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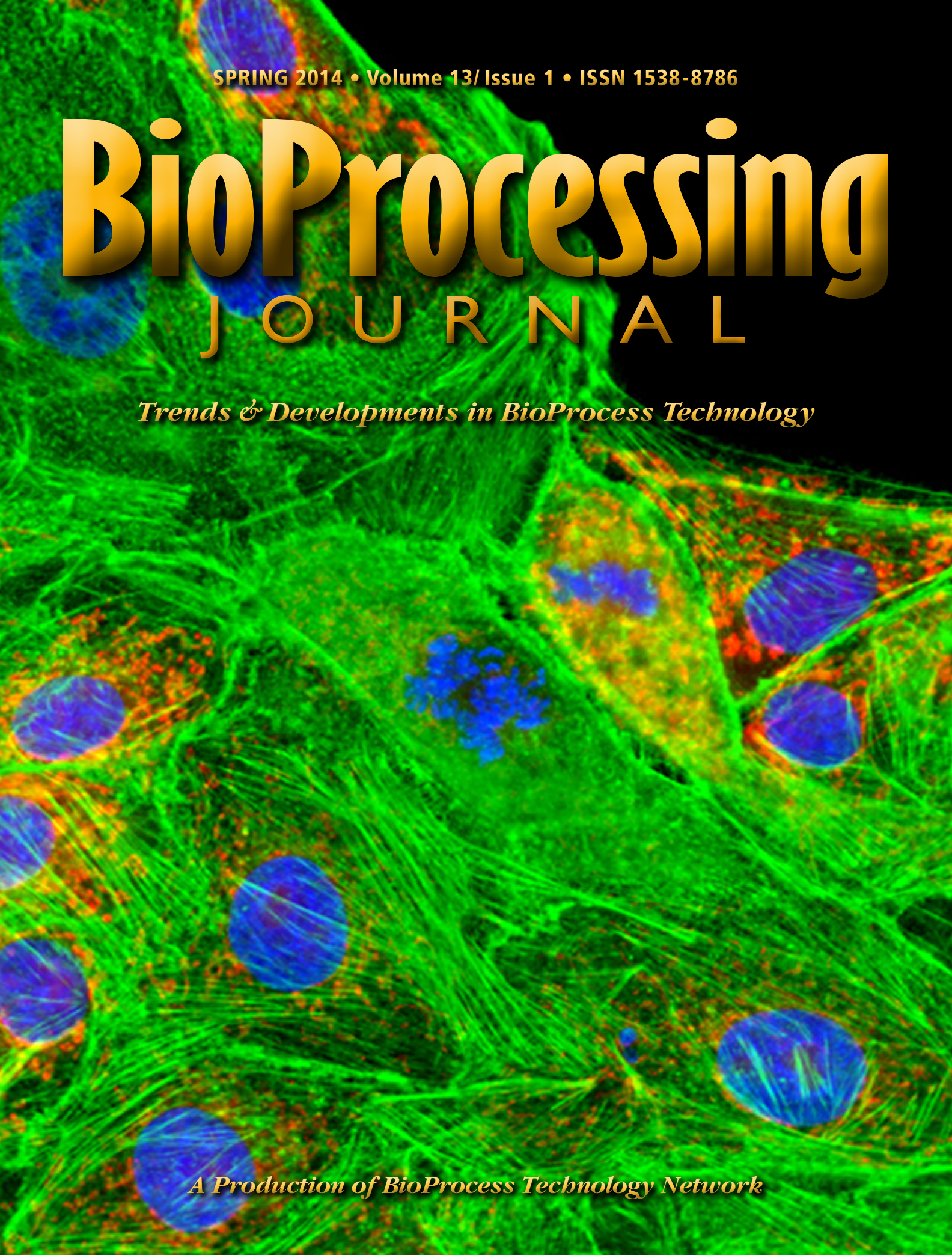
Trends & Developments in BioProcess Technology



A Production of BioProcess Technology Network

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TRENDS & DEVELOPMENTS IN BIOPROCESS TECHNOLOGY

Fetal Bovine Serum: *What You Should Ask Your Supplier and Why*

By DEVIN DAVIS and SHERRIE DRAKE HIRSCHI

Introduction

In today's volatile sera market, it is critical that sera users worldwide thoroughly review their supply relationships and update sourcing and risk mitigation strategies. *BioProcessing Journal's* recent article by Siegel and Foster highlighted the impact of selecting the appropriate country of origin as one criterion for purchasing decisions.[1] Many more vital selection criteria exist to ensure a sera supplier provides long-term assurance of supply and integrity of supply. This article identifies critical questions sera users should ask their suppliers and explains why they should ask them.

