"Every day I've felt I've
done something worthwhile."

An introduction to Australia's
Commonwealth Serum Laboratories

A note from The Director

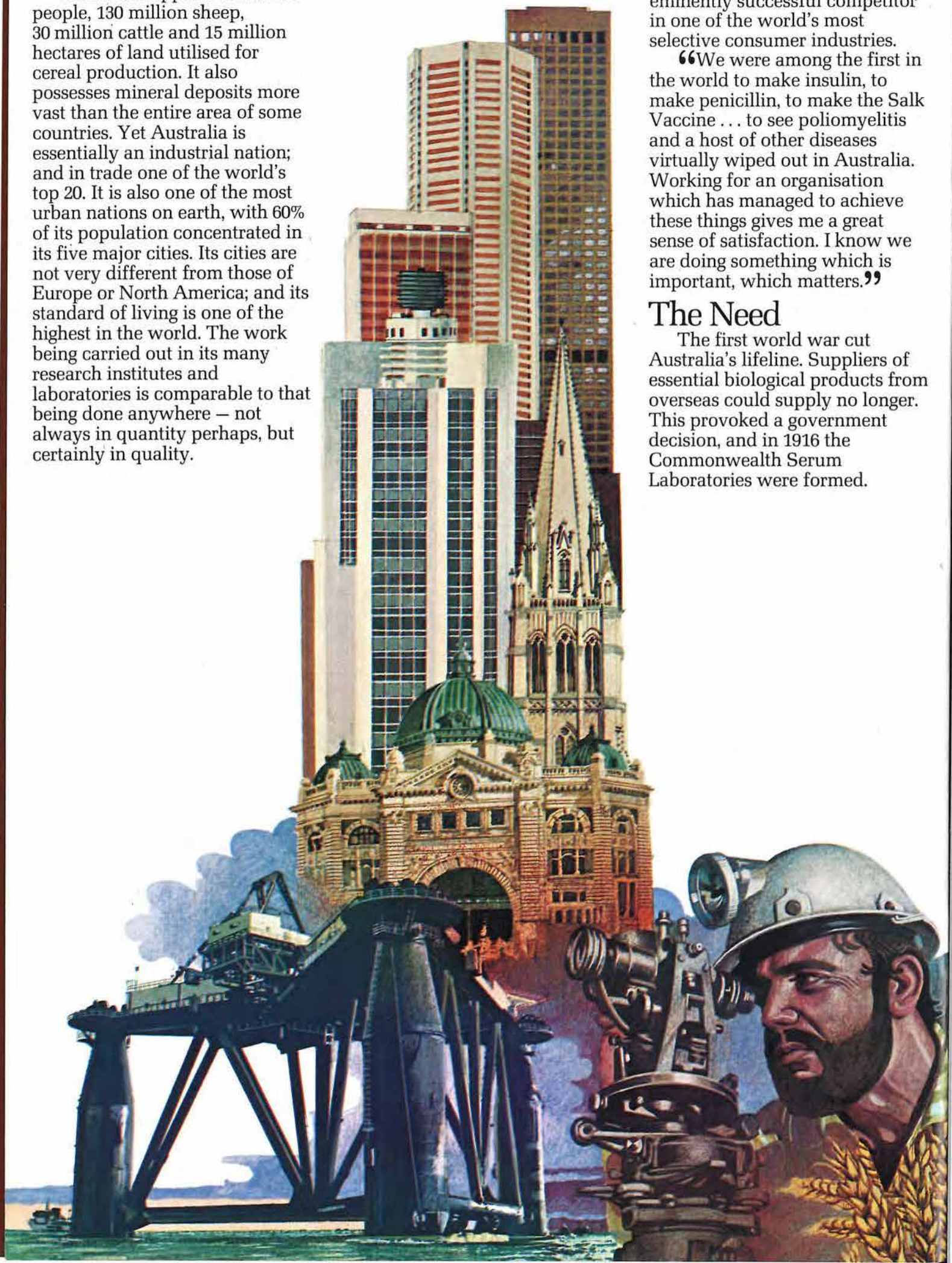
Throughout this booklet are quoted random comments from members of CSL staff.

These people are individuals who proudly put their name to every job they do; yet, curiously, prefer to remain publicly anonymous. Perhaps it is their group pride in CSL as an organization; a realization that it is not just the outstanding individual, but the dedication of all the individuals which brings about success.

