



SURGING AHEAD

Since COVID-19 hit Australia earlier this year, the pandemic has had a negative impact on many industries. The med-tech and pharmaceutical sector, in particular, has faced significant challenges, notably in terms of running research projects and clinical trials during lockdown. Carole Goldsmith reports on two medical manufacturers that are nonetheless moving forward, and an exciting new national program to develop the industry.

The BridgeTech Program is a national professional development program that trains researchers and entrepreneurs on how to effectively navigate the med-tech commercialisation pathway. The program's Director - Professor Lyn Griffiths, is also Executive Director of the Institute of Health and Biomedical Innovation (IHBI) at the Queensland University of Technology (QUT). She explains that the BridgeTech Program is convened and administered by QUT.

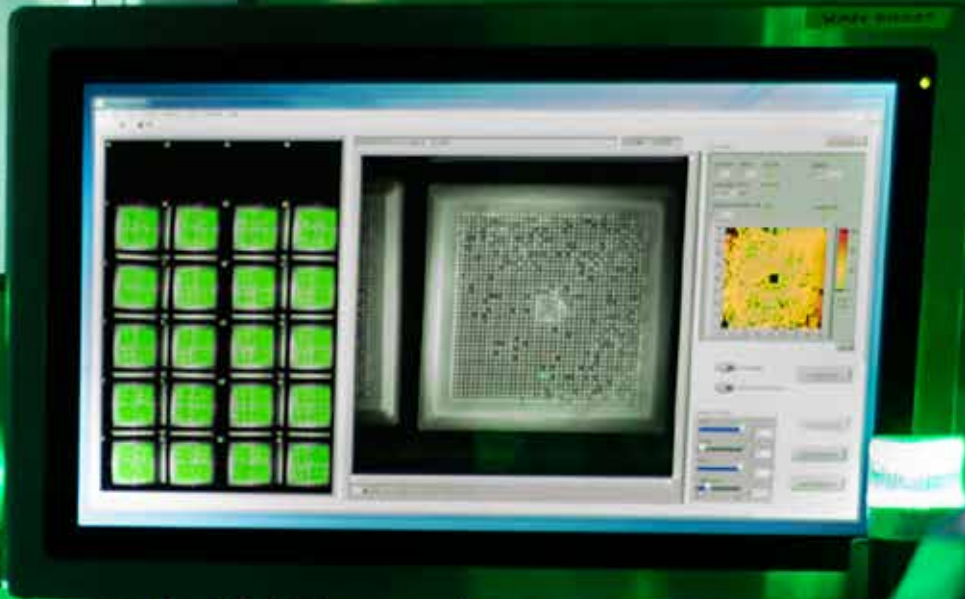
"Funded by MTP Connect and industry, the BridgeTech Program commenced in April 2018. It involves a consortium of 16 partners including med-tech and pharmaceutical companies, universities

and industry associations. Leveraging off the industry expertise and global connections that the consortium offers, the BridgeTech Program equips its participants with the skills and networks to enable med-tech commercialisation."

The Program's 16 partners are a powerhouse of organisations comprising universities (Melbourne, Western Australia, Newcastle, Macquarie, Flinders and ANU) and industry-leading companies (Cochlear, Stryker, Siemens, Vaxxas, Bosch, Gadens, Solentropy, Magnetica), as well as industry association Life Sciences Queensland, and the Australia China Technology Incubator (ACTI), a business accelerator providing access to the Chinese healthcare market.

"Each year we select 80 participants for the BridgeTech Program, and 100 participants for the Bridge Program, which trains people for commercialisation in the pharmaceutical industry," Griffiths explains. "The Bridge Program, which I am also director of, is funded by MTP Connect and industry. It has been running for four years and together 460 alumni have gone through our training programs. Around 30% of participants in both of the programs are entrepreneurs and 60% to 70% are mid-career researchers."

On the coronavirus pandemic's effect on the sector, Griffiths says:



*Professor Lyn Griffiths,
Director of the BridgeTech
Program.*

“COVID-19 has put a dampener on some of the research projects and clinical trials being conducted by Australian med-tech and pharmaceutical companies. They have found it difficult to recruit participants, particularly during lockdown periods. Also, our

educational seminars and lectures have been conducted online instead of in face-to-face sessions.”

Both the BridgeTech and Bridge Programs are free of charge to all selected participants and they can access the program’s online training modules delivered via QUT’s website. The BridgeTech Program provides specific training on the scientific, legal, financial, clinical, regulatory and reimbursement disciplines that are essential to med-tech commercialisation. It also involves webinars, specialist speakers, followed by a three-day BridgeTech symposium.



