Biomanufacturing is evolving

Single-use technologies have reshaped how we produce biologics. Today manufacturers face new challenges to produce more efficiently with increased quality. Many facilities house a mix of old and new equipment, often running independently on custom software. Intensified processes require a higher level of automation and often call for the rapid addition of sensors, pumps, and other ancillaries. Regulatory requirements are driving an overall increase in data collection, including electronic batch records. Finally, efficient facility management demands integration of the overall process with plant Manufacturing Execution Systems (MES). These challenges require a new way of thinking.
The Finesse solution

Over the past decade Finesse has introduced a Silicon Valley approach to biomanufacturing. We believe that intelligent, integrated systems are essential to our customers' success. Our solution is a Smart approach to bioprocess management consisting of three platforms: SmartParts, SmartSystems and the SmartFactory with SmartMES software controlling key unit operations.

**SmartParts** enhance system performance with intelligent components for modular bioprocess measurement and control.

**SmartSystems** combine universal controllers with flexible software to enable all scales of upstream and downstream processes.

**SmartFactories** integrate unit operations into a single seamless network that optimizes resource utilization and generates batch reports.

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Smart Platforms combined with technical expertise, offer unique advantages:

» A universal automation platform compatible with all leading suppliers

» Service, automation, and integration expertise to harmonize old and new equipment

» Configurations from preclinical through production scale

» Addition of new sensors and peripherals without software modifications

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Controllers

G3Lab Universal
The G3Lab Universal controls single-use or reusable bench-top bioreactors and rockers, and consists of a utility tower and TruFlow gas manifold. By leveraging SmartParts across the range of configurations, G3Lab Universal systems enable fully traceable cGMP process scale-up or scale-down in the laboratory environment.

G3Pro Universal
The G3Pro Universal controls single-use bioreactors (25L to 2000L) and mixers (50L to 2000L). The system consists of a utility tower, a TruFlow gas manifold, and a vessel adaptor box (VAB) specific to the vessel being controlled. G3Pro controllers may be mounted on fixed skids or movable carts, can be quickly reconfigured or expanded for multi-product applications, and have complete cGMP documentation.

G3Lite+
The G3Lite controls Thermo Scientific HyPerforma™ SUBs (25L to 2000L) as well as Millipore Mobius CellReady™ and Xcellerex XDR™ bioreactors. The G3Lite control tower leverages SmartParts; transmitters, MFC’s, and pumps. G3Lite controllers are self-contained, movable units that can be operated singly or networked.

G3Flex
G3Flex systems are custom designed to run unique or highly complex processes in challenging environments (e.g., BSL-3). G3Flex systems can be fully integrated or modular. A typical system will include a utility tower, pump tower, and gas manifold, with optional accessories for perfusion, harvest, or gravimetric feeding.

A universal approach
Highly configurable G3 SmartControllers scale from lab to cGMP-compliant production with ease. The G3Lab™ Universal controls both single-use and sterilizable bench top bioreactors. The G3Lite™ is a mobile and cost-effective option for R&D or production. The flexible and robust G3Pro™ supports any brand of single-use bioreactor, up to 2000L. The G3Flex™ System is our fully customizable offering.
### Universal control