Whatever the reason, these spontaneous remarks reflect what I believe is the spirit of the Commonwealth Serum Laboratories.

The Setting

Australia supports 14 million people, 130 million sheep, 30 million cattle and 15 million hectares of land utilised for cereal production. It also possesses mineral deposits more vast than the entire area of some countries. Yet Australia is essentially an industrial nation; and in trade one of the world's top 20. It is also one of the most urban nations on earth, with 60% of its population concentrated in its five major cities. Its cities are not very different from those of Europe or North America; and its standard of living is one of the highest in the world. The work being carried out in its many research institutes and laboratories is comparable to that being done anywhere – not always in quantity perhaps, but certainly in quality.



This is the environment in which CSL has developed into an eminently successful competitor in one of the world's most selective consumer industries.

"We were among the first in the world to make insulin, to make penicillin, to make the Salk Vaccine . . . to see poliomyelitis and a host of other diseases virtually wiped out in Australia. Working for an organisation which has managed to achieve these things gives me a great sense of satisfaction. I know we are doing something which is important, which matters."

The Need

The first world war cut Australia's lifeline. Suppliers of essential biological products from overseas could supply no longer. This provoked a government decision, and in 1916 the Commonwealth Serum Laboratories were formed.

The founding Government charter stated:

"... the principal sera that we propose to make are those against diphtheria, tetanus, dysentery, cerebro-spinal meningitis, streptococcal infections and perhaps pneumococcal infections."

The Record

From need, CSL developed rapidly. In 1918 it was granted an 11 hectare site at Parkville, in Melbourne. Today its laboratories and facilities employ more than a thousand people.

"Most people have no idea of the scope of our activities."

1923. Within months of Banting and Best's discovery of insulin, it was made at CSL.

1925. CSL pioneered the production of sera from people recovering from infectious diseases.

1944. CSL enabled Australia to become the first country to supply its civilian population with penicillin.

1956. CSL became one of the first laboratories to produce Salk Inactivated Poliomyelitis vaccine.

1967. CSL became one of the first laboratories to produce Rh(D) immunoglobulin for the prevention of haemolytic disease of new born babies.

1976, CSL became a major supplier of A/Swine influenza vaccine for the northern hemisphere, as well as meeting Australian requirements.

Today, CSL produces a comprehensive range of vaccines, antitoxins, toxoids, insulins, hormones, including H.G.H. and F.S.H., heparins, biologically-based antibiotics, allergen extracts, antivenoms, blood fractions and diagnostic agents for human and veterinary use.

