SGS makes major contribution to success of Ventilator Challenge UK Consortium

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VENTILATOR CHALLENGE UK
Penlon
Happy 72nd Birthday
NHS
and Thank You!

The days immediately preceding the announcement of the first UK national COVID-19 lockdown are remembered by most people for not only numbers of infections and deaths spiralling out of control, but uncertainty, anxiety and fear. For Abingdon-based SGS client Penlon, they marked the prelude to an astonishing journey with unprecedented challenges, demands and achievements.

BACKGROUND

The company that is now Penlon was originally established in Oxford in 1943 to satisfy the need for an accurate, lightweight chloroform vaporiser to drop to airborne forces on the battlefield and in field hospitals, supporting UK and allied troops fighting in World War 2. Steady post-war growth in sales and a series of mergers, acquisitions and company moves led to Penlon becoming a leader in the design, manufacture and sales of world beating ranges of vaporisers, anaesthesia systems, laryngoscopes and associated products.

THE CHALLENGE

On March 15, 2020, in the week before the first UK national lockdown was announced, the government issued an urgent 'call to arms' to provide the NHS with a substantial number of ventilators in the early fight against COVID-19. Its strategy included procuring ventilators from overseas, scaling up production of existing devices and calling on manufacturers of other products to help design and build new models, benefiting from their expertise and skills as well as manufacturing the components and finished items. The UK Regulatory Authority MHRA (Medicines and Healthcare products Regulatory Agency) had set out the clinical and design requirements under a Rapid Manufacturing Specification.

Penlon's pedigree, range of relevant certifications and existing, proven AV-S anaesthesia ventilator, which could be modified for the purpose, stood the company in good stead to lead the new Ventilator Challenge UK Consortium. Also key was the fact that it had an excellent existing relationship with its Notified Body SGS, which would be able to prioritise the submission for MHRA Emergency Use Authorisation and updates to the existing CE and QMS (Quality Management System) certifications. SGS immediately stepped up with the promise of prioritisation and dedicated, flexible resources to support the vital national effort.

THE PROCESS

Several days of round-the-clock working by Penlon's design, engineering, quality and clinical teams resulted in a solution that would not only deliver an effective product to satisfy MHRA specifications and demanding regulation, but also a way to manufacture it in the required volume and timescale. The new ventilator was nominated 'clinicians' choice' from a shortlist of suppliers by a team including the Cabinet Office, NHS, DHSC and MHRA, and set about establishing relationships with leading suppliers in engineering, manufacturing, logistical, consultancy and other roles.

At the same time, Penlon got underway in compiling an update to its existing ISO 13485 scope and developing a technical file whilst conducting due diligence on all new manufacturing partners in an enhanced supply chain, working towards achieving the relevant approvals in a record timeframe. The key manufacturing and inspection partners in the Penlon Ventilator Challenge UK Consortium included Airbus, High Value Manufacturing Catapult, NSF, DHL, Ford, GKN Automotive, McLaren, Siemens Healthineers and STI. Deloitte was also engaged to assist in financial due diligence and other projects that would include the introduction of a certified 'Veeva' electronic device history records system.

The following weeks saw long working days for Penlon and its Consortium partners with production processes being set up, quality procedures checked and rechecked and operators across all sites trained and upskilled to meet all aspects of the challenge. Personnel from each partner site should be trained both at Penlon's premises and at their own facility to ensure that every aspect of the project was completed according to specification and in synergy. Penlon was supported by Siemens in redesigning its manufacturing headquarters to ensure optimum protection from COVID-19 infection for its vastly increased cohort of employees, partners and volunteers.

Penlon's Director of Innovation, Technology & Regulatory Affairs, Mary Ryan, audited each partner in accordance with their role under the Penlon Quality Management System and their ability to meet the manufacturing challenges of a medical device production environment, which was something of which many had no experience. Mary recalls: "As the Penlon Person Responsible for Regulatory Compliance I had to ensure that no stone would be left unturned, ensuring that all pathways to assure specification and legal compliance would be met and validated."

