World Premiere of MCO-20AIC Incubator at HET

Netherlands

The Het Instrument Exhibition (better known as HET) was held from October 9 to 13, 2000 in Utrecht, the Netherlands. In western Europe, HET is one of the major exhibitions in the field of analytical and life-sciences laboratory equipment.

In a 110m² booth, SANYO Gallenkamp BV displayed several new products including the new MDF-U50V VIP freezer and the MPR-513 pharmaceutical refrigerator.

But the eye-catcher this time was the new MCO-20AIC CO_2 incubator. SANYO proudly presented the future in high-performance CO_2 incubators with IncuSafe interior and UV sterilisation.

To celebrate SANYO Gallenkamp's 10th anniversary, we invited our guests for a cocktail 'Campai' in a bar situated in the centre of our stand. It goes without saying that many cocktails were served and that relations with present and future clients were intensified.

New Products

MCO-20AIC

Direct Heat Air-Jacketed CO_2 Incubator

- Incu-Safe copper alloy stainless steel and Safe-Cell UV light sterilization to create contamination-free incubating condition
- IR sensor for precise CO_2 control and fast recovery after door opening
- Easy-to-use front-mounted control panel
- Comes with Sanyo's exclusive remote monitoring system (optional)

195 liters (6.9 cu.ft.)

MCO-20AIC

MDF-U333/U537/U537D

Upright Biomedical Freezers

- Better temperature uniformity
- Enhanced safety alarm system
- Comes with Sanyo's exclusive remote monitoring system (optional)
- Temperature control range: -20°C to -30°C

274 liters (9.7 cu.ft.) | 482 liters (17.0 cu.ft.) | 452 liters (16.0 cu.ft.)

MDF-U333 | MDF-U537 | MDF-U537D

MDF-136/236/436

Chest-type Biomedical Freezers

- Better temperature uniformity
- Enhanced safety alarm system
- Temperature control range: -20°C to -35°C
- Comes with Sanyo's exclusive remote monitoring system (optional)

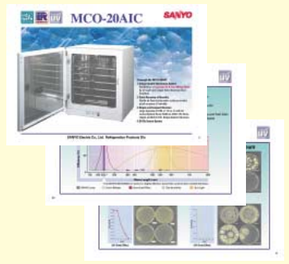
138 liters (4.9 cu.ft.) | 221 liters (7.8 cu.ft.) | 426 liters (15.0 cu.ft.)

MDF-136 | MDF-236 | MDF-436

Ad and sales tools (MCO-20AIC)

Advertising

8-page Brochure



Incu-Safe & UV Promotion Kit

CO_2 Incubator Handbook

Printed on recycled paper

SANYO Electric Trading Co., Ltd.

SFA004M

SANYO

synapsis

Biomedical Technology Newsletter Spring 2001

Medical Centre in Australia relies on Sanyo CO_2 Incubators and Ultra-Low Temperature Freezers

Australia

Dr. Detlef Geleick, the Senior Biologist at the Ludwig Institute

The Ludwig Institute for Cancer Research is an international non-profit organization that initiates and conducts long-range research programs directed toward the ultimate goal of eradicating cancer. To this end, there are now ten Branches of the Institute in seven different countries. The Institute has a strong commitment to translate its basic research discoveries into therapeutic practice and is an active sponsor of many early-phase clinical trials investigating novel treatment modalities discovered in the Institute's research laboratories.

To facilitate the transition from the laboratory to the clinic, the Biological Production Facility (BPF) was established in 1995 at the Austin and Repatriation Hospital in Australia as part of the Melbourne Tumour Biology Branch. Applicable current Good Manufacturing Practices (cGMPs) are observed at the BPF to ensure the material produced is safe and reproducible. cGMPs are the internationally recognized benchmark conditions and procedures for the manufacture of material for use in humans.

Since it was established, the facility has produced, purified and formulated two monoclonal antibodies for clinical use: Anti-A33 (huA33) which recognizes a 43 kD glycoprotein with selective expression in normal and malignant epithelium of the gastrointestinal tract and Anti-Le^y (hu3S193) which binds to an oligosaccharide epitope expressed on glycolipids and glycoproteins expressed on a wide range of epithelial cancers. In 1997/98 two production episodes generated a total of fifteen grams of hu3S193, and production in 1999/2000 yielded fourteen grams of huA33. Additionally, three antibodies have been supplied for clinical use from bulk material obtained from external sources.