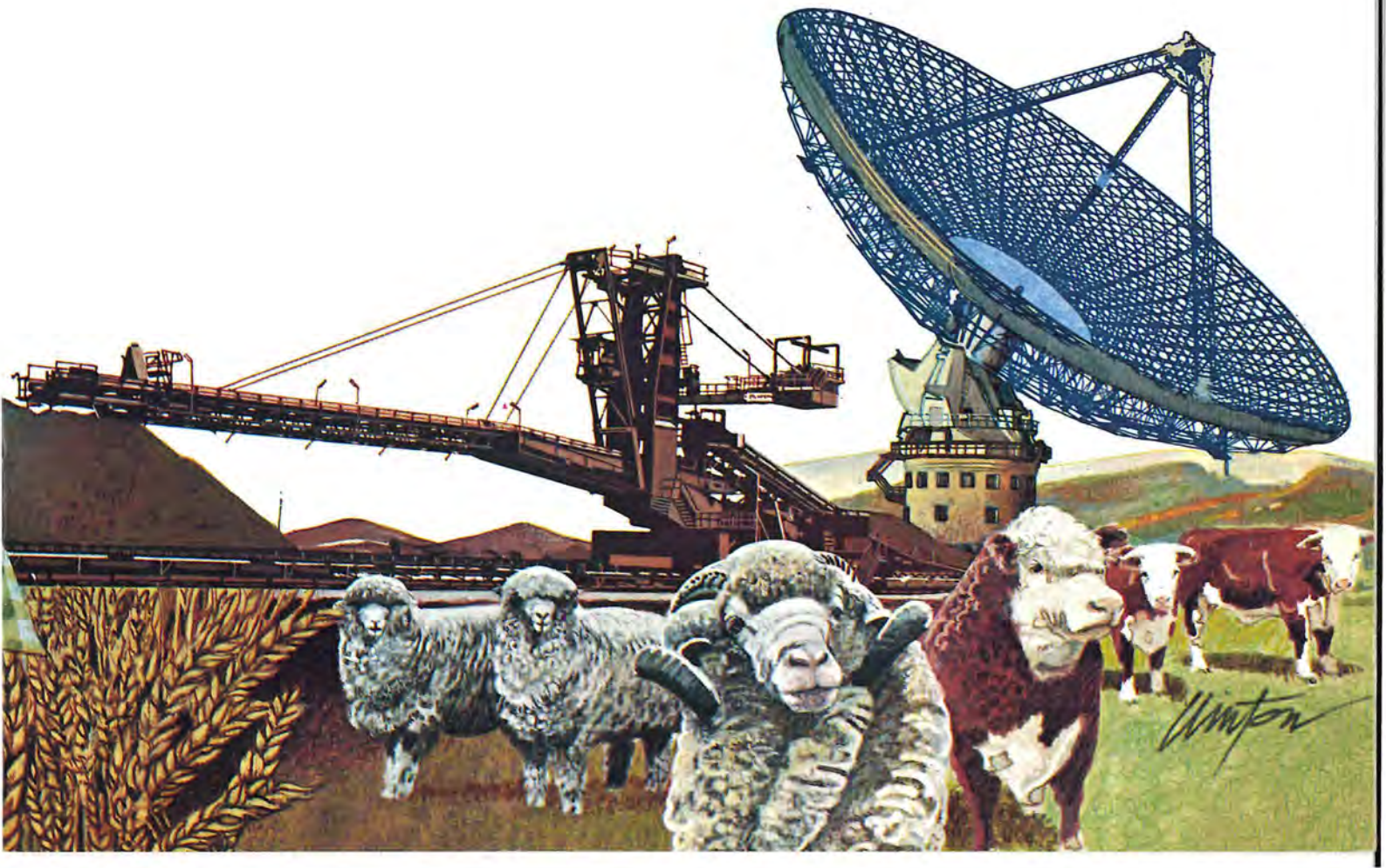
It exports to over 100 countries, maintains vast reserve stocks and has the capacity to produce all of Australia's essential biological products for human and veterinary use.

The People

CSL holds special place in the minds of the Australian people. Generations of school children learn of CSL via the vaccines which immunised them against once-dreaded diseases.

People remember the emergency airlifts of CSL medical supplies sent to alleviate the effects of natural disasters. The news of a new flu vaccine, a new snake bite antivenom. To these people, CSL means hope. But there's an even deeper feeling for CSL among all those who work in the laboratories. A feeling of responsibility and of knowing each individual job is of vital importance to the whole nation. This feeling, this pride, is the strength of CSL.

"I think it's an organisation with a soul. One you can believe in."



Human Medicine

The prevention of human disease.

"Preventive medicine is just so much cheaper and less risky than the more dramatic and heroic measures which have to be taken after a patient's life has been threatened."

There are no longer any tetanus wards in Australian Hospitals. Nor diphtheria, cholera, poliomyelitis, whooping cough or yellow fever wards. Yet all these diseases were present at the turn of the century. Most of them were as feared as cancer is today.

But now there are effective vaccines or toxoids for them all.

"We're questioning everything we do. Looking to see how it can be done better. Continually."

Photograph: courtesy of Royal Melbourne Hospital

The treatment of human diseases.

CSL produces antibiotics, antitoxins, heparins, allergen extracts, blood fractions and insulins.

CSL produce penicillins in huge quantities. Antitoxins for diphtheria, tetanus and gas gangrene.

CSL produce Allergens for diagnosis and desensitizing.

CSL was one of the first laboratories in the world to successfully grow the house-dust mite, and also produces extracts from animal danders, pollens, insects and moulds.

CSL also produce a wide range of diagnostic agents and cell culture products.

"... the Rh negative mother carrying an Rh positive foetus ... Our Rh(D) immunoglobulin was used to treat something like 30,000 women last year, and it's virtually eliminated the problem."

Human blood: In Australia, whole blood and fresh plasma donations are collected by the Red Cross Transfusion Service through a free donor service. It is then processed by CSL into serum fractions. This work was pioneered by CSL in 1925. Today the serum is processed into many forms, including plasma volume expanders, clotting factors, normal and specific immunoglobulins.

N.B. The export of (Australian) human blood products is prohibited by law.

