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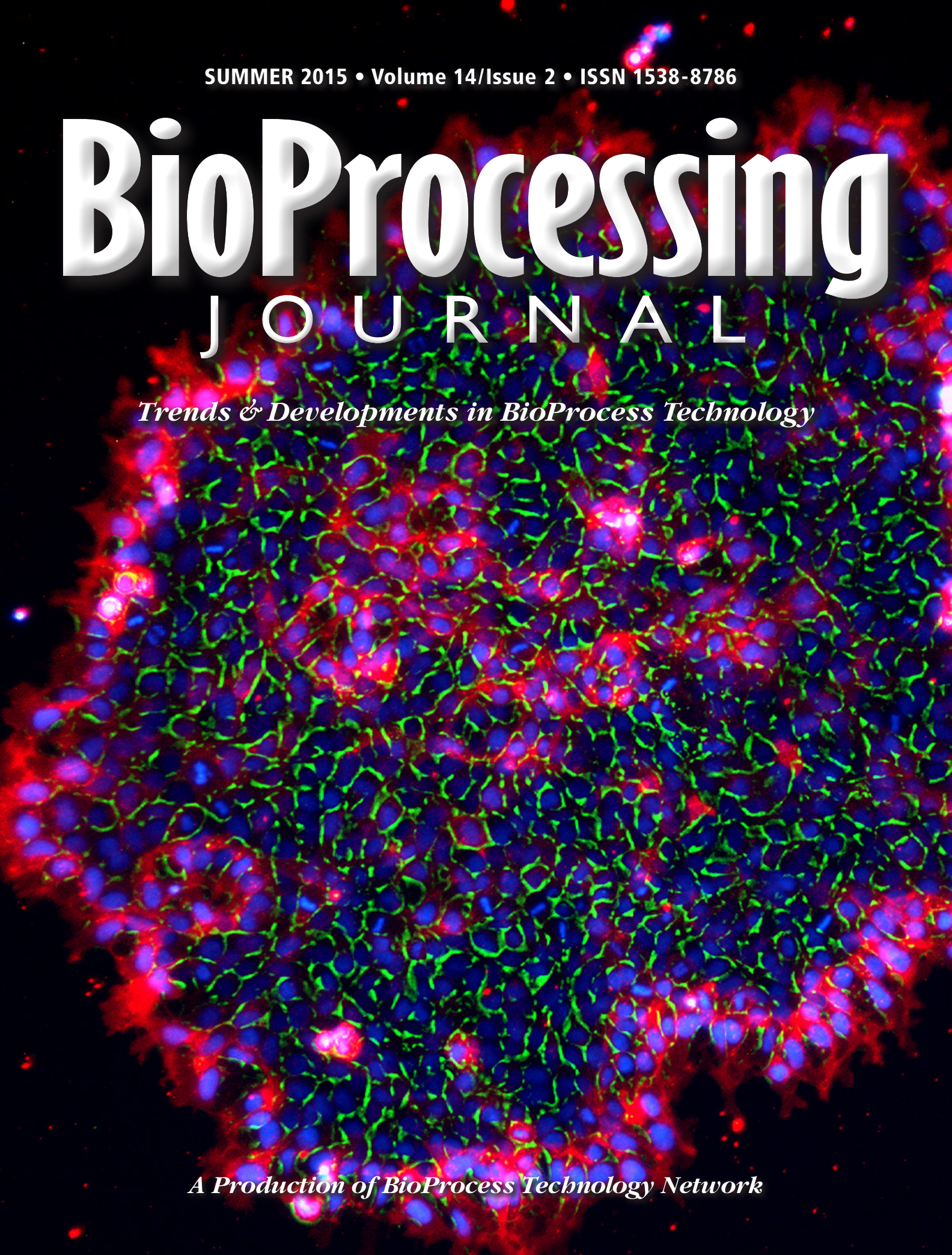
BioProcessing JOURNAL

Trends & Developments in BioProcess Technology



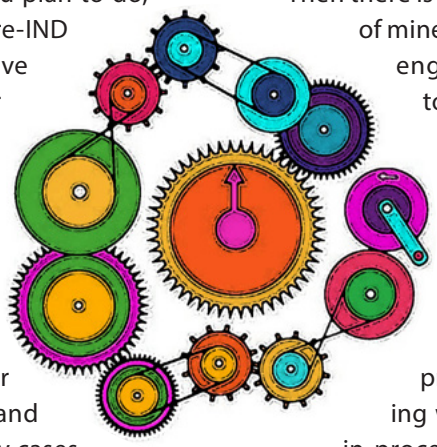
A Production of BioProcess Technology Network

From the Editor-in-Chief

Unfortunately, "FDA would never allow that" has been a phrase too often used by inexperienced QA and Regulatory Affairs personnel in the industry. This mindset has stifled many process improvements, or has completely derailed the development of new products.

The fact is: "FDA will allow almost anything" as long as you thoroughly explain what you want to do, why you want to do it, and how you will be able to test the results of what you did. And then, shouldn't you be doing this type of descriptive analysis anyway?

Another key factor is to set up a pre-IND meeting with your FDA reviewer to explain what you plan to do, and you can even do this prior to a pre-IND meeting. Actually, the more substantive communication you have with your reviewers, the better your outcome will be.



As an industry, we need to do far more to implement technologies and work with FDA, not only to keep them informed, but to make sure they are aware of industry trends and newer technologies. Remember that CBER and CDER have their own labs, and in many cases, they will want to bring in the technologies you want to use and see how they work in their own experiments.

The biotech industry has been so slow to adopt available technologies that it is known as one of the least innovative industry segments in the world economy. It has taken this industry over 30 years to adopt and implement single-use technology, and essentially as long to accept perfusion technology. But now these technologies are the rave and are considered "new and revolutionary."

Then let's talk about "in-process" testing. We can no longer rely on final product characterization to determine if everything in the processing steps has gone as planned. Every process needs to be monitored and have its data collected from multiple stages at regular intervals. We need to know what nutrients are being used and which ones aren't, plus what metabolites and waste gases are building up to damage the product. All of these measurements need to drive the feed and harvest strategy, as well as the gas flow and composition strategy. And perfusion should be a primary driver of in-process analysis since we shouldn't base the perfusion rate solely on product concentration.

But in-process testing shouldn't be limited to the bioreactor. We need to define meaningful stages in clarification, concentration, purification, and diafiltration where key variables can be monitored and used in the overall integration of the process.

Then there is automation. This is a primary interest of mine since I started my career in a leading engineering and design firm, plus the top control valve and instrumentation company. Let's face it: we've been doing continuous processing in petrochemical plants for at least 50 years, and it's time we applied more automation to our bioprocessing.

So let's start implementing the latest process analysis technologies and finding ways to either measure key variables in-process, or with recirculating slipstreams attached to the bioreactor and other essential operations. Then let's use existing technology and software to automate these key systems and integrate them in a way that optimizes the entire process. This work will give us better and more consistent product with less degradation and heterogeneity. It will also make the regulators much more comfortable with what is being done, as well as the end-products they must regulate.

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