During the design of the facility, the decision was taken to adopt the continuous cell culture technology based on bioreactors with hollow fibre cartridges. These systems permit high cell densities and yields, possess advantages in scale and cost and simplify downstream processing steps. The disadvantage is that process validation is more complex for continuous cell culture processes compared to batch processes. However, protocols have been devised which ulitise physical and biochemical tests to characterise the cell line and the secreted product through the continuous run and compare the results obtained from the same tests on the starting cells.

Prior to scale-up for clinical production, an extensive development program is undertaken including media trials and optimisation of the hybridoma culture conditions to maximise antibody production, laboratory-scale bioreactor studies to establish production feasibility and the establishment of master and working cell banks as required under cGMP. A production run is initiated by thawing a cryovial from the working cell bank and growing the cells in tissue culture flasks. Sanyo CO_2 Incubators (Model MCO-17AI) are used in the facility and their air jacketed design simplifies control procedures when operating in a cleanroom environment. After this preliminary expansion phase, the cells are transferred to roller bottles and expanded further. At least five roller bottles (the equivalent of 10^8 to 10^9 cells) are required to inoculate each bioreactor.

Two production-scale hollow fibre bioreactors (AcuSyst Maximizer™ 1000, Cellex Biosciences, Inc. MN) are housed in the cell culture room (Class 100,000) and use fully disposable pre-sterilised cartridges and flow paths which eliminates the need for CIP/SIP. Each bioreactor has a cell contact surface area in excess of two square meters. Aseptic fluid connections to each bioreactor, product harvests and sampling occur in a biohazard cabinet as does the work up of the inoculum to ensure sterility of the process. The cells are transferred to the bioreactor cartridge in suspension using a peristaltic pump. Temperature, pH and dissolved oxygen are monitored continuously by each instrument. Fifteen different media parameters can be measured off-line using a metabolite analyser. Cell culture supernatant from each bioreactor is harvested every day and stored frozen after centrifugation. At the conclusion of a bioreactor run which typically lasts for 50 days, these daily harvests are pooled and purified by a series of chromatographic steps carried out using a large-scale chromatography system and bioprocess columns. Purified bulk material is transferred to the sterile filling room (Class 10,000) via a pass-thru cabinet. All dispensing and stoppering activities are performed in a Class 100 laminar flow cabinet. Bulk purified product is sterile filtered and dispensed into sterile vials using a programmable batch-dispensing pump. The vials are stoppered, crimp sealed, labelled and inspected before transfer to the finished product store. Most antibodies are stored at -80ºC in Sanyo Ultra Low Temperature Freezers (Model MDF-U4086S).

Separate from the cleanrooms, the facility has laboratories equipped for cell line optimisation, small-scale bioreactor runs, chromatography development, in-process testing, product characterisation and final product testing. Although the facility was originally designed to produce humanised monoclonal antibodies, the existing systems and environment have been adapted to supply other reagents for the LICR clinical program. The facility also prepares finished formulations of peptides, proteins, and small molecules and conducts product characterization, quality control, stability and safety testing to meet international requirements. The Institute is one of a few academic organizations with a production facility that can produce study agents that satisfy the rigorous criteria of cGMPs. Currently, products from the facility are being used at nine sites in seven countries.

Facility Manager at AIDS research center praises Sanyo incubators and freezers

U.S.A.

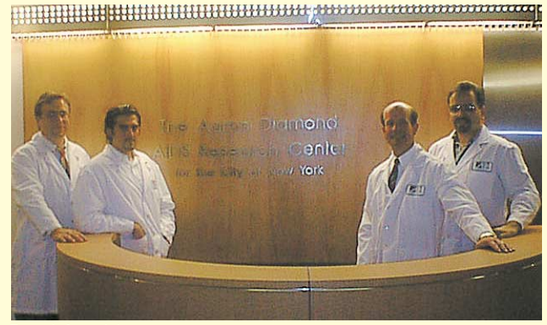
The Aaron Diamond Aids Research Center, an affiliate of Rockefeller University in New York City, was established in 1991. Building on a growing reputation of "front line" research, ADARC has attracted dedicated and talented scientists.

