

Automated Aseptic QC Sampling

The EMPAT™ System for QC Sample Collection in Biopharmaceutical Production

Biopharmaceutical companies are increasingly interested in single-use innovations to improve performance and alleviate up- and downstream bottleneck constrictions. High-priority considerations for improvement include decreasing the number of process steps, reducing the risk of cross-contamination, and achieving a higher sterility assurance level. One bottleneck today is a need to collect QC samples at various steps during biopharmaceutical commercial-scale cGMP manufacturing, which typically is a labour-intensive manual activity that holds a potential risk of contaminating product or personnel.

Alfa Wassermann Separation Technologies (www.awst.com) is a leading provider of industrial process equipment for biopharmaceutical manufacturing. It recently launched EMPAT™, a fully automatic aseptic QC sampling system especially designed for biopharmaceutical cGMP manufacturing. The compact EMPAT system is designed for flexible and reliable operation and seamlessly fits with existing QC sampling planning.

ASEPTIC QC SAMPLING

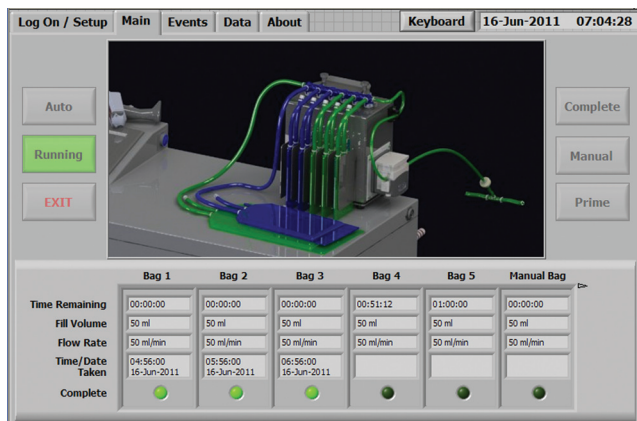
Flow-Path and Sterile Connection: The EMPAT system sampling flow-path is a sterilized disposable multisample bag set for seven samples, which is easily mounted on the EMPAT system and will stay connected during an entire day (batch). The bag set assembly inlet tube ends with a sterile Kleenpak™ connector, which is aseptically connected to a production vessel or line. After connection is established and a sampling plan for that batch is selected from the menu, the EMPAT system automatically collects multiple QC samples of user-defined

Table 1: Specifications of the EMPAT™ aseptic QC sampling system

Parameter	Specification
Industrial HMI	NEMA 4x/ P65
Electrical enclosure	NEMA 4x/IP54
Data input	IP65 touch screen and/or 2D barcode scanner
Data output	Digital file transfer by Ethernet or USB
Sampling flow range	5–80 mL/min
Dimensions (width x depth x height)	43.3 in. (110cm) x 30.2 in. (77cm) x 52.0 in. (132cm)
Electrical supply	230 VAC, 50/60HZ, 10A, single phase
Analog inputs	16 (8 inputs for 4-20mA and 8 for 0-10Vdc)
USB ports	7
Ethernet ports	2
Operating system	Windows XP
Regulatory compliances	21 CFR part 11, CGMP, NEMA 4x, CE
Manufacturing compliances	ISO 13485:2003

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volumes and at user-defined intervals during the entire batch run, without the need for additional intrusions to the production vessel or line.

Reproducible and Reliable Results:

- Reduced risk of contamination or sterility breach, assured product sterility at all times
- Reduced risk of subjecting operators to hazardous materials
- Elimination of QC sampling errors, minimizing risk of delay in product release by having to investigate false positive QC results
- No cross-contamination between samples, improving the quality and reproducibility of QC sampling
- Reduced need for paper-based sampling schedules, records, and notes

Quality by Design Features:

- E-signature, user name log-in and multilevel password authorization
- Menu selection of preprogrammed sampling protocol
- All operating and batch data is stored in an SQL database
- Batch data automatically archived (critical process parameters, events and alarms)
- Report generator included, data communication enabled (Ethernet and USB)
- IP65 touch screen, bar code reader and bar code printer included

The system is operated by plug-and-play Windows platform software and is designed for paperless operation with 21 CFR and quality by design in mind. 🌐

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