Changing Market Dynamics Necessitate Review

The sera industry has experienced substantial changes in the last year. Mergers and divestitures have introduced instability to, and turnover of, once-stable supply relationships. The first mass recall of fetal bovine serum (FBS) in history for adulterated product affected a large number of sera suppliers and users.[2] The World Organisation for Animal Health (OIE) announced the risk status of bovine spongiform encephalopathy (BSE) upgrade in the United States to "negligible risk," establishing US-origin FBS as equal in safety to that of Australia and New Zealand.[3] In addition, new industry standards for quality and traceability have been established to inform, protect, and support sera users in selecting a sera supplier.[4]

These historic changes—combined with reduced availability of sera due to historically low cattle inventory levels[5]— demonstrate that the traditional paradigm for sourcing sera is no longer valid. Sera users can use the following discussion points to kick-start a conversation with existing and potential sera suppliers to ensure their research or production requirements are uninterrupted by these dynamics.

WHY QUESTION THE STATUS QUO?

UNPRECEDENTED INDUSTRY CHANGES IMPACT SERA USERS

- Mergers & divestitures
- Product recalls
- BSE risk status change
- Reduced product availability
- New industry standards for quality and traceability

Discussion Point #1: *Assurance of Supply*

Assurance of supply resides at the source—the abattoirs where the raw materials for sera products are procured. Sera suppliers attempt to provide sourcing stability to their customers by establishing strong relationships at the source. Many of these relationships have shifted due to the merger and divestiture activity of the past year, and those shifts have altered the ability of suppliers to provide long-term supply stability.

Similarly, a sera supplier's relationships at the source have a dramatic impact on the quality of products they supply. Product quality indicators—such as endotoxin and hemoglobin levels—are driven by the care and attention given to the raw materials when initially collected and processed. Not all abattoirs, collection techniques, and raw material processing steps are created equal.

Reputable sera suppliers take the time to educate their customers about their supply relationships, collection and processing steps, and any changes that have occurred as a result of the market dynamics previously mentioned. Sera users should thoroughly investigate the ability of a supplier to provide long-term assurance of supply. This investigation may validate current sourcing practices or uncover sourcing risks that were not previously known.

ASSURANCE OF SUPPLY

WHAT QUESTIONS TO ASK	WHY IT IS IMPORTANT
• Describe your supply relationships at the source.	• Allows the supplier to articulate their story
• Where do you collect? Which beef packers do you work with? Why do you work with them?	• Quantifies the scope of their supply chain and why they are organized that way
• Are you single-sourced or multi-sourced?	• Quantifies risk of interruption; given reduced product availability, multi-sourced is more secure
• Do you do the work yourself or involve a partner? Why do you do it that way?	• Pros and cons exist for both vertically integrated or outsourced supply chains. Find out why the supplier prefers their approach and which certified partners they work with
• What kind of agreements are in place?	• Understand what type and length of contracts are in place to reduce risk of supply interruptions
• Has any of this changed recently?	• Assurance of future supply may be at risk due to supply realignment; reputable suppliers support full transparency and will be forthcoming about impact of any changes
• Can we make a site visit? Perform an audit?	• Demonstrates transparency and standards compliance, provides opportunity to validate supplier claims; go where you want to go, see what you want to see

Discussion Point #2: *Integrity of Supply*

Integrity of supply means that all aspects of product quality and traceability are well-documented, validated by independent audit, and completely transparent. In their recent article, Siegel and Foster[1] emphasized the importance of "exercising extra vigilance in confirming the integrity and authenticity" of information provided by a supplier and performing "due diligence in vendor qualification of all serum suppliers." They encouraged sera users to do a "thorough audit of the traceability system," to "know your vendors," to conduct "proper and periodic on-site audits," and ask for the appropriate "credentials." These recommendations underscore the fact that strategic, quantifiable differences exist between suppliers, their products, and their operations.