**G3LAB UNIVERSAL COMPATIBLE BIOREACTORS**

<table>
<thead>
<tr>
<th>Glass</th>
<th>Total Volume (L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finesse SmartGlass</td>
<td>1, 3, 7, 15</td>
</tr>
<tr>
<td>Applikon</td>
<td>1, 2, 3, 5, 7, 15, 20</td>
</tr>
<tr>
<td>Sartorius STR®</td>
<td>1.6, 3, 6.6, 13</td>
</tr>
<tr>
<td>Eppendorf (NBS)</td>
<td>1.3, 3, 7.5, 14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Single-Use</th>
<th>Total Volume (L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Millipore Mobius CellReady™</td>
<td>3</td>
</tr>
<tr>
<td>Eppendorf (NBS)</td>
<td>1, 5, 14, 50</td>
</tr>
<tr>
<td>Xcellerex XDR™</td>
<td>10</td>
</tr>
<tr>
<td>CerCell CellVessel</td>
<td>All sizes ≤ 75</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rocker</th>
<th>Total / Working Volume (L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finesse SmartRocker</td>
<td>50/25, 20/10, 10/5</td>
</tr>
<tr>
<td>GE WAVE Bioreactor®</td>
<td>50/25, 20/10, 10/5</td>
</tr>
<tr>
<td>Sartorius Biostat® RM</td>
<td>50/25, 20/10, 10/5</td>
</tr>
</tbody>
</table>

**G3LITE+ COMPATIBLE BIOREACTORS**

<table>
<thead>
<tr>
<th>Single-Use</th>
<th>Total Volume (L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermo Scientific HyPerforma™ SUB</td>
<td>All sizes ≤ 2000</td>
</tr>
<tr>
<td>Thermo Scientific HyPerforma™ SUF</td>
<td>All sizes ≤ 300</td>
</tr>
<tr>
<td>Millipore Mobius CellReady™</td>
<td>All sizes ≤ 200</td>
</tr>
<tr>
<td>Xcellerex XDR™</td>
<td>All sizes ≤ 2000</td>
</tr>
</tbody>
</table>

**G3PRO + G3FLEX COMPATIBLE BIOREACTORS**

<table>
<thead>
<tr>
<th>Single-Use</th>
<th>Total Volume (L)</th>
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</thead>
<tbody>
<tr>
<td>Thermo Scientific HyPerforma™ SUB</td>
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<tr>
<td>Thermo Scientific HyPerforma™ SUF</td>
<td>All sizes ≤ 300</td>
</tr>
<tr>
<td>Millipore Mobius CellReady™</td>
<td>50, 200</td>
</tr>
<tr>
<td>Xcellerex XDR™</td>
<td>50, 200, 500, 1000, 2000</td>
</tr>
<tr>
<td>Pall PadReactor®</td>
<td>25, 50, 300, 600, 1350</td>
</tr>
<tr>
<td>Sartorius STR®</td>
<td>50, 200, 500, 1000</td>
</tr>
</tbody>
</table>

Compatibility with all leading suppliers offers freedom to choose preferred bioreactors.
Single-use sensors

**SmartPuck pH+dO2**
The SmartPuck™ pH+dO2 sensor contains single-use sensors for dissolved oxygen, pH, and temperature, in a compact assembly which is welded securely into a single-use SmartBag™ or SmartVessel™ bioprocess container.

**TruFluor pH and TruFluor DO**
TruFluor® pH and DO sensors consist of a disposable sheath, an optical reader and a transmitter. The optical reader utilizes a patented design that minimizes photodegradation of the active sensing element.

**TruTorr**
The TruTorr® headspace pressure sensor provides precise pressure monitoring to prevent single-use bioprocess container rupture. The TruTorr sensor loop consists of a disposable pressure sensor, a cable, and a transmitter blade that is seamlessly integrated into a Finesse bioreactor controller.

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**Excellence in bioprocessing measurement**
Designed for maximum stability with minimal drift, our single-use sensors contain an embedded SmartChip™ that holds manufacturing lot and factory calibration information. Finesse single-use sensors implement a patented optical design using only USP Class VI materials. All sensors are sterilized in place and pre-calibrated.
Sterilizable sensors

**TrupH**
TrupH 12mm pH electrodes are designed to provide a robust solution with better measurement repeatability, low drift, and fast response time. The reference electrode is designed to minimize fouling even in a high cell-density bioprocess.

**TruDO**
TruDO re-usable dissolved oxygen sensors are a cost-effective solution in which each sensor can be renewed (membrane or electrode). Benefits include a fast response time, resistance to bubbles, and repeatable performance.

