



BioPAT® Spectro

A Quality by Design
Tool That Unlocks the
Full Potential of Raman
Spectroscopy

Simplifying Progress

SARTORIUS

A Quality by Design Tool:

BioPAT® Spectro in Ambr® and Flexsafe STR®

The bioprocessing industry has always recognized the significant potential of Raman spectroscopy – it provides substantially more process data, leading to more robust processes and resulting in products of high and consistent quality. However, translating this potential into practice has been an issue because of the need to collect and consolidate data from disparate sources in order to build models, only to face additional hurdles when trying to apply those models at scale.

Now, thanks to BioPAT® Spectro, the game has changed.

BioPAT® Spectro embraces Quality by Design (QbD) principles to unlock the full potential of Raman spectroscopy. Automated data acquisition and consolidation in high-throughput, small scale Ambr® system leads to highly robust models that can be applied in high-throughput process development and are easily transferred to manufacturing in single-use Flexsafe STR® bags. BioPAT® Spectro is compatible with the two leading providers of Raman spectrometers (Endress+Hauser; Tornado Spectral Systems).

BioPAT® Spectro in Ambr® 15 and Ambr® 250 high throughput reduces model building time by 50%, can result in up to a 95% reduction in operator involvement and up to 80% savings in media costs when compared to conventional model building*

- Enables a QbD approach in high-throughput process development, measuring several analytes simultaneously during Design of Experiments (DoE)
- Offers fully automated data consolidation and contextualization of Raman spectral data with all process data by Ambr® software
- After one high throughput Ambr® run, the consolidated data file can be readily imported into SIMCA®, where the larger design space means more robust models than formerly possible



The BioPAT® Spectro single-use port is fully integrated into Flexsafe STR® bags

- Scalable platform with standardized optical probe interface across Ambr® and Flexsafe STR® facilitates model transfer
- Fully integrated and qualified single-use port reduces set-up time and decreases contamination risks
- The use of a flow cell in the design decouples the measurement from disturbances through process conditions such as gassing and stirring
- The shielded design of the measurement path eliminates noise through ambient light



* Assumptions:

- conventional model building is done with two runs of four benchtop reactors in parallel of 2 L working volume
- Ambr® 250 with 12 vessels; BioProfile® FLEX2 (Nova Biomedical) connected to Ambr® 250

Meeting the Needs of Process Development:

Easier and faster model building, high-throughput process development with Raman spectroscopy

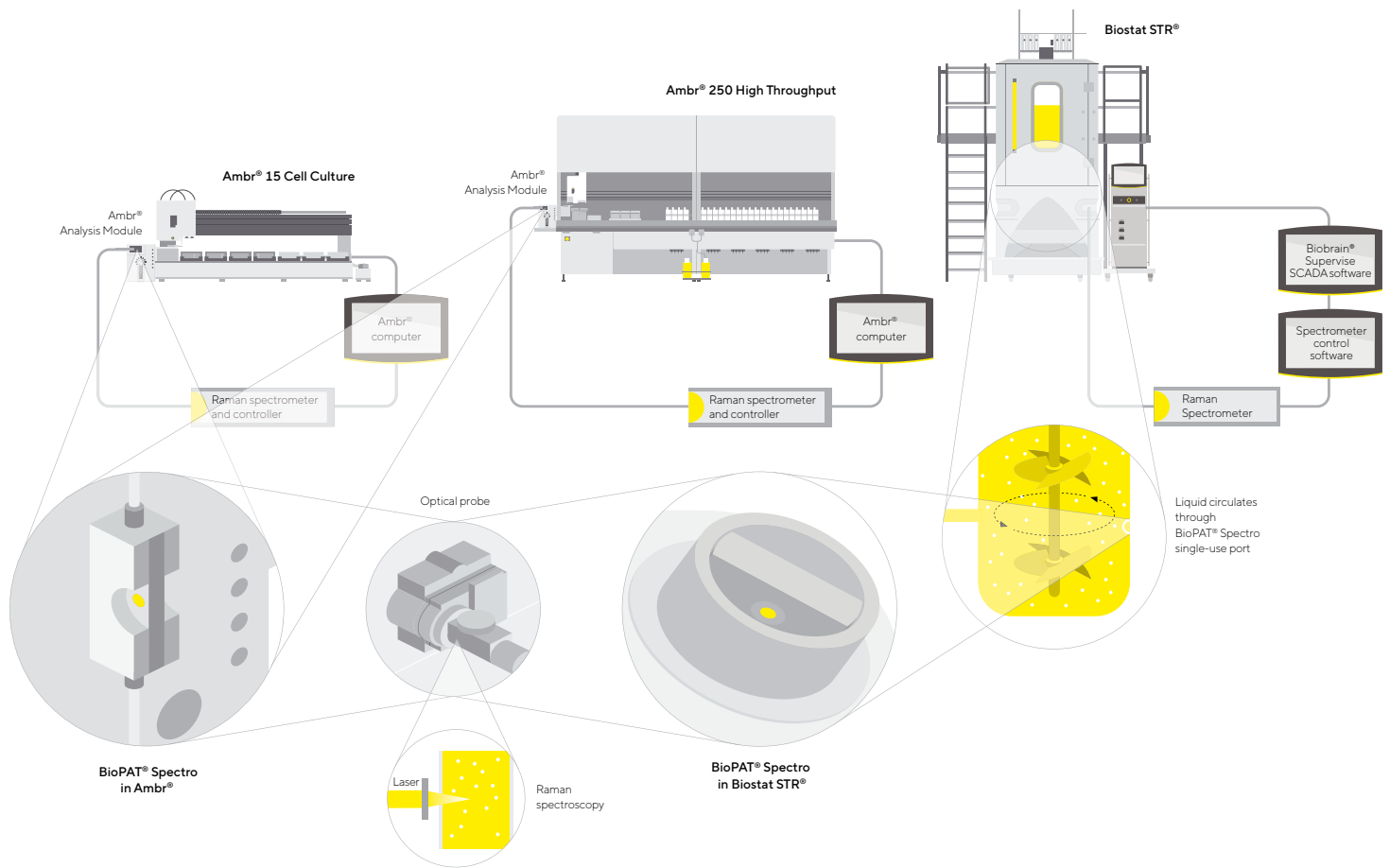
Process Development Need	BioPAT® Spectro Solution
Fully automated data acquisition, consolidation and contextualization	Raman spectral data, Ambr® process data and other integrated analyser data for up to 48 bioreactors in parallel are automatically consolidated and contextualized by the Ambr® software. Additionally, the data can be exported as a SIMCA® ready file for model building
Robust models	Increased model robustness by exploring a bigger design space and using all process data for model building
Process knowledge and robustness	Enables true QbD and high-throughput process development

Meeting the Needs of Commercial Manufacturing:

Single-use Raman spectroscopy integration with faster set-up time, reduced contamination risk, and efficient transfer from process development

Commercial Manufacturing Need	BioPAT® Spectro Solution
Regulatory Compliance	The BioPAT® Spectro single-use port in Flexsafe STR® is fully integrated and qualified and comes ready-to-use
Efficient transfer of models from process development to manufacturing	Models developed in Ambr® are transferable to Flexsafe STR® due to their robustness and the identical optical design of BioPAT® Spectro probes
Assurance of quality and more predictable results	More robust processes with QbD, enabling inline, non-invasive 24/7 process monitoring and controls, measuring multiple analytes





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