The International Serum Industry Association (ISIA) has established industry standards and certification programs to aid sera users in substantiating integrity of supply.[4] Five years ago, the ISIA developed and implemented a rigid program of independent audits to verify compliance with traceability standards. Elite status as an ISIA Traceability Certified supplier is awarded to those who demonstrate full compliance with ISIA guidelines and are the subject of a successful audit. Further, it has established strict guidelines for product quality testing and reporting on documents like certificates of analysis (CoA). Sera users should source exclusively from ISIA-certified companies to ensure traceability and product quality. A list of certified suppliers, filtration partners, and raw material providers is maintained on the ISIA's website.[6]

Product quality and traceability is also enhanced by validated technology enhancements in the manufacturing process. Implementation of single-use, disposable filtration technology eliminates cross-contamination risk from lot-to-lot and maintains true traceability—a technology that is widely used downstream in bioproduction environments. Additional measures such as maintaining the cold chain during filtration ensures that the bioburden of the sera is unchanged during processing and final packaging.

Sera users should use the above standards, programs, and technologies to comprehensively examine

NEW STANDARDS TO INFORM, PROTECT, AND SUPPORT SERA USERS IN SELECTING THE IDEAL SUPPLY PARTNER:

- **ISIA Traceability Certification program**
- **ISIA sanctioned testing and reporting standards**
- **Verified by independent audit**
- **Compliant companies listed at www.serumindustry.org/traceability.htm**

INTEGRITY OF SUPPLY

WHAT QUESTIONS TO ASK	WHY IT IS IMPORTANT
• Is your entire supply chain ISIA Traceability Certified (raw material collection, processing, filtration, fulfillment)?	• Identifies suppliers you can trust; addresses the issues that prompted mass product recalls
• Is your product documentation ISIA compliant (CoA)?	• Demonstrates commitment to the most relevant quality and traceability standards
• Is your product testing done in-house or by independent labs?	• Ensures transparency and accuracy
• Have you implemented validated technology enhancements in your manufacturing process?	• Eliminates cross-contamination risks from lot-to-lot and maintains true traceability
• Do you maintain the cold chain during manufacturing?	• Minimizes bioburden and endotoxin contribution of all processes
• Has any of this changed recently?	• Identifies effort to comply with standards or exposes inability to comply
• Can we make a site visit? Perform an audit?	• Demonstrates transparency and standards compliance, provides opportunity to validate supplier claims; go where you want to go, see what you want to see

a supplier's integrity of supply, conduct on-site audits, and identify and discuss any points of non-compliance. Any hesitation in this regard on the part of a supplier is a serious cause for concern.

Conclusion

Changing market dynamics have altered the historical paradigm for sourcing sera. Sera suppliers may be hesitant to explore the impacts of these dynamics with sera users, as it exposes problem areas that, to this point were overlooked or ignored. However, the exercise serves the long-term interests of both sera suppliers and users. The responsibility to scrutinize the supply strength and product integrity of a supplier rests squarely on the shoulders of sera users. The discussion points outlined in this article will facilitate sera users in the discharge of that responsibility and lead to a stronger, long-term relationship with their ideal sera supplier.

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About the Authors

Devin Davis is the founder and Vice President of Seradigm, now part of VWR International. Prior to founding Seradigm, Mr. Davis held various positions over several years at Thermo Fisher Scientific supporting the HyClone brand.

Email: devin_davis@vwr.com
Phone: 435-232-1378

Sherrie Drake Hirschi is Marketing Manager for Seradigm, now part of VWR International. Previously she spent nine years at HyClone and was HyClone's Serum Product Manager for seven years.

Email: sherrie_hirschi@vwr.com
Phone: 208-220-0928

Seradigm, a division of VWR International, Radnor Corporate Center, Bldg. One, Suite 200, 100 Matsonford Rd., Radnor, Pennsylvania 19087-8660 USA | Website: www.vwr.com