

Traceability

An important risk mitigation program

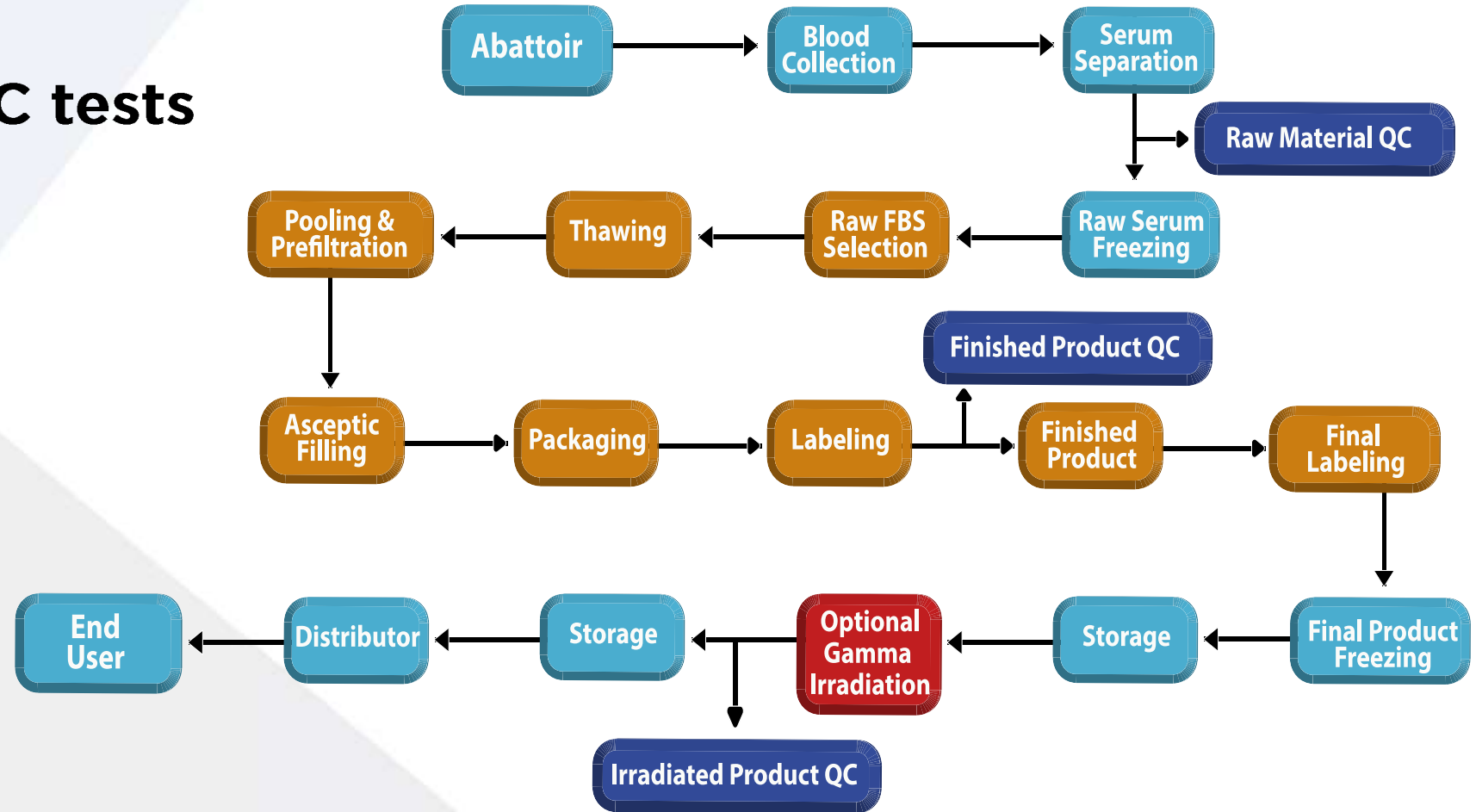


NOTHING
WORKS
LIKE
SERUM

INTERNATIONAL SERUM
INDUSTRY ASSOCIATION

Process Flowchart

17 steps
3 sets of QC tests



Modular Audit Focus

	Section
A	Auditor and Company Guidelines
B	Overview
C	Raw Materials
D	Blood Collection
E	Blood Transfer – Collection to Primary Processing
F	Primary Processing – Blood Processing to Serum or Plasma
G	Serum and/or Plasma Transfer – Primary Processing to Final Processing
H	Secondary Processing – Finishing of Serum or Plasma
I	Serum and/or Plasma transfer to other locations (including intercompany)
J	Finished Material
K	Shipping
L	Contract Manufacturing Companies
M	Samples for Geographic Testing
N	Bovine Serum Albumin Manufacturing
2	Auditor Summary



Why the program works!

- **Covers all aspects of what happened to the product every step of the way from the abattoir to the customer**
- **Covers all transactions in the company**
 - **Not just those for a specific customer**
- **Focuses on each handoff**
 - **Not a financial audit but**
 - **What came in at what price?**
 - **What went out at what price?**



How the Program works!

- **Independent Third-Party Audit**
 - Performed by an ISIA approved/trained auditor
 - To an ISIA approved audit plan
 - Using a detailed ISIA audit checklist
- **Modelled after ISO audits**
- **Involved origin testing of auditor selected batches**
- **Initial certification requires at least one year of data**



Traceability

- **Suppliers are certified for the piece of the process they perform**
 - **One step or all steps**
- **Certification not available for purchase**
 - **You must meet ALL the requirements**
 - **Ordering and shipment audits for distributors**
- **Certification is granted for three years**



Traceability Certified Companies

- **Animal Technologies Inc.**
- **Atlas Biologicals**
- **AvantorSciences**
- **Axenia BioLogix**
- **BioMin Biotechnologia S.A.**
- **By Productos S.A. de C.V.**
- **Central Biomedica Inc**
- **Corning Inc.**
- **Cytiva HyClone**
- **Gibco Thermo Fisher Scientific**
- **Life Science Production Group**
- **Moregate Biotech**
- **Newman Biotech Australia**
- **Orygina a JBS Company**
- **River City Biologicals**
- **River City Biotecnologia Ltda.**
- **Rocky Mountain Biologicals**
- **SeraTec LLC**
- **TCS Biosciences, Ltd**

Others in process



Recognition by Government Regulators

- This program is recognized by government regulators world-wide as one that contributes to the integrity of serum distribution and the serum industry in general.
- Many customer require ISIA traceability certification.
- Some countries are asking in their import documentation if the serum being imported is ISIA Traceability Certified.
- Trends suggest that the requests by customers to be certified will result in more countries/regulatory agencies deciding to add this qualifier to their import documents.

ISIA Certificate of Traceability	<input type="checkbox"/> Yes <input type="checkbox"/> No	E q
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Status and Continued Improvement of the ISIA Traceability Certification Program

- **85+% of material used in bio-processing applications in the EU, Japan, Australia, New Zealand and USA is currently certified.**
- **Increased focus from customers and regulators strengthens the program.**
- **ISIA works to strengthen through program revisions.**