A BridgeTech Program seminar in Perth: (from left to right) Professor Griffiths, Graham Marshall (Motherhood Innovation), Professor Fiona Wood (Fiona Wood Foundation), David Cannington (Nuheara Innovation), Rolee Kumar (UWA).

“Each year we do a review of the programs with our participants,” Dr Griffiths advises. “We asked the 2018 BridgeTech cohorts how the program had helped them: five participants have R&D contracts, eight have pitched to investors or industry, four have had discussions with incubator staff, three have initiated or completed a patent, two have launched a new product, and four have developed a new start-up business. These participants will be followed up every year to continue to see their progress.”

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Dr Griffiths adds that this year will see the launch of an exciting extension of the Bridgetech and Bridge Programs: “The Researcher Exchange & Development Initiative (REDI) Bridge/BridgeTech Intern Fellowship’s program will provide 20 competitive fellowships annually. It will support travel costs and enable the recipient to spend time with an industry partner, either in Australia or overseas.”

Funded by the Federal Government’s Medical Research Future Fund, this initiative will roll out this year over a four-year period.

Vaxxas – Revolutionising vaccine delivery

For all of us who don’t like being jabbed by needles for our annual flu shots or other vaccinations, then Queensland-based clinical stage biotech company (and Bridgetech partner) Vaxxas may have the answer, in the form of its HD-MAP (High Density Microarray Patch) vaccine patch technology. Chief Development and Operations Officer Angus Forster has been with Vaxxas for eight years. Speaking from the company’s Brisbane head office and lab, he explains: “Our technology is still in the stage one phase of clinical trials in Australia; however there has been a lot of global interest in it, since the WHO declared COVID-19 a pandemic in March this year.

“Also, in May, we announced two independent partnerships with international industry leaders: Harro Höfliger, a global leader in pharmaceutical manufacturing; and with pharmaceutical giant Merck Sharp & Dohme (MSD) to support the commercialisation and industrial-scale manufacturing of our HD-MAP vaccine patch technology. That’s generated a lot more interest, and we have been working with both companies for several years in research phases.”

Harro Höfliger will partner with Vaxxas to develop the world’s first pilot sterile production line of HD-MAP in Australia during 2021. This pilot line will hopefully be set up in Brisbane, and will have the capacity to manufacture up to five million vaccine-coated patches per week. A modular approach will enable the later expansion to full-scale lines to produce tens of millions of vaccine-coated HD-MAPs per week. Simultaneously, the collaboration with MSD will see one of MSD’s vaccines advance towards clinical development utilising HD-MAP. This partnership is a validation of Vaxxas’ technology given MSD is one of the world’s largest vaccine companies. MSD has an exclusive license from Vaxxas conferring worldwide rights for a specific vaccine.



Mike Junger, Head of Medical Device & Process Engineering at Vaxxas, applies the HD-MAP vaccine patch to a subject.

So, how does the H-D MAP technology work?

“Previously called the Vaxxas Nanopatch, our HD MAP combines a vaccine coated patch with an applicator for its delivery,” explains Forster. “It’s easy to use and comes with instructions in a sterile pack. You apply it to the skin of the upper arm, just like the flu vaccine. Push the button on the top of the device and that triggers the patch to vaccinate. Remove the patch and dispose of it like a Band-Aid, in the bin.



Manufacturing clinical trial products in the cleanrooms of the Translational Research Institute in Brisbane.

“HD-MAP has good stability for 12 months at temperatures as high as 40 degrees Celsius, eliminating refrigeration, which vaccines need. Clinical research reveals that only one-sixth of a dose of influenza vaccine on the patch produces an immune response similar to a full dose by needle and syringe. Theoretically, in a pandemic, if a person has used the vaccine before, the HD-MAP could be put in the post and they could apply it themselves, particularly if they are in isolation.”

Founded in 2011, Vaxxas employs 42 people including biological scientists, researchers, engineers, pharmacists, a quality team and other professionals. David Hoey, the company’s CEO, works at Vaxxas’ US office in Boston. Dr Forster, a pharmacist and previously a life sciences consultant, explains that Vaxxas is participating in several global vaccine research projects.

“Among these are a \$10m Gates Foundation funded clinical study to develop rubella and measles vaccine patches. We are also researching the development of polio vaccine patches with the WHO.”

COVID-19 has certainly affected the business, advises Dr Forster: “We have, however, been very fortunate to keep the R&D activities going in the lab. Maintaining a physical distance is challenging with intensive clinical research. Some employees are working from home, such as our Quality Manager who manages her Brisbane quality team from her home office in Melbourne. At least we can move the business forward, which is important for a privately-funded business.”

