



# ISIA Overview

## 2016



# International Serum Industry Association

- **International Association of serum producers, suppliers and customers, founded in 2006**
- **Members 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 54 members**
  - All major suppliers
  - Several large end-user companies





# ISIA 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 SAFE USE** - Primary focus will be on safety and safe use of serum and animal derived products through proper origin traceability, truth in labeling, and appropriate standardization and oversight.
- **EDUCATION** - Work to educate stakeholders on the scientific foundation of the safe use of serum and animal derived products.





## REGULAR MEMBERS

- Abattoir Basics Company
- Access Biologicals
- Allevamento Blood
- Antibody Production Services
- Animal Technologies Inc.
- Atlanta Biologicals
- Auckland BioScience
- Ausgenex Biologix
- Axenia Biologics
- BioArra
- BioCell
- Biological Industries
- BioMin Biotechnologia
- BioSul Productos Biologicos
- BioWest SAS
- Boval Company, LP
- ByProductos, S.A.
- California Biologicals, Inc.
- Central Biomed Inc.
- Corning/ Mediatech Inc.
- Gemini Bio-Products
- Hemostat
- HyClone/GE Healthcare
- JR Scientific
- LaCell LLC

**ISIA TRACEABILITY CERTIFIED MEMBERS**

**ABATTOIR BASICS COMPANY**  
ANIMAL TECHNOLOGIES, INC.

**APS**

**AXENIA BIOLOGIX**

**BIOARRA**

**biomin**  
biotecnologia s/a

**Boval**  
Boval BioSolutions, LLC

**CENTRAL BIOMEDIA INC.**

**GE Healthcare**

**gibco**  
by Thermo Fisher Scientific

**MOREGATE BIOTECH**  
AUSTRALIA

**NEWMAN BIOTECH AUSTRALIA**

**Proliant BIOLOGICALS**  
The Science of Protein

**River City Biologicals, Inc.**

**RMBIO**  
Rocky Mountain Biologicals, Inc.

**SERUM TECHNOLOGIES**

**VWR**  
SeraSign LIFE SCIENCE

**VACCA**  
BIOLOGICS LLC

**REGULAR MEMBERS**

**Access Biologicals LLC**

**Allevamento BLOOD**

**AmCell BIOSCIENCES**

**ATLANTA biologicals**

**AUCKLAND BioSciences**

**AusGeneX**

**Biocell**

**BI**  
Biological Industries

**biosul**

**biowest**  
THE SCIENCE OF PROTEIN

**ByProductos**

**CBP**  
CALIFORNIA BIOLOGICALS

**CORNING**

**ExCell Bio**

**GEMINI BIO-PRODUCTS**

**HEMOSTAT**

**JRScientific Inc.**  
advantage inside

**LaCell**

**LAMPIRE**  
BIOLOGICAL LABORATORIES

**MINHAI BIO**

**MILLIPORE SIGMA**

**NICHIREI BIOSCIENCES INC.**

**Pel-Freez**  
BIOLOGICALS

**River City Biologicals, Inc. Brazil**

**SERUM SOURCE INTERNATIONAL**

**STEMCELL TECHNOLOGIES**

**tcs**

**WISENT BIOPRODUCTS**

**ASSOCIATE MEMBERS**

**SILVER FERN FARMS**

**vrrd**

**BD**

**IDEX LABORATORIES**

**Johnson & Johnson**

**LGC**

**KERRY**

**VS**  
Viral Science

# Members

- Lampire Biological
- Lanzhou Minhai Bio-Engineering
- Millipore Sigma
- Moregate Biotech
- Newman Biotech
- Nichirei Biosciences, Inc
- Pelfreez
- Proliant Biologicals
- River City Biologicals, Inc.
- Rocky Mountain Biologicals
- Serum Technologies
- Shanghai Excell Bio
- TCS Biosciences
- Thermo Fisher Scientific
- VWR/ Seradigm
- Vacca
- Wisent

## ASSOCIATE MEMBERS

- Beckon, Dickenson & Co
- IDEX Laboratories
- Johnson & Johnson
- LGC Standards
- Sheffield Biosciences/ Kerry
- Silver Fern Farms
- Viral Sciences
- VMRD



# 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 around 700,000 liters per annum**
  - **Liters of other serum are significantly larger**
- **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**



