

## PROCESS MONITORING AND VALIDATION

**Portable data logger**

OMEGA (Stamford, CT) announces the OM-2000 Series, a new line of microprocessor-based portable data loggers. They are compact, battery-powered units that record and store data from 1–6 input channels that are individually programmable for 9 different thermocouple types and three DC voltage ranges. Features include RS-232 communication interface, backlit LCD display, and analog output. A memory card allowing expansion of data storage capability is available.

**Tel: +1 800 848 4271**

**Fax: +1 203 359 7700**

**RSN 972**

**Virus validation**

Q-one Biotech (Glasgow, UK) offers a virus validation service to biotechnology and pharmaceutical companies manufacturing products from human or animal tissues. Facilities include a containment level III suite for working with hazardous viruses and fully validated cell culture assays. Comprehensive final reports and regulatory advice are included in the service.

**Tel: +44 141 946 9999**

**Fax: +44 141 946 0000**

**RSN 973**

**Manufacturing support and validation**

Oread's (Lawrence, KS) CertiPharm is a pharmaceutical/biotechnology manufacturing support and validation company offering a full range of services, including IQ/OQ of facilities and processing equipment, cleaning validation, process validation, and computer validation, as well as quality assurance services such as internal audits, vendor certifica-

tion, SOP preparation, training, preapproval mock inspections, DMF audit and certification, and post-FDA inspection consultation. CertiPharm also offers calibration programs for laboratory and recording instruments.

**Tel: +1 913 749 0034**

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**RSN 974**

**Bioreactor monitoring**

The Bioreactor Operating and Supervision System (BOSS) from INCELTECH (Toulouse, France) is a Windows-compatible supervisory system using Intellution software and a FIX database for validated data storage. BOSS offers automatic sterilization, transfer cycles, and control of peripheral units such as centrifuges, filtration loops, and tanks. A Siemens programmable process controller is fitted at reactor level in line with FDA standards.

**Tel: +33 61 43 65 43**

**Fax: +33 61 41 51 78**

**RSN 975**

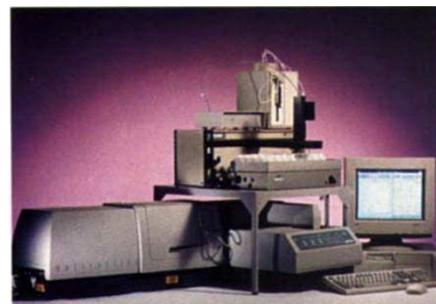
**Validation system software**

Kaye Instruments (Bedford, MA) announces its Windows-based software application for the Kaye Validator system. It reduces the time needed for validation, and simplifies test procedures, equipment calibration, and data collection and storage, resulting in significant time savings and reduced risks. The software works in a closed-loop system, eliminating all manual aspects of calibration and therefore any chance of human error. Comprehensive documentation details the entire validation process from setup to calibration to test results.

**Tel: +1 617 275 0300**

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**RSN 976**

**Diffraction autosampler**

The Diffraction Autosampler from Malvern Instruments (Southborough, MA) is designed for use on Malvern Mastersizer systems that include a large-volume, automated, liquid dispersion unit. It provides reliable, flexible automation with a high degree of user control for high-throughput particle sizing. Users simply queue up samples, which may be presented as dry powder or as liquid slurries, and the system automatically performs the measurements. New samples can be added during operation, and priority samples can be brought forward in the measuring sequence. The autosampler and the Mastersizer system are both controlled by scheduler software, run as a separate task.

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**RSN 977**

**Process validation**

Corning Hazleton (Harrogate, UK) offers a GLP-compliant process validation service using quantitative plaque, focus, or TCID50 assays for a wide range of challenge viruses, including HIV, HTLV, parvovirus, and hepatitis A. All challenge viruses are available serum-free at extremely high titers. The service includes a level III containment facility with a remote control audiovisual link between client and operator, and advice on design and regulatory issues.

**Tel: +44 1423 500 011**

**Fax: +44 1423 569 595**

**RSN 978**