SPRING 2015 • Volume 14/Issue 1 • ISSN 1538-8786

BioProcessing JOURNAL

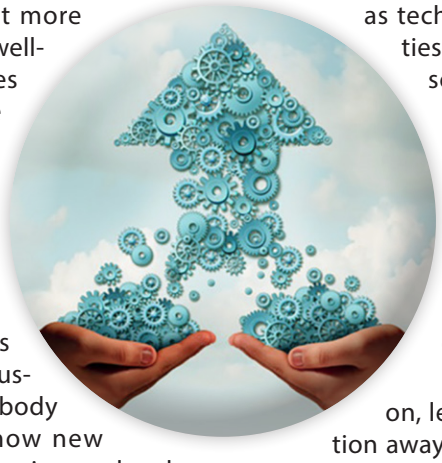
Trends & Developments in BioProcess Technology

A Production of BioProcess Technology Network

From the Editor-in-Chief

It appears that the state of the biotech industry continues to improve. We now have a licensed cellular therapy that Dendreon developed, and which has now been sold to another firm that thinks it can make and administer this prostate cancer vaccine more efficiently, plus provide a more effective product. There is also a viral gene vector that has been licensed in Europe, and an application for US licensing has been submitted. Then there is the licensed influenza vaccine that is made with baculovirus technology, plus a second baculovirus-derived flu vaccine that is near licensure. The two companies with these flu vaccines are now charging ahead with their baculovirus expertise to produce Ebola vaccines.

With the knowledge that the product sponsors and regulatory reviewers have gained from these products, there is a good indication that more products will be able to follow a fairly well-defined development model, and ones with which FDA reviewers would have experience and precedent to go by.



Then on the therapeutic protein side of the biologics industry, we now have better linkers that are allowing product developers to attach the desired number of small molecule drugs to the desired sights on antibody molecules. Since the industry has so much experience with antibody development and licensing, and now new products with attached drugs or imaging molecules, it appears that the industry has many products it can develop with far less risk, which always makes raising money a lot easier.

And now with the volatility seen in so many stock markets throughout the world, mergers and acquisitions (M&As) don't appear to be as attractive as they used to be since the lion's share of an M&A's success often comes from the stock values of both the acquired and acquiring firms increasing. I would think that this phenomenon would guide more firms to focus on a hand-full of products and technologies with which they already have a reasonable amount of experience, and push these through to completion. Just think of the money they will save in legal and investment bank fees, as well as selling off assets at bargain-basement prices, and providing conscionable severance packages for the flocks of people they have been laying off.

Then additional concepts have been learned, such as the admission by the Dendreon founders that they wished they had planned to freeze and thaw their autologous cellular vaccine (Provenge). They found it is far too expensive to start from scratch every time additional doses must be administered over fairly lengthy time periods. In addition, there is a need for product retention samples that might have to be stored for a long time. Besides, there is so much inherent variability among the batches of a cellular product that dosing and efficacy can vary considerably, which can greatly affect patient outcomes and regulatory confidence.

Thankfully, we seem to be experiencing breakthroughs in cell freezing and thawing technology. Within a few years, we may see the use of novel cryoprotectants which are far less harmful to the patients, as well as techniques which give us higher viabilities along with cells that are ready much sooner for additional processing.

With viral gene vectors, we are seeing products that are more effective, more reproducible, and less immunogenic. Then the techniques that can prevent viral replication after initial transfection are becoming more reliable and more quickly discernible.

So with so many products to work on, let's hope the industry shifts its attention away from M&As and takes the "good old fashioned" approach of sticking to what they know and do best. And who knows? The industry might also get over its fixation on biosimilars, which were only within reach of the big biopharma companies anyway, or the developing-world product portfolios which typically can be licensed with less regulatory scrutiny. The bottom line is that firms now have so many more product and technology opportunities to work on that have better potential outcomes and less regulatory uncertainty. This sounds like a pretty good environment to me.

Keith L. Carson, Editor-in-Chief
kc@bioprocessingjournal.com
www.bioprocessingjournal.com