Insulin: "We've got 35 million head of cattle, 2½ million pigs. Think of them as raw material."

The world desperately needs more insulin. One animal pancreas produces only enough insulin for one diabetic for approximately 10 days. An entire new building at CSL is now devoted to the production of insulin. To make more of it, more efficiently and of greater purity.

In 1928 CSL developed the first effective snake bite antivenom, a monovalent. Now there is a single CSL polyvalent antivenom which can be used in treating the bites of all venomous snakes of Australia and Papua New Guinea.

CSL also developed the Stone Fish, Sea Snake and Box Jellyfish antivenoms, but antivenoms are only one aspect in the treatment of human disease.

"Our antivenoms are not commercially important, but they're terribly important if you happen to be bitten by a snake."

CSL laboratory products

Blood Bank Reagents
Prepared Bacteriological Media
Bacterial and Viral Antigens
Immunological Kits

Cell culture products ranging from cell lines, growth media and sera, to chromosome analysis reagents. Also, CSL has a capacity to prepare special formulations of growth media, made to the customer's requirements.

All CSL products are backed with full documentation that describes how they should be stored, how they should be used, and precisely what effects may be expected.

Animal Medicine

Animal health care.

"If you can prevent disease, you have a unique position as a veterinarian."

In a country with such an enormous domestic animal population, concern with the prevention and treatment of animal disease is natural. CSL produces vaccines, specifically prepared for animal health care.

However, to produce effectively, CSL must also farm. At Woodend, 65 km from Melbourne, CSL has a 610 hectare property for breeding horses, cattle and sheep, producing blood and sera for quality control and research.

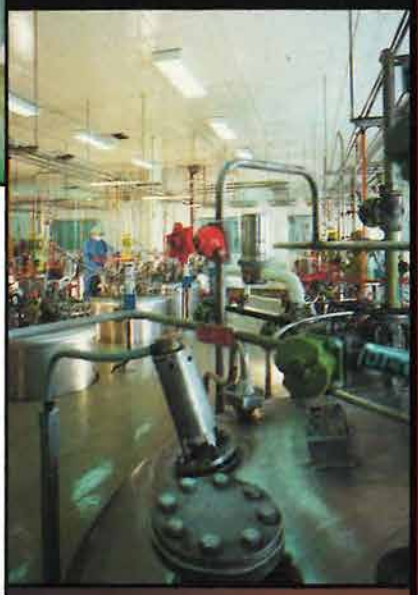
At Parkville, it has special buildings for housing specific pathogen-free animals, breathing special filtered air, eating sterile food, drinking sterile water.

This specific interest in animal care and husbandry provides benefits to both the laboratories and to farmers, and enables CSL products to be thoroughly tested under field conditions for safety and efficacy.

"We are held in high esteem for our veterinary products. We're seen as innovative producers of very high quality products."

CSL makes products the veterinarian or farmer can work with quickly and safely and which offer the highest degree of effectiveness. Vaccines which give long term immunity and combination vaccines which control a variety of diseases with a single inoculation.

"Our products have a long lead time and they're not easy things to make. But we know our own production capabilities. Having said we're going to supply, we do."



The production processes

CSL is responsible for producing Australia's essential biological products for human and veterinary use. In addition, CSL is expected to maintain adequate reserve stocks at all times, and to be capable of producing the stocks necessary to meet any defence emergency or human or livestock epidemic.

"We have reserves. If there's sudden demand, or if a batch fails, we've got stocks we can fall back on."

It is essential that CSL's production processes be kept flexible; automation and computerization is required. Reserves of raw materials must be kept; as must reserves of partly-finished products which can be held for long periods in a stable state, awaiting reconstitution.

Production lines must be capable of producing relatively small quantities economically, yet also producing vast quantities when required.

In as little as four months after a new influenza strain has been identified, sometimes 10 million doses may be required . . . sometimes two million.

"We've been inspected by overseas regulatory authorities. I think many of them have been surprised. They didn't expect to find our level of technical expertise in Australia."

CSL manufacturing

"The manufacture of biological products, derived from living organisms, involves very complex processes. It requires processing equipment and control systems of sophisticated design and construction, as well as the every day requirements for large quantities of steam, distilled water, hot and cold brine for control of warm rooms and cold rooms (the latter varying from −30°C to 8°C), solvent reticulation, compressed air and so on.