The initial batch of 75 ESO 2 ventilators was produced at Abingdon for process validation and testing, including on-patient clinical assessment. Penlon received approval from MHRA for the ESO 2 to go to market under Emergency Use Authorisation exactly one month after the Government's initial call to arms. 'Emergency Use' is a temporary derogation on the UK Medical Device Regulations, necessitating a substantial effort behind the scenes to achieve the relevant certifications to ensure products remained on the market for full device life. Mary worked closely with – and under the independent assessment of – SGS and MHRA to achieve CE Marking, replacing the MHRA EUA label.

A total of 11,683 ESO 2 ventilators were delivered in just four months, an astonishing testament to robust management, the power of unbending cooperation

under immense pressure and a common will and drive to save lives.

After several months and units had been successfully deployed, a number of updates became necessary to both the device's mechanical pneumatics and software to enable additional critical breathing modes in response to the ongoing mutations of the virus. This work had been completed by December 2020.

Prompted by the need to handle the backlog of semi-elective surgeries that had built up over the previous nine months, January 2021 saw another chapter in the ESO 2 story owing to regulatory changes in the UK and the NHS's request to widen its clinical use from COVID-19 treatment to environments such as intensive care and operating theatres.

The new UKCA (UK Conformity Assessed) Mark – required for most products being placed on the market in Great Britain that had previously required the CE Mark – was needed for these additional applications. Certification to the mark required separate auditing of both technical files and QMS. Penlon worked closely with several clinical specialists, analysts and consultants as well as MD-TEC (Medical Devices Testing and Evaluation Centre) to prepare the revised Clinical Evaluation. The ESO 2 was one of the first medical devices globally cleared under UKCA, supported throughout by SGS.

The ESO 2 has subsequently been exported to several countries following completion of Penlon's commitment to the NHS.

HOW THE PROCESS HAS BENEFITTED PENLON

As well as having successfully delivered the new ventilators that have saved so many lives, there have been many other positive outcomes for Penlon.

According to Mary Ryan: *"Driven by necessity and determination, our processes have become a lot smarter and easier. We have been 'turbocharged' into a revolution in competence and confidence, giving us the ability to embrace new challenges head-on, including the introduction of a number of exciting new products."* At the time of writing, a number of new products are under development, incorporating lessons learned from the ESO 2 journey.

Mary continues: *"Addressing the clinical need, defining processes and conformance to safety standards was uppermost in the whole process, but there was and is no rulebook for the pandemic itself and how it drove what we did. The agility we developed remains, giving us further confidence that we can achieve anything."*

Led by Tony Serratore, Penlon's Head of IT, Digital transformation also played an important role in the project's success and continues to contribute to more efficient and timely working in every part of the company.