Aaron Diamond's research incorporates defining the mechanism by which HIV destroys the immune system. Their approach has been a "multidisciplinary" one including virology, immunology, molecular biology and clinical medicine trials.

In one of the trials, Dr. David Ho, director of research and CEO of ADARC, is using a new AIDS drug developed by Abbott Laboratories, in hopes of creating a therapy to slow the spread of the virus. Another research lab, Abbott Laboratories, has developed Kaletra.

Sanyo, through the efforts of the local New York representative, has sold two CO_2 incubators (MCO-17AIC) and a -152 degree C freezer, MDF-1155ATN to ADARC. The facility manager, Daniel Staehs, has spoken to us and stated that the researchers were very impressed with the rapid CO_2 recovery and the incubator's reliable performance. He further stated that at no time were any critical HIV specimens lost due to inaccurate CO_2 levels or temperature fluctuations. In fact, Mr. Staehs further stated that "the design of the Sanyo incubators is by far the most advanced and most maintenance-free that ADARC has ever used." This is surely a welcome endorsement from such a prestigious institute.

Mr. Staehs went on to say that ADARC has had many ultra-low



From left to right:
Joe LaPorte (Sanyo Scientific), Drew Kevorkian (Northeast Scientific), John Bergen (Sanyo Scientific) and Daniel T. Staehs (Aaron Diamond)

temperature freezers from other manufacturers and stated, "We find that the Sanyo freezer outperforms all others in operation and we have welcomed its advance design. We found this quite evident in the dramatic reduction of 'heat load output.' The design of the cooling chamber surpasses other freezer manufacturers. The Sanyo freezer holds temperature far better than any other freezer in the industry."

The Aaron Diamond Institute Research Center will truly be a great reference for others in the field of research. The Sanyo name is becoming synonymous with quality and innovation.

Sanyo CO_2 incubators used by Cambridge Scientists in cutting-edge research

U.K.

Dreams of a modern research facility in Cambridge, where clinical and basic science could converge in the study of mechanisms of disease at the molecular level, turned to reality in 1993 with a major capital award from the Wellcome Trust to the University of Cambridge School of Clinical Medicine. At the same time the British Medical Research Council was looking to re-house its Dunn Human Nutrition Unit. A joint project was conceived and, after two years of planning and two years of building at a cost of £26 million, the NEW Wellcome Trust / MRC Building emerged on the Addenbrookes Hospital Site in Cambridge.

The University's Wellcome Trust-funded 60% share of this building was to house the NEW Cambridge Institute for Medical Research (C.I.M.R.) and the first groups of Scientists moved into the building

Ian Flack, the Laboratory Manager of Cambridge Institute for Medical Research (left), Arun Parmar, Technical Sales Specialist, SANYO Gallenkamp PLC (right)

in October 1998. In October 1999, the C.I.M.R. was granted Wellcome Trust Centre Status, and is now synonymous with the Wellcome Trust Centre for Molecular Mechanisms in Disease. The building was officially opened in November 2000 by HRH the Princess Royal.

Major research at the Wellcome Trust Centre focuses on the genetics of human disease, cell biology, immunology and cancer.

Ian Flack, the Laboratory Manager who oversees the purchase of laboratory equipment used in the Centre's laboratories, commented, "Our requirement was for an Air Jacketed CO_2 incubator in which we would have complete confidence. When purchasing equipment, we want to be sure that it will give good, reliable service over as long a period as possible."

Over the last two and a half years the Wellcome Trust Centre have purchased 40 MCO-17AI CO_2 Incubators with infrared CO_2 sensors and stacking kits.

Mr. Flack also stated that "our Scientists demand a high standard with regard to equipment and are happy with the Sanyo incubators since they are very simple to use with precision control and a quick recovery time. They also like the fact that they are extremely easy to clean and have proved to be contamination-free in use. The safe stackable function offered by the units in a busy laboratory is a major positive feature. Overall the MCO-17AI CO_2 Incubator has been very reliable and the level of service offered by Sanyo Gallenkamp has been of a high level."

As research continues and the need for more CO_2 incubators grows, Sanyo Gallenkamp will continue to offer the latest technology and the highest level of service to such an eminent research centre.