"Much of the very large scale processing equipment such as bacterial fermenters, extraction vessels, etc. have been specifically designed by CSL engineers for the purpose; other large equipment like continuous centrifuges, egg inoculation and harvesting machines, zonal gradient centrifuges, and for concentration of bacteria, viruses or products derived from their growth have been procured, modified and installed only after long evaluation of available types and discussion with overseas experts.

"Buildings have been designed by CSL staff specifically for designated production processes. This involves attention to the most minute detail, from the design of a bench top to the design of maximum security laboratories for handling highly pathogenic organisms protecting products, operators and the external environment."

Quality control

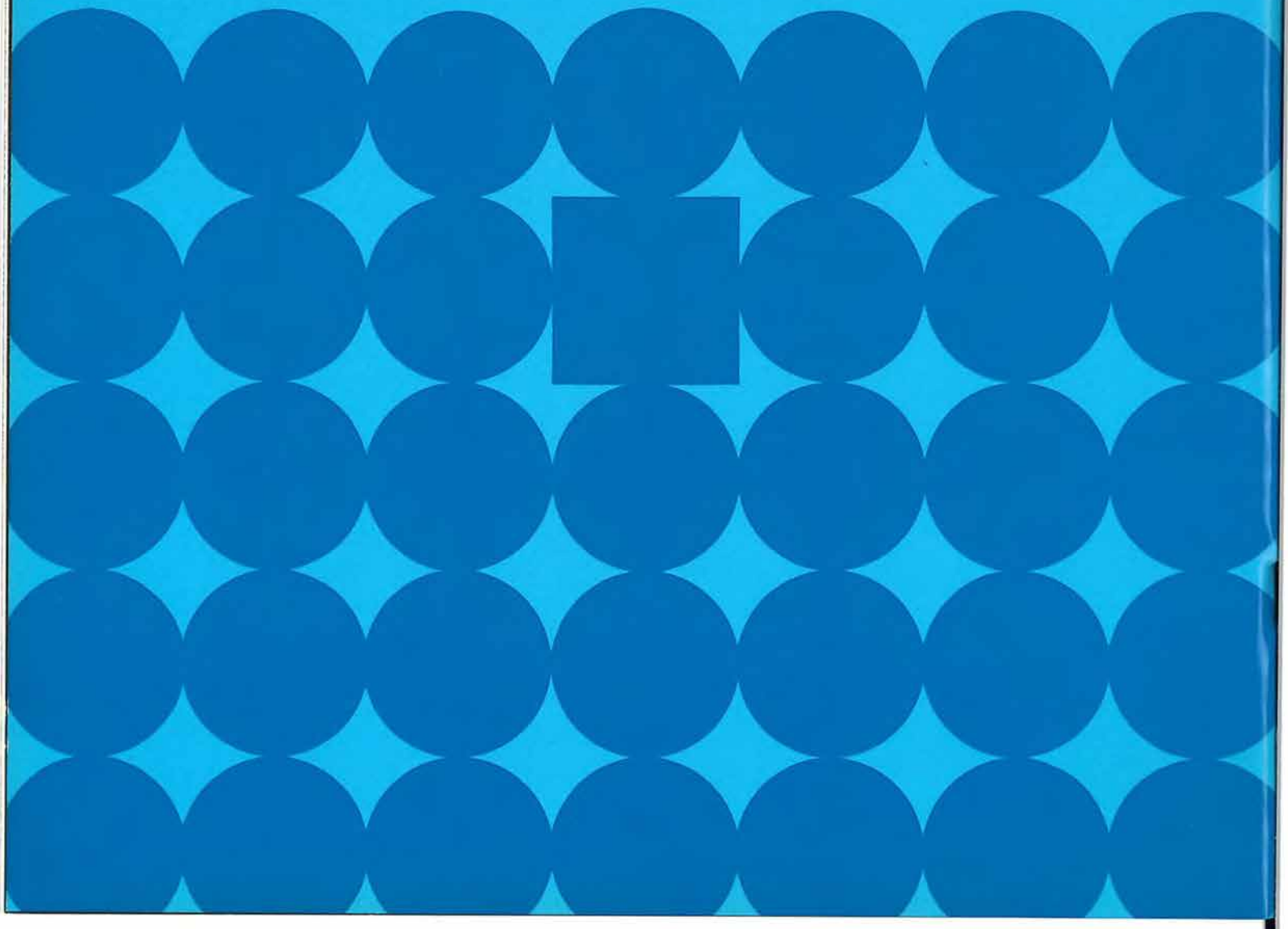
At CSL, quality control works in complete parallel to the production process, but independently, from start to finish. Tests are made at every stage, from raw material to bulk processing, partly processed products, finished in their final packages throughout their shelf life.

Tests are monotonously repetitive.

The results are measured, not just as 'positive' or 'negative' but with a grading of its accuracy, stringency of its test, and its results.

Every batch of products for Australia or export is

"The real protection against error is in the discipline and the training of our people."



accompanied by its own test record. The whole story. All the tests. All their results. The names of the people who did them. And the names of the people who supervised them.

CSL maintains a close liaison with health and testing authorities throughout the world. It supports the standards of the W.H.O., B.P., B. Vet. C., major national pharmacopoeias, and the Australian Code of Good Manufacturing Practice. In fact it has been consulted in the writing of many of these standards.

"For the most part the various codes are describing minimum requirements. Nowhere do they say we should not do better."

Research and development

CSL research is directed towards three basic areas:
* more effective and less reactive biological products.
* greater basic knowledge of biological products.
* new and more efficient manufacturing processes.

Major projects are being carried out in:

Bacteriology: Developing new bacterial vaccines and new diagnostic agents and improving existing ones.

Biochemistry: Developing more purified insulins and more effective control sera for hospitals.

Immunology: New RIA systems and new methods of improving immunological responses.

Virology: Developing new influenza vaccines as each new influenza strain appears. Developing new human vaccines with fewer side effects.

Pharmacology: In co-operation with laboratories in various parts of the world, working to reduce the undesirable side-effects of rapid exchange transfusions of stable plasma.

Serology and Blood Research: Tests of rare blood types. Developing production processes to improve yields of immunoglobulins and other blood fractions.

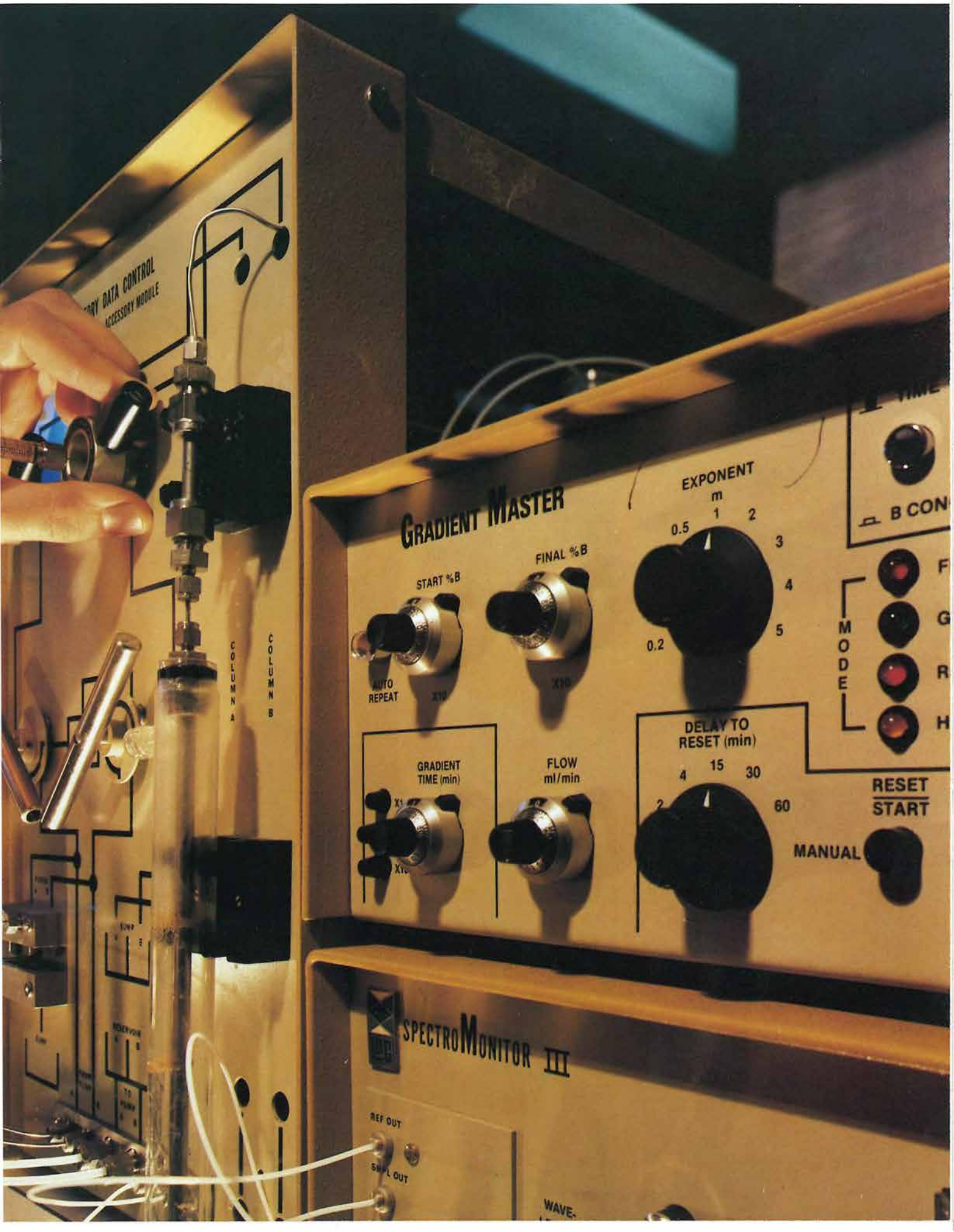
Electronics: Designing and making instruments for process monitoring and control.