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WORKING WITH SGS

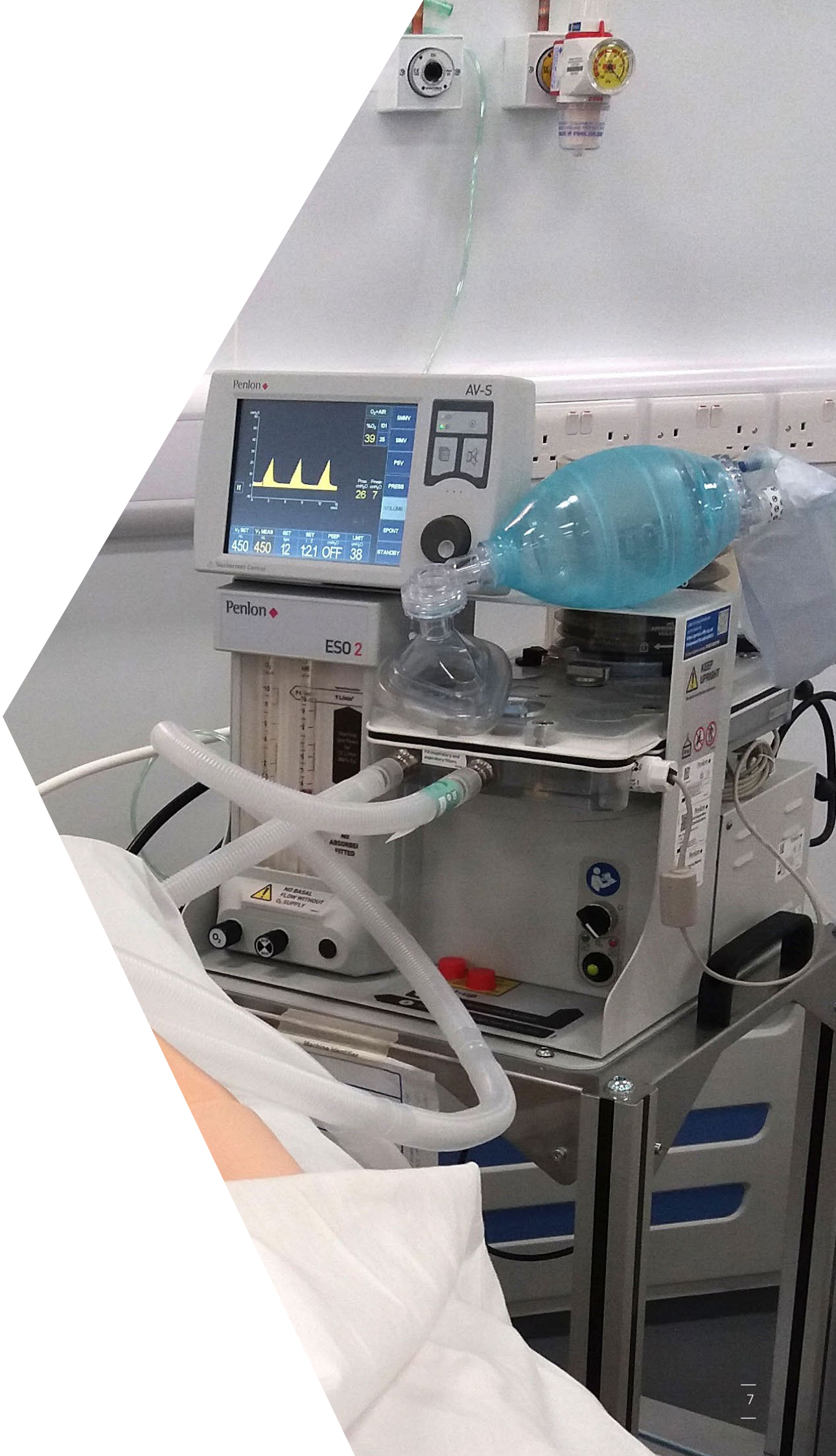
Mary Ryan had enjoyed an excellent relationship with SGS over many years whilst in various roles in other manufacturing companies, Notified Bodies and on working groups. *"SGS have always done integrated audits so well,"* she says, *"and they have a passion for making regulations understandable. I also knew that they would be able to work within the phenomenally short timeframe available for the project, even though some of what we had to do was equally as new to them as it was to us."*

She adds: *"They shared our single compelling goal of saving and changing lives."*

Mary recounts the importance of the unparalleled partnership between the Consortium partners, regulators and certifying bodies to the success of the project. Three different departments within SGS, situated both in the UK and Belgium, all played a significant part in the race against the virus including the speed with which QMS updates and technical files were being constantly updated. *"We were totally transparent in our expectations from the outset,"* she says, *"and SGS has been a 'diamond' throughout."*

ABOUT SGS

We are SGS – the world's leading testing, inspection and certification company. We are recognised as the global benchmark for quality and integrity. Our 96,000 employees operate a network of 2,600 offices and laboratories, working together to enable a better, safer and more interconnected world.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