# ISIA Areas of Focus

**Standardization**

**Community Relations**

**Traceability and Audit**



# Standardization

- **QC Testing**



- A set of testing methods and recommended specifications was determined
- A certificate of analysis framework was agreed
- Serum definitions and standardized FBS QC tests and specifications are published on the website

- **USP Collaboration**

- QC testing standards have been harmonized in conjunction with USP in Chapter 2024 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**

- Completed and available on the website





# Community Relations Philosophy

- The blood derived products industry is considerably more complex than expected by non-participants
- ISIA is committed to the simplification and global harmonization of appropriate regulation
- ISIA believes that education should precede regulation
- Failure to educate has led to complexity and impracticality of regulations







# ISIA Network





# ISIA as a Resource

- In the decade of its existence, **ISIA has become a key player** in helping industry, end user, 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 or complications to importing and exporting of serum become known to government agencies.



# **“Knowledge is a viral barrier”**

Ivar Kljavin, Ph.D.  
Genentech



# Bovine Derived Raw Materials

- Fetal bovine serum (FBS) has an impressive historical validation after more than 65 years of demonstrated safe use
- No known substance has the same broad spectrum cell growth promoting capabilities
- Over time, concerns have arisen over utilization of bovine derived materials in healthcare related manufacturing
  - Regulatory guidance over many years
    - Possible presence of adventitious agents
      - New testing methods
    - Post manufacturing treatments





# The Animal Derived Materials Saga

- **Serum is going away!**
  - Considerable efforts have been made to remove animal derived materials and FBS from use with some success
- **The Holy Grail**
  - A medium that will grow all cells in the absence of animal derived materials
    - Found for some specific cell lines
- **Alternatively sourced materials have their own problems**
  - Plant derived materials contaminated with animal derived organisms as well as new adventitious agents
- **Can't live with it – Can't live without it?**
  - Many important cells lines need serum present to manufacture biologically active and/or commercially viable materials
- **These materials will continue to be used in biopharmaceutical and vaccine production for many years**





# Sourcing Areas of Focus

- **Geography**
  - **Disease localization**
    - TSE, FMD, Blue tongue etc.....
- **Infrastructure**
  - **Country, legal and vendor**
    - Systems and record keeping
    - Quality systems
    - Animal tracking
- **Customer preferred sources for Biopharma applications**
  - **NZ, AUS, USA**
    - NZ can only produce a fraction of the material needed



# International Serum Industry Association







# Why Traceability Matters

- Serum from certain geographic regions is preferred by bio-pharma customers, based on disease profile and infrastructure
- There are no tests currently available to determine geography or the age of the animal that serum came from
  - We are working a test for geographic origin
- Since all finished serum looks alike, there has been an incentive to switch origin, age of animal



# What is the Program?

- The ISIA Traceability Certification Program was one of the first initiatives embraced by the Association in 2006
- ISIA Traceability Certification is available only to members of the Association
- Certification requires successful completion of a third party audit by an approved auditor and audit plan to the ISIA audit checklist
- The company may combine this third party audit with another quality systems audits such as ISO 9000
- Certification is granted for maximum of three years or until ISO re-audit
  - No historic claims





# Traceability Certification



**ISIA Traceability Certification, the right to 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.**



# Certified Companies

- **70% of companies that have been members for more than 2 years are certified or in the certification process**

**Antibody Production Services  
Abattoir Basics Company  
Animal Technologies Inc.  
Axenia BioLogix  
BioArra  
Biomin Biotechnologia LTDA  
Boval BioSolutions  
Central Biomedica Inc  
GE Hyclone**

**Gibco by Thermo Fisher Scientific  
Moregate Biotech  
Newman Biotech Australia  
Proliant Biologicals  
River City Biologicals  
Rocky Mountain Biologicals  
VWR/Seradigm  
Serum Technologies  
Vacca Biologics LLC**

**Several additional companies in process!**



# Education

- **ISIA is involved in many programs/ initiatives designed to educate members and users about the industry**
  - Presentations at important meetings in the US, Europe, and Asia
  - Heavy involvement in USP chapters <90> and <1024>
  - Access to independently written articles
  - Gamma Irradiation Task Force
  - APHIS Risk Assessment
  - Technical white papers
    - PCR testing and correlation to live virus





# Conclusion

**Can we help you?**

Find out more about us at

[www.serumindustry.org](http://www.serumindustry.org)



Or contact us at  
**info@serumindustry.org**