

ISIA

Why You Should Join!



NOTHING
WORKS
LIKE
SERUM

INTERNATIONAL SERUM
INDUSTRY ASSOCIATION

The International Serum Industry Association ~ ISIA



INTERNATIONAL SERUM
INDUSTRY ASSOCIATION

*Click the image above to watch Dr.
Versteegen, ISIA's CEO, discuss the benefits
of being an ISIA Member.*

- **Founded in 2006**
- **51 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 the industry, our end users and by 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

- Membership has grown more than threefold since inception in spite of market consolidation
- Members come from 14 countries worldwide



Industry Background

- Fetal bovine serum (FBS) has impressive historical validation after more than 65 years of safe use
- Animal serum is used extensively in



- Life science research
 - Production of human and animal vaccines
 - Production of biopharmaceuticals
 - Production of diagnostic products
- Total FBS produced is in excess of 600,000 to 700,000 liters 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 material



Strategic Areas of Focus

- **Traceability Certification**
- **Standardization**
- **Regulatory updates/ Issues**
- **Global Outreach**



Traceability Certification



- Traceability is defined as a “documented unbroken chain”
- For serum, traceability is the capability to know where the product originated, and to be able to follow an unbroken paperchain from there to the end user.
- This is not only the law but 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.



Traceability Certification



- ISIA traceability certification is based on an independent third-party audit conducted by an ISIA approved and trained auditor to 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 cover three years of data.
- 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



90% of companies that have been members for more than 2 years are certified or in process

[Animal Technologies](#)

[Avantor Sciences](#)

[Axenia BioLogix](#)

[Biomin Biotechnologia LTDA](#)

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

[Central Biomedica Inc.](#)

[Corning Incorporated](#)

[Cytiva / HyClone](#)

[Gibco by Thermo Fisher Scientific](#)

[Life Science Group, Ltd](#)

[Moregate Biotech](#)

[Newman Biotech Australia](#)

[Orygina / JBS](#)

[River City Biologicals](#)

[River City Biotechnologia Brazil Ltda](#)

[Rocky Mountain Biologicals](#)

[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, truth in labeling, appropriate standardization and oversight.

Available on the ISIA website:

Guidance document for CoA

Definition for Origin of Bovine Sera

QC Test Methods and Why we test for these analytes

Bovine Serum Processing Flow Charts



Regulatory

Mission:

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

- **Strengthen Global Regulatory and Compliance reach**
- **Provide guidance on import/export (what can go where, when and how)**
- **Work with global competent authorities to seek out and report on potential regulatory issues that can impact the serum industry worldwide**
- **Provide education and guidance: Gamma irradiation, Humane and Ethical FBS collection, Animal By-Product guidance, OIE animal disease updates, Competent Authority updates about imports and exports**
- **Work proactively within the ISIA to support the industry and our customers**



Global Outreach

- ISIA has become a key player in helping industry, end users, and regulatory decision-makers understand the complexity of these markets and products and is now viewed by many as a valued partner.
- In many cases ISIA is contacted directly as updates to regulations about importing and exporting of serum are being developed by government agencies.
- Our Traceability Certification Program is recognized as the serum industry standard for integrity.
- ISIA representatives are asked to present at major scientific conferences because of our industry influence and detailed knowledge.



Strategic Membership Benefits

- 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
 - Members receive continual updates on interactions with these regulatory agencies
 - ISIA is often asked for comments on regulations prior to implementation, allowing specific concerns to be heard.



Strategic Membership Benefits

- ISIA provides summaries of complex legislation for its members, developing guidance that can save you the time and costs associated with problem shipments.
 - Our network of regulators help resolve member issues quickly.
- ISIA Traceability Certification recognized by industry end users and government agencies throughout the world as the best way to ensure credibility with regards to the 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



If you are involved in the Serum Industry You Should be a Member of ISIA!

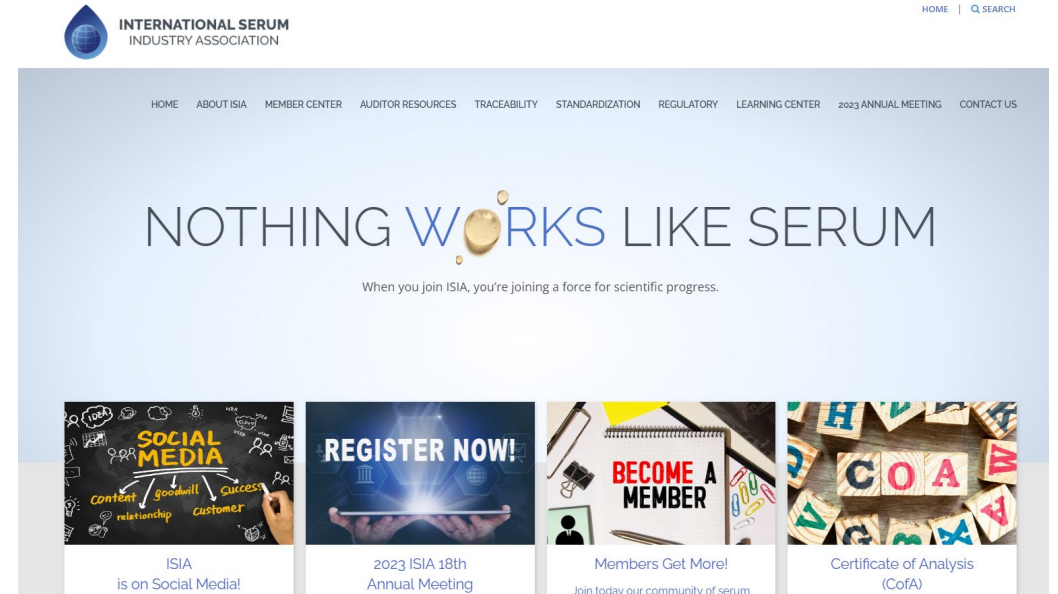
- ✔ • Give your customers confidence in your integrity
- ✔ • Government regulators will know you meet high standards
- ✔ • Be a part of an association that understands your concerns and works to get answers and solve problems
- ✔ • Join others in your industry that promote uncompromised ethics and standards



Learn more about ISIA on our website

www.serumindustry.org

Contact us: info@serumindustry.org



Follow us on LinkedIn and Facebook to get the latest global information on regulatory issues and other industry and ISIA newsworthy items