**TruDO Optical**
TruDO optical sensors provide comparable performance to electrochemical sensors, but do not use electrolytes, require polarization or require frequent membrane replacement. The probe can remain in the bioreactor during a sterilization process which reduces damage or contamination risk.

Finesse provides re-usable sensors for cell culture and fermentation process monitoring. TruDO® and TrupH® sensors have been specifically designed to minimize drift, survive frequent sterilization cycles, and ensure measurement consistency from batch to batch.
Software

TruBio, TruChrom and TruPur harmonizes and upgrades existing, proprietary upstream and downstream control systems that may no longer meet current bioprocess needs. Finesse software is a cost-effective means to extend the useful life of existing capital, unify the user interface for a variety of controllers, and aggregate process data in a common, robust DeltaV historian.

**TruBio**
TruBio provides automation hardware independence, allows for seamless acquisition of third party data and unifies all upstream process trains to enable easy scaling from development to full production.

**TruChrom™ and TruPur™**
TruChrom and TruPur have recently been developed to control common third party chromatography and purification skids. Both are based on the same robust, validated software platform as TruBio and allow for integration and control of downstream processes.

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**From bench top to full scale manufacturing**
Based on the DeltaV® control platform, TruBio® software is user-friendly, highly configurable and capable of controlling any bioreactor from lab through production scale. TruBio also supports SCADA and OPC connectivity to third party devices. It has been developed with the latest GAMP revision methods and is validated for cGMP applications.
Vessels

SmartRocker
The Finesse SmartRocker™ brings next generation control and measurement to rocking bioreactor applications. A SmartRocker is controlled by a G3Lab Universal Controller and Finesse TruBio software, providing a complete solution for research, process development, or seed train production applications.

The SmartRocker uses a SmartBag™ single-use bioprocess container which provides up to 25L of working volume and integrates a novel SmartPuck combined pH, DO and temperature sensor.

SmartGlass
The SmartGlass™ bioreactor is available in 0.7, 2, 5 and 10L working volumes. These vessels are manufactured with the highest standards for materials and surface finish, are quick to assemble, and easy to operate. SmartGlass impellers have been developed to provide maximum mixing with minimum shear force, resulting in a higher average kLa. The cold finger has been replaced by a cooling loop to increase the thermal surface. Current performance tests demonstrate a cooling rate two times better than a sample of competitive products.
Modern measurement and control equipment manufactured by Finesse is very reliable and requires minimal servicing. However, some processes can be quite aggressive, so that the equipment and instruments will need maintenance, calibration, or replacement parts from time to time.

Finesse qualified field service engineers are available at a moment’s notice by telephone for remote support.

Plans offer:
- Special discounts for spare parts
- Hands-on training classes
- Custom software module development
- Same or next business day remote support

When required, on-site service response can arrive within 2 to 4 business days depending on the location.

Flexible service solutions for all budgets and operating plans

**COMMISSIONING**
- Software installation
- Accredited calibration services
- System installation
- System startup training
- Process tuning and system configuration

**ONGOING SUPPORT**
- Warranty support
- Remote access
- Preventative maintenance
- Repairs
- cGMP documentation support
- Technical questions
- Safety stock and spare parts

**UPGRADE / DECOMMISSION**
- System decommissioning
- Hardware integration / addition and upgrades
- Custom software development
Finesse SmartFactory™ has been optimized to increase productivity and maximize asset utilization, while retaining an open architecture. Bioproduction process flows can be designed with best-of-breed equipment (including Finesse SmartSystems) in a modular and scalable manner, without compromising quality and compliance. Unit operations are pre-validated, skidded, production ready and ERP capable. The SmartFactory Manufacturing Execution System (MES) provides an operations management solution for single-use facilities that optimizes plant-wide resource utilization, integrates manufacturing (batch) information, and facilitates training and validation record management.