

## Switching to SAS

Paul E. Blankenship. Environmental monitoring is essential to our Monsanto (USA) processing facility, the world's largest automated bulk protein production operation. It produces Posilac, a sterile injectable pharmaceutical used to treat dairy cows to increase milk output.

Six months service delay and frequent false positives and deviations with media strips provoked a consultant formerly from the FDA to highly recommend we switch to the SAS microbial air sampler. After installation of 36 SAS Super 180 units to monitor our ten isolators and two clean rooms, we prevented all false positive and the fingerprint "phenomenon" we had with strips. Less expected were the extensive cost savings with SAS. Each SAS sampler paid for itself in just two months. In only six months, we saved \$380,000 in media, preparation time and down time for calibrations.

The 48 hours turnaround for calibration and service of Bioscience International allows me to keep my 24-hour-a-day production cycle of four continuously rotating shifts 365 days a year running strong. We have a joke here at Monsanto that as soon as we ship a unit to Bioscience for calibration and the delivery person takes it out the door, the return delivery person passes him in the doorway with the returned unit.

SAS also saves operating time because of its high speed of 180 lpm, the simplicity of inserting agar plates and the ruggedness of SAS to withstand sanitization. With our prior air samplers, when a technician sprayed the room during decontamination, liquid penetrated and ruined the circuit board. SAS keeps fluid out of the instrument. Turbulence was another issue with prior samplers. Before purchasing the SAS, we conducted smoke studies with SAS and observed that it greatly reduces turbulence and has a clean unilinear air flow.

In addition to cost savings and method improvement, the SAS provides the benefit of being a reference sampler. In a recent FDA inspection, the inspector saw the SAS and immediately commented "great" without the more typical response of ten questions for other instrumentation. (Having been validated in the field since 1979, SAS is referenced in the ACGIH Guidelines and the USP section 1116).

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