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1. Finesse offers complete turnkey solutions. Can you walk us through the differences between your T300, T500, and T700?

Yes - we offer complete solutions to the marketplace on two control platforms: DeltaV and Wintel. The DeltaV platform is cGMP-ready and the software is GAMP5. The Wintel platform has plug-and-play capability and will be cGMP on 2013.

The T300 series consists of controllers and vessels that are used in laboratories. Specifically, T300 controllers, called G3lab are designed for vessels whose volume does not exceed 50L: single-use rockers, glass vessels (both single-wall and jacketed) and single-use stirred vessels. The T500 series is our OEM series for customers such as Millipore, ATMI, and Thermo Scientific (HyClone). T700 series is our large-volume, GMP suite of controllers for single-use stirred-tank bioreactors ranging in volume from 50L to 2,000L. The T700 equipment consists of our G3/G3mini hardware, our single-use sensors, and our TruBio software, all of which are integrated with the single-use bioreactor of choice.

2. How is Finesse working to improve upon the functionality of disposable processing systems?

The whole goal of single-use systems is to provide flexible, adaptable solutions that are easily reconfigured for multi-product development and manufacturing. However, the controllers and infrastructure that are often integrated when implementing single-use systems today often lack this flexibility. Our current systems are quite flexible, but lack true plug-and-play capability like a MacMini with a HP printer. If the user wishes to switch bioreactor brands, or add third party peripherals, custom engineering is required. Therefore, we are now working on next generation modular, intelligent processing systems, where the goal for 2013 will be to have true "plug-and-play capability" or the various components. The system components will become more like lego blocks, so that users can assemble and re-assemble their system for any vessel brand, type, size, or application.

3. When considering the industry as a whole, are there any standards that should be implemented to optimize processes?

Absolutely, the industry is lacking in many standards. The first and most obvious standard is for leachables and extractables. While efforts are being made in that direction, there is no set of complete criteria required to automatically qualify a new product for use in production.

More participation from end users to drive these requirements would be welcome. The second standard that is lacking is a configuration for bags of different sizes. There is still a great deal of customization of such bags, and establishing a "generic" port and sensor configuration for rocker and stirred-tank bioreactor bags would enable end users to second source more easily. Finally, having communication standards established for transmitters and off-line instrumentation would allow much easier integration into their systems, and mitigate the significant cost we see today to add capability to systems after they are installed.

1. How has Finesse identified what works best in terms of integrating single-use sensors into the control platform?

As single-use sensors represent a paradigm shift for both the bioreactor manufacturers and the end user, the best practice is to educate both in their function and use. As with any new technology that is substantially different from the existing venue, many questions and issues arise. Most of these can be easily addressed by providing information and training.

However, there are more basic issues that are not as easily solved. One of these is the lack of detailed scientific knowledge by both parties. For example, the fundamental concepts behind measurements like pH are clearly not understood, nor is the role of standards bodies like NIST or IUPAC (International Union of Physical and Analytical Chemists). This leads to confusion about why different sensors do not always agree and which is correct.

2. What types of features do the different single-use sensors offer?

First and foremost, single-use sensors should provide measurements that equal or exceed traditional sensors in accuracy, precision, long-term drift, and process robustness. While this is true today for dissolved oxygen, temperature, and headspace pressure, many questions remain about pH measurements in general, and a general realignment of the industry will be necessary for adoption of optical technologies for pH in the next three years.

In addition, ideal single-use sensors are USP Class VI, ISO 10993 compliant and have undergone a full set of toxicity tests. They are also pre-calibrated for use "out-of-the-bag" yet allow the user to maintain their current processes, such as performing two-point calibration or one-point standardizations. These devices should also have intelligence built into their transmitters, for communicating diagnostic status to the control system, such as a user disconnection of the measurement loop from the single-use element. With these features, single-use sensors should provide ease of use and high quality measurements for bioprocessing.

3. We know that Finesse's single-use sensors have been designed specifically for single-use systems. Can you talk about the four process parameters involved (pH, dissolved oxygen, temperature and headspace)?

The four parameters that you mention include three critical process parameters (pH, dissolved oxygen and temperature) and one system integrity parameter (pressure). The process parameters are essential for maintaining good process control and providing the cell culture with optimal growth and product production conditions. Pressure monitoring is crucial so that the bag is not blown up owing to excessive gas flow into the system.