

With medical cannabis receiving a high level of media interest in the past year, Senzer, a medical device and pharmaceutical company that focuses on inhaled cannabinoid therapies, tells *Quality World* how it is using an effective quality policy and quality management system to break new ground

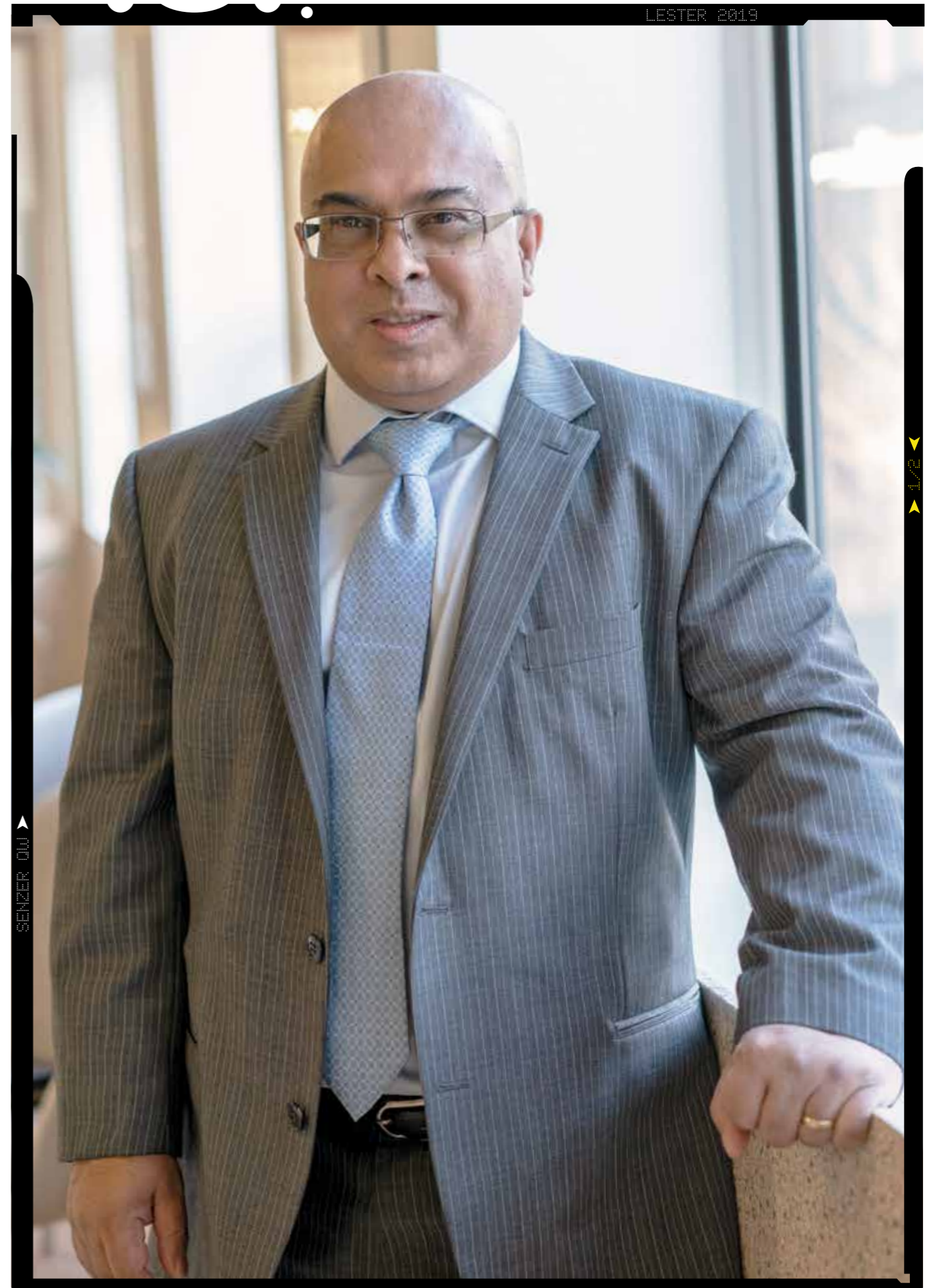
Image: (right) Lester Gleeson, Quality Director photographed on location at Senzer

# Unlocking the potential of cannabinoids



Words: Dina Patel

Photography: Matthew Gonzalez-Noda/Senzer



**In** November 2018, medicinal cannabis was made available on prescription in the UK for the first time after the government approved its use. Home Secretary, Sajid Javid, said: "Recent cases involving sick children made it clear to me that our position on cannabis-related medicinal products was not satisfactory". Karen Gray's story went viral last year after she launched a petition for medicinal cannabis to be made available on the NHS so that her five-year-old son Murray could manage his epileptic seizures. Their story, and others, brought attention to the benefits of medicinal cannabis products for people suffering from various illnesses.

Dina Patel speaks to Lester Gleeson, Quality Director at Senzer, a medical device and pharmaceutical company founded in 2015, to find out how the company is aiming to help cancer care patients manage their symptoms with respiratory devices supplying cannabinoid medicines.

**Putting down roots**

Based in London, Senzer is poised to enter the US and UK pharmaceutical market to target cancer patients with their inhaled therapies. Gleeson says the