000 to 700,000 per annum**
 - Other serum are in excess of millions of liters per annum
- **The Biotechnology industry is a multi-billion dollar business affecting healthcare worldwide, and relies extensively on the use of serum and animal derived products as essential raw materials**



Areas of Focus

- Traceability Certification
- Standardization
- Regulatory
- Global Outreach



Traceability Certification



- What is Traceability?
- The word traceability is used in many industries, from food to the systems and software development sector and even in forestry. The National Institute for Standards and Technology (NIST) uses the words “documented unbroken chain” to describe traceability.
- In every use of traceability, the beginning origin must be known for the product or system to be traceable. The same is true for the serum industry. With serum, traceability is the capability to discover information about where a product originated, to be able to follow an unbroken paperchain through every stage of production - from where it originated to the end user.



Traceability Certification



- This process is the law and a core component of the ISIA ethos. What you see on the label must be a true and accurate description of what is in the bottle.
- ISIA traceability certification is based on an independent third-party audit. These audits are only conducted by ISIA approved and trained auditors with an approved audit plan. Any nonconformities identified are categorized and reported to the auditee in a timely manner.
- Traceability certification is not available for purchase, nor can it be transferred under any circumstances.



Traceability Certification



- Initial certification requires an audit of at least one year of data and is granted for three years. Recertification audits review the last three years of data. ISIA will not comment on claims made prior to the formation of the Association.
- Companies are certified for the piece of the process they perform. This may be one step or, for vertically integrated companies, it may be every step.





Traceability Certified Companies

65% of companies that have been members for more than 2 years are certified or in process

[Atlas Biologicals, Inc.](#)

[Axenia BioLogix](#)

[Avantor Sciences](#)

[Biomim Biotechnologia LTDA](#)

[Biowest](#)

[By Productos S.A de C.V.](#)

[Central Biomedica Inc.](#)

[Corning Incorporated](#)

[Cytiva/ HyClone](#)

[Flint Bio](#)

[Gibco by Thermo Fisher Scientific](#)

[Orygina/JBS](#)

[Life Science Production](#)

[Moregate Biotech](#)

[Newman Biotech Australia](#)

[Proliant Biologicals LLC](#)

[River City Biologicals](#)

[River City Biotechnologia Brazil Ltda](#)

[Rocky Mountain Biological](#)

[SeraTec](#)

[Serum Technologies](#)

[TCS Biosciences, Ltd](#)



Standardization

Mission:

Our primary focus will be on safety and safe use of serum and blood derived products through proper origin traceability and truth in labeling, and appropriate standardization and oversight.

Available on the ISIA website:

Countries of Origin for Bovine Sera

QC Test Methods/ Why Test Methods, CoAs

Bovine Serum Processing Flow Charts available on the ISIA website.

USP Collaboration

- QC testing standards have been harmonized in conjunction with USP in Chapter 204 on Bovine Serum and Chapter 90 on Fetal Bovine Serum
- ISIA and ISIA members have been actively working with USP to develop a Fetal Bovine Serum standard
 - Released for sale June 2014

What is Bovine Serum FAQ



Regulatory

MISSION:

Strengthen our position as the industry resource and liaison with global regulatory agencies. Educate members and consumers on import/export regulations.

- Broaden the scope to become more global
- Revisit what can go where, when and how
- Actively seek out and report on potential regulatory issues that may have an impact on the serum industry worldwide.
- Review all governmental updates for potential impact
- Identify topics for regulatory updates
- Actively choose one country to review in detail each meeting
- Create a white paper on Humane and Ethical FBS collection
- Based on slaughter regulations and 3Rs
- Focused on the OIE position on these issues
- Propose three topics from each meeting to be forwarded to the Marketing Team



Strategic Membership Benefits

- **ISIA has developed strong relationships with regulators and Associations worldwide.** As a member of ISIA, you will benefit from ISIA's global connections and gain a competitive advantage by obtaining relevant information at an early stage!
- **ISIA membership will help you to make faster and better decisions, and save you time and resources.** Your password protected entrée to the "Members Only" Section of the ISIA website gives you easy access to a wide variety of information relating to ongoing and past ISIA activities and global regulations.
- **ISIA is proactive, holding regular meetings with regulatory groups world-wide and in many cases receiving information prior to it being made available to the general public.** Members receive continual updates on interactions with these regulatory agencies and are often asked for comments on regulations prior to their implementation, thus allowing specific concerns to be heard.
- **ISIA provides summaries of complex legislation for its members, developing guidance that can save you the time and costs associated with problem shipments.** Due to ISIA's continuous communication, our network of regulators helps resolve member issues very quickly.
- **ISIA Traceability Certification** - This program is now recognized by industry and government agencies throughout the world as the best way to ensure credibility with regards to the source serum.
- **ISIA membership introduces you to a strong network, enabling you to exchange best practices and views on key issues of interest to our industry.** Volunteer for one of our regional committees and help to influence our future regulatory environment by sharing information, pooling resources, and dealing with issues of common interest.



Can we help you?



- You can learn more about ISIA at our website. www.serumindustry.org
- Follow us on LinkedIn to get the latest global information on regulatory issues and other industry and ISIA newsworthy items
- To contact us: info@serumindustry.org