On Vaxxas’ future, Dr Forster says: “We will deliver on our collaboration with MSD to help them progress their vaccine to market, as well as continue our research with the Gates Foundation and the World Health Organization (WHO). We want to grow the business to around 100 employees, progress to late-stage clinical studies and eventually commercialise our technology, working with our investors to global successful outcomes.”

Med-Con – Whirlwind success

Regional Victorian medical manufacturer Med-Con’s co-owners Steve Csiszar and Ray Stockwell have experienced a whirlwind turnaround for their business since COVID-19 hit Australia. Before the pandemic they had both been planning an early retirement, with family members trained up to continue operating the business. The Shepparton-based company was running only four by seven hour shifts a week, which was enough work to keep them and their 17 loyal staff busy. They were producing around two million disposable surgical face masks a year, plus the other items of protective apparel in their range of products.

Since March, Med-Con’s manufacturing operation has been running 24 hours a day, seven days a week, with plans to produce a total of 59 million face masks by December this year. The Federal



Med-Con's manufacturing facility in Shepparton has been running 24 hours a day, seven days a week since the COVID-19 pandemic reached Australia.

Government is its main client for the masks, which Med-Con supplies to hospitals, doctors and medical centres around Australia. "So much for our early retirement," says Csiszar, who has been Med-Con's CEO since 1992. "Ray is our Operations Manager and we are both back to working full time. We expect to have 100 employees by the end of the year to handle our face mask manufacturing and other operations. Most of our employees have been recruited from the Shepparton region, so that's a great boost for the regional economy."

When the bird flu and SARS pandemics hit in recent years, Med-Con had approached the Federal Government offering to supply Australian-made face masks, but at the time Canberra was happy to stay with imported masks. It was a different story when COVID-19 hit Australia; the Department of Industry, Science & Technology (DIST) approached Med-Con to produce disposable surgical face masks. At that time Med-Con had three original mask-making machines that its founder and original owner, engineer Joe Carmody, had built. "Once the Government got on board, together with an appropriate grant for the project, they helped us to source more raw materials from around the world and with freight logistics," Csiszar continues. "Until we could engage more staff, DIST also sent Australian Defence Force personnel, to assist with mask production. When we identified that we needed more mask manufacturing machines, the Government helped us to purchase three more machines initially, and two months later four more machines, all from Foodmach, an Echuca machine manufacturer. "

Csiszar speaks highly about Foodmach and its ability to work with Med-Con to produce the machines it needed in record time. Foodmach has a dedicated 'Project Med-Con Delivered' daily log link on its website, and its challenge was to recreate the seven life-saving mask production machines, which were originally designed and manufactured by Carmody 40 years ago.

Foodmach took just 60 days to produce the first three machines and have them running successfully at Med-Con. The extra order for the other four machines was rolled out weekly thereafter.

"We are very grateful to Foodmach for its dedication to our project and working 24/7 to get our machines completed in such a short time," says Csiszar. "It's also been a massive challenge for us to handle the mask production output over the past four months. What we have achieved as a small regional family business is nothing short of a miracle."

As with most family-owned businesses, it's all hands on-deck at Med-Con. Csiszar's oldest son Justin occupies the role of Marketing Manager, while Csiszar's wife Michelle and Stockwell's son Mitchell handle Med-Con's customer service, and Stockwell's ex-wife Lyn is a senior machine operator.



Med-Con plans to produce a total of 59 million face masks by December this year

"We've extended the factory to handle the increased production and we needed more warehouse space," says Csiszar. "That included building a mezzanine level and now we have a double decker factory, part of which will be used for warehousing, and we've put a temporary clean room in. We are also renting a new manufacturing facility in Shepparton."

Med-Con has a five-year contract with DIST for ongoing mask supply. Csiszar explains: "We needed a long-term contract with the Government as the other part of the business in personal protective gear and our imported sterilisation products from Europe has been a bit slower than usual. Our European suppliers are happy, however, with all the publicity that we have received and they are hoping that will result in increased sales.

"Med-Con has been really lucky this year with the face mask contract, as we have gone through a couple of horrid years of low sales and devastating competitiveness. All of a sudden, the business has been turned around in an upward move and we have never been busier. My advice to all manufacturers is: if you believe in your business, your staff and your product, make sure you persevere and never give up. Success will come to you." **AMT**



Med-Con co-owners Ray Stockwell (top) and Steve Csiszar.

www.research.qut.edu.au/bridgetech
www.vaxxas.com www.medcon.com.au
www.foodmach.com/project-med-con