

Bovine Serum

Introduction

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Brief introduction

- Today's and tomorrow's presentations, represent the voice of many collaborators => **WE**.
- Our main objective is to **inspire** and **initiate a process** towards giving bovine serum, the fair position, which it really deserves.
- What's new? The way we bring the different **fact based**, aspects, related to the **use** of bovine serum together, to create more **clarity**.

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Some history

- Bovine serum has > 70 years of history in large scale production of human and animal biological products starting with Salk Polio (IPV) vaccine, licensed in 1955.
- This is the starting point of bovine serum's glorious career:

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Serum Saves Lives – Animal Welfare

The Global Serum Alliance supports the **3R** statement of William M.S. Russell and Rex.L. Burch in The Principles of Humane Experimental Technique, published in **1959**, in which they classified humane techniques under the headings of **R**eplacement, **R**eduction, and **R**efinement, now commonly known as the **3Rs**.

The objective is to **minimise the need for experiments on lab animals**.

Cell culture is the perfect instrument to comply with this.

Animal **serum is the essential fuel to grow cells** for research and production of life saving technologies.

The Global Serum Alliance defends a **5R** position to include the **R**esponsibility that, as long as the killing of animals is needed to feed the world, humans have the ethical obligation to efficiently use and **R**ecycle every piece and drop of the animal to the benefit of **human and animal welfare**.

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Serum Saves Lives – Sustainability

- The serum industry **recycles** a by-product of milk and meat production to turn it into a highly valuable component for production of medicinal products.
- Bovine and other animal sera are of key importance in the context of:
 - Human and animal **welfare**
 - **Sustainability**
- A few examples:
 - Human and animal vaccines
 - Revolutionary, stem cell based, cancer therapies
 - ...

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Serum Saves Lives – Sustainability – Example

**Improved animal husbandry,
biosecurity and vaccination as
a strategy to reduce
antimicrobial use**



World Organisation
for Animal Health
Founded as OIE

https://www.woah.org/en/document/improved-animal-husbandry-biosecurity-and-vaccination-as-a-strategy-to-reduce-antimicrobial-use/?utm_source=chatgpt.com

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Serum Saves Lives – Sustainability - Example

- Animal vaccination is of crucial importance to:
 - Prevent animal illness, to avoid => use of **antibiotics**.
=> **killing** large numbers of healthy animals.
 - Animal welfare => avoid animals **suffering** from illness
 - Sustainability => avoid **environmental** impact of needless destruction of animals (transportation & incineration).
=> avoid considerable **economical** losses.
- Cells + Culture Medium + **Serum** + Virus of interest, seems to be the most efficient way for development & production of animal vaccines.

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Use of Animal Serum in Production Reality of Life & Solutions

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WHEN TRYING TO WORK
ACCORDING TO REGULATIONS,
MAN'S BIGGEST ENEMIES ARE...



AS A RESULT...
EVERYONE IS CONFUSED!



DIFFERENT PERCEPTIONS, INTERPRETATIONS, ASSUMPTIONS, EMOTIONS AND IGNORANCE LEAD TO CONFUSION...
AND CONFUSION PREVENTS CLEAR, CONSISTENT, AND SAFE PUBLIC HEALTH OUTCOMES.

What is it about?

- Animal derived is to be avoided – non-animal is safer. **Is this true?**
- Rules for import of bovine serum vary from country to country. **Why?**
 - For import from **LSD** affected countries, **UK** requires a **negative PCR** whereas **Japan** needs ≥ 25 kGy gamma **irradiation**.
 - **US** requires bovine serum **safety testing** in **sheep**.
 - **EU** allows importation of **bovine serum** from countries which are eligible for import of **bovine meat**. Bovine serum from some other countries may be eligible after ≥ 25 kGy gamma **irradiation**.
 - **South Korea** only accepts bovine serum from **NZ, Australia, US & Canada**.
 - **US** allows importation of serum from USDA approved slaughterhouses in **11 countries**.
 - **US** requires master **seeds** to be **PCR (-)** for **BVDV**

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This is also important to know

- Bovine serum is a lot more than FBS:
 - Newborn calf
 - Calf & veal calf => Iron Supplemented Calf
 - Adult bovine
 - ...

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We are her for a reason !!
Thanks to IABS for the initiative.



International Alliance for
Biological Standardization

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TOGETHER, WE FIND SOLUTIONS FOR GLOBAL HEALTH

CONSTRUCTIVE COLLABORATION FOR SOLUTIONS THAT WORK FOR ALL

DIFFERENT ROLES, SHARED GOAL: HEALTHIER PEOPLE EVERYWHERE!

OPEN DIALOGUE, SCIENCE-BASED DECISIONS, MUTUAL RESPECT!

WE NEED SAFE, RELIABLE SERUM TO DELIVER QUALITY MEDICINES AND VACCINES.

WE ARE COMMITTED TO QUALITY, TRANSPARENCY AND CONTINUOUS IMPROVEMENT.

WE LISTEN, WE SHARE, WE WORK TOGETHER FOR THE GREATER GOOD.

TOGETHER, WE BUILD TRUST, SHARE KNOWLEDGE, AND CREATE LASTING SOLUTIONS.

AUTHORITIES

- Protect Public Health
- Set Clear Expectations
- Enable Solutions

PRODUCERS OF MEDICINAL PRODUCTS USING SERUM

- Ensure Product Quality
- Manage Risks
- Need Reliable Supply

SERUM PRODUCERS

- Provide Quality Serum
- Ensure Traceability & Safety
- Invest in Excellence

TOGETHER WE ACHIEVE

- Stronger Systems
- Better Outcomes
- A Healthier World

SOLUTIONS FOR ALL

SAFETY FIRST
ACCESS & AFFORDABILITY

QUALITY ASSURED
SUSTAINABLE SUPPLY

INNOVATION & CONTINUOUS IMPROVEMENT

GLOBAL COLLABORATION – LOCAL IMPACT – SUSTAINABLE FUTURE



STRONG REGULATORY FRAMEWORKS



PARTNERSHIP & TRUST



SCIENCE & INNOVATION



RISK MANAGEMENT & QUALITY SYSTEMS



GLOBAL SUPPLY & CONTINUITY



SHARED BENEFITS: PATIENTS, COMMUNITIES, AND FUTURE GENERATIONS

BETTER TOGETHER FOR A HEALTHIER TOMORROW!



ONE WORLD. ONE GOAL. HEALTH FOR ALL.

Let's join forces for solutions => objectives

- Serum using **producers of medicinal products** and **serum producers** need to work closely together and propose constructive solutions to **global authorities**.
- **Educate** and keep on **convincing** the world about the importance of serum in the context of:
 - Human and animal **health**
 - Human and animal **welfare** (5R)
 - **Economical** impact in terms of employment and funding in the areas of:
 - Production of life saving & preventive **medicinal products**
 - Production of **diagnostics**
 - Academic and industrial **research**

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Let's join forces for solutions => objectives

- Facilitate the international trade of safe serum to:
 - Simplify and harmonise the rules where possible
 - Optimise safety when using serum in production processes
 - Optimize => supply chain security
=> Supply chain sustainability => e.g. minimize transportation

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A short word about the global FBS market

- There is a surprisingly **large spread** in published market estimates, because different reports define the market differently.
- It's forbidden for sector associations to talk about economics.
- With a little help of some friends (members & other allies), we have made a **summary proportional data**, related to different regions of the world.

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Volume and Average Cost Raw by Country

Relative comparison (no figures shown)



Please feel free to contact us for:

- Further information.
- Membership (serum producers & suppliers)
- Associate membership (companies in other serum related sectors and serum using organisations)



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