Bioengineering: Designing new laboratories and production processes.

"If there is to be any hope of providing the under-developed countries with the vaccines they'll need by 1990, we'll have to develop vaccines which don't need refrigeration."

In addition, basic structures are currently being carried out on many pharmacological aspects of biological products, including the development of products which require less refrigeration and offer longer expiry dates.

"Not every project will be a success. Research isn't like that."

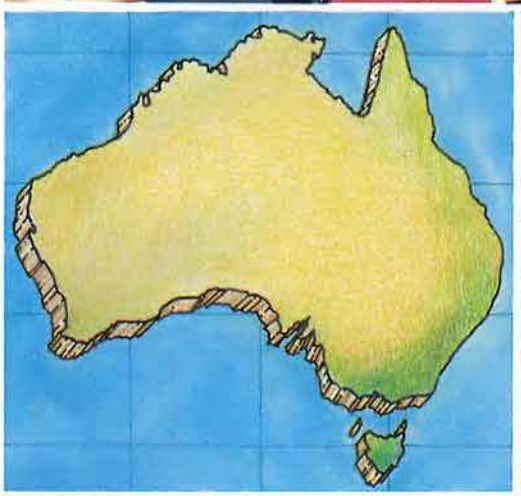

GRADIENT MASTER
START %B
FINAL %B
EXPONENT
m
0.5
1
2
3
4
5
0.2
AUTO
REPEAT
MODE
F
G
R
H
GRADIENT
TIME (min)
FLOW
ml/min
DELAY TO
RESET (min)
4
15
30
60
RESET
START
MANUAL
SPECTROMONITOR III
REF OUT
COLUMN A
COLUMN B

