

An eye on world markets

Optical lens solution maker Opto-Pharm is a small but highly qualified company — with big plans.

By SHERRIZA JALIL

In a manufacturing environment so stringently monitored even particles fear to intrude, Opto-Pharm's facilities have an annual production capacity of 10 million bottles (250-500 ml) and 40 million tubes and ampoules (5-15 ml) of optical solution.

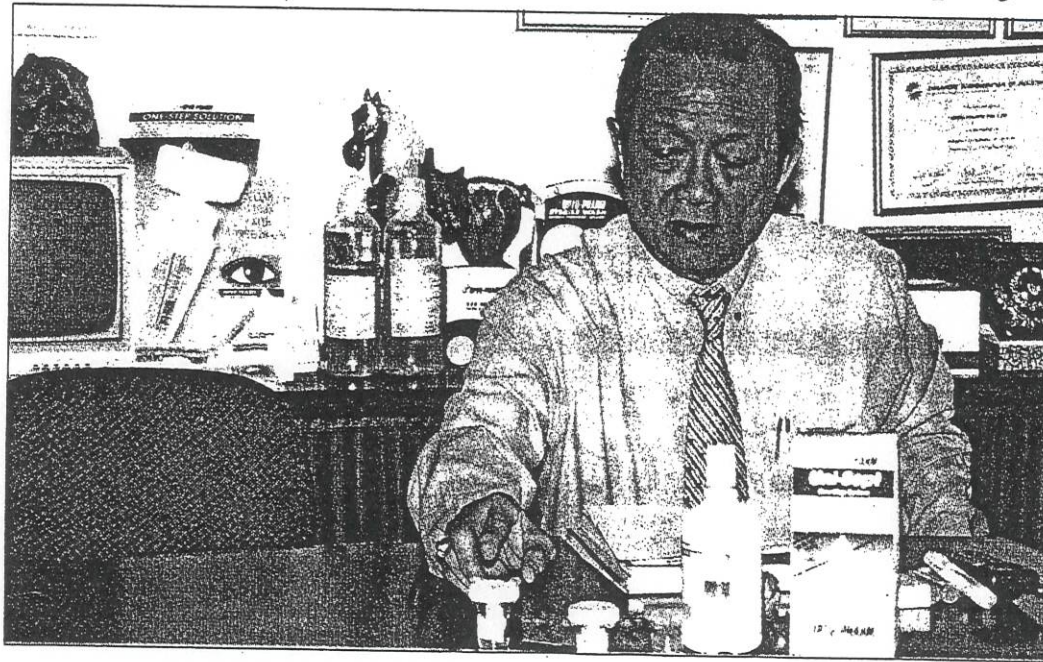
This amazing productivity is propelled by full automation, the able leadership of the management team, and the support of pharmacists, chemists, engineers and chemical engineers, microbiologists and technicians.

The grand total of personnel — a mere 28!

Opto-Pharm Pte Ltd, a manufacturer of optical lens solution under its own label as well as a contract manufacturer for other labels, recently earned ISO 9002 certification.

Besides earning the ISO, Opto-Pharm is the first in Singapore and Asia to win the prestigious CE certification, enabling its products to be exported to Europe, Australia and the US with no hassles.

The trek to success wasn't always hurdle-free. Managing director Mr



Opto-Pharm's managing director Mr Robert Khoo says that its armory of certification, including the ISO 9002, is crucial to the company's future success in overseas markets.

Robert Khoo founded Opto-Pharm in 1988 when he lost the agency of optical products producer Barnes Hind.

At first, Opto-Pharm produced IV (intravenous) and contact lens solutions. "Competing against the

MNCs in the IV market was tough. Local companies did not receive special privileges. And we couldn't better the MNCs in terms of pricing," recalled Mr Khoo.

Another obstacle came in the form of new regulations

clamped down by the Ministry of Health immediately after Opto-Pharm's birth. Companies manufacturing contact lens care supplies were required to have a manufacturing license abiding by World Health Organisation GMP guidelines.

With the new regulations, Opto-Pharm's progress was again thwarted before it could take off.

But the company bounced back.

Mr Khoo saw the future in overseas markets and embarked the company on

a quest to gain international certification with the WHO GMP for export to Third World Countries, and the Therapeutic Goods Administration (TGA) GMP for Australia, a member of the Pharmaceutical Inspection Convention (PIC).

Timely certification

In 1993, the European Union established the Medical Device Directive (MDD 93/42/EEC) which required a new type of certification, the CE certification, to export to Europe, taking effect from July this year.

To obtain this certification, Opto-Pharm needed the ISO 9002 and EN 46002.

Today, all three are firmly in Opto-Pharm's grasp. In fact, Opto-Pharm was the first company in Singapore and Asia to clinch CE certification.

With other tight step-by-step monitoring and documentation of processes, coupled with the "licenses" to export abroad, Opto-Pharm is all set to storm international markets.

◆ Sherriza Jalil is a freelance writer.

What makes their product different

What's the difference between the various contact lens solutions in the market? Opto-Pharm's managing director Mr Robert Khoo explains that all optical lens solutions are equally good. The difference lies in the bottling.

Opto-Pharm's other competitors purchase bottles from a supplier. As and when needed, the bottles are washed, dried, and filled. On each bottle, the neck is plugged in, and a cap screwed on.

Problem is, the nozzle at the tip of the neck already has a pre-existing hole which is plugged by a protrusion inside the cap once it is screwed on.

Leakages and thus contamination can occur because of this hole and joints in the bottles.

Noted Mr Khoo: "If something can come out, then something can get in, too, and possible contamination may occur."

Opto-Pharm drastically reduces the risk of contamination with strict hygiene standards and the use of state-of-the-art Rommelag equipment. The Rommelag, costing \$2 million each, enables the processes of forming, filling and sealing the bottle (in

one piece, with no joining parts) to be done in a single operation.

First, liquid plastic oozes out, and is captured by the mould. Hot air blows the malleable plastic into shape, and icy jets of cold water harden it. Immediately, the bottles are filled with the optical solution and sealed. A ring is placed around the neck and the bottles are capped. So every single part of an Opto-Pharm product is "oven-fresh", you might say.

"Our contact lens care solution also uses very high quality water, called Water for Injection or WFI. We have the facilities to ensure such hygiene in water because of our

IV-manufacturing background," explained Mr Khoo.

On top of the WFI and aseptic microfiltration facilities under laminar flow, the environment in which the processes take place also makes life hard for bacteria and particles.

This environment is termed Class 100 Laminar Flow status, meaning that in every one cubic millimetre of air, no more than 100 particles are present. Compare this to a normal, air-conditioned room which has a Class 100,000 status!