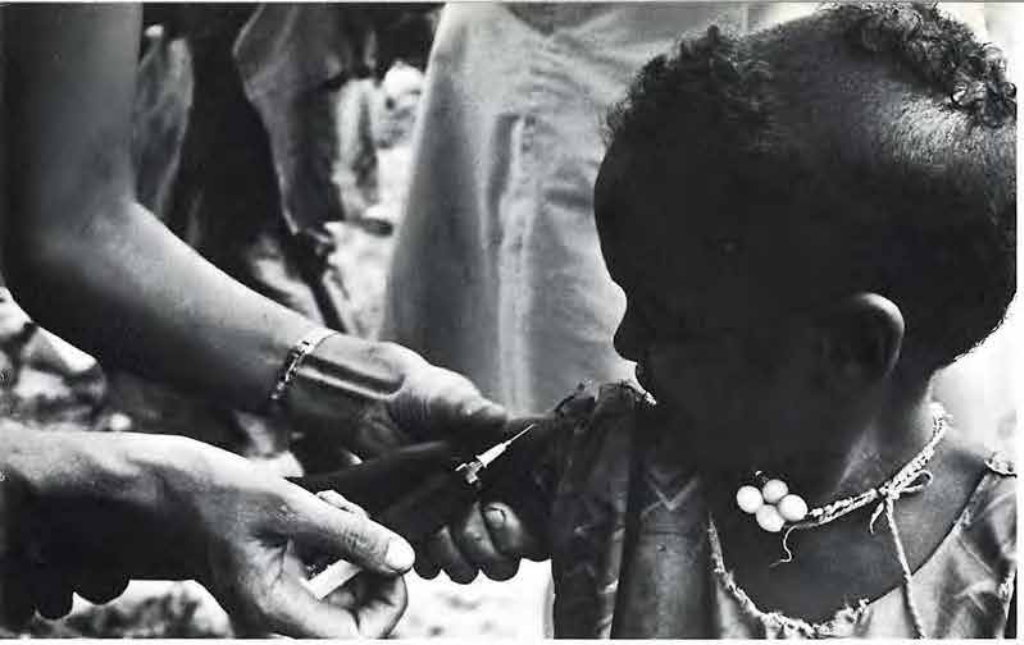
The Australian market of CSL

"How are we regarded? We are trusted."

An active CSL sales force operates throughout Australia, dealing directly with Government purchasing authorities, doctors, hospitals, pharmacists, veterinarians, farmers. Via branch offices in each State it provides the highest standard of service, information and advice.

CSL has achieved this high level of customer service by overcoming the enormous transport and distribution problems of a vast, sparsely populated land mass (the size of Europe and Scandinavia) with marked climatic variations. Such competence and expertise has merited the nation's trust.





CSL export markets

"Reputations are very hard to gain and easy to lose. Particularly in our market."

CSL has only one quality standard; and that standard is the same for products destined for use in any of its 100 export countries as it is for Australia. It is a standard which conforms to W.H.O. guidelines, conforms to all appropriate pharmacopoeia, and conforms to all appropriate codes of good manufacturing practice. CSL has without doubt earned the 'preferred supplier' status it has achieved in many of its export markets.

CSL's marketing philosophy favours long term relationships. It is not interested in one-shot sales to alleviate a home-market glut.

It will only service those markets it can service well, and has occasionally declined to supply when the correct handling of its products could not be assured. It will only supply products which meet a real need in the country to be supplied.

And it will not take on a new client when supplying that client may jeopardize supplies to an existing client.

From CSL almost everything travels airfreight, in specially designed containers. CSL only uses forwarding agents who know how that product would be handled at any trans-shipment point. It is CSL's responsibility to see the product arrives in its original condition in the customer's store.


The Veterina Record
BURNET
VOLUME 135 • SEPTEMBE
Jour
Bacteri
BURNET LIBRARY
BRITISH J
OF
HAEMAT
EDITO
S. M. LEW
EDITORIAL BO
BLOOD
The Journal of The American Society of Hematology
ACTA PATHOLOGICA ET MICROBIOLOGICA SCANDINAVICA
Section B MICRO OLOG
Cancer Research
VOLUME 38 • NO. 3 CNREA8 • PP 485 875
March 1978
an Journal of Medicine.
IPOSIUM ON
RT FAILURE
JOURNAL OF
JAMA
THE JOURNAL of the American Medical Association
February 2
AL JOURNAL OF AUSTRALIA
IAN MEDICAL ASSOCIATION
THIS NUMBER COMPLETES VOLUME 57
VOLUME 57, NUMBER 2, JUNE 15, 1978
Virology

International activities

"We have quite a number of overseas visitors who are very highly regarded in their fields throughout the world. Their reaction is generally one of surprise; particularly at the range of our products and the quality of our new facilities."

CSL maintains a relationship with the World Health Organization; particularly in reference to international questions of clinical safety, quality control and good manufacturing practices.

Two members of CSL's staff are also members of the W.H.O. Expert Advisory Panel on Biological Standardization.

CSL staff regularly participate in major international conferences and contribute articles to the major medical and scientific press throughout the world.

"If you don't talk with the rest of the world's scientific community you run the danger of finding yourself in a backwater."

There are people from many nations, under the aegis of W.H.O., the Bureau presently undergoing training at CSL. There are also many CSL people helping overseas countries develop their own facilities for producing human and veterinary biological products.

"There's a strong feeling of identification, an appreciation of what we can do for the community of Australia and the world."

"If I didn't believe in what I'm doing, I wouldn't be doing it."

CSL

Commonwealth Serum Laboratories.

45 Poplar Road, Parkville,
Victoria, Australia.
Postcode 3052.
Telephone: 389 1911
Telegraphic code:
Serums Melbourne
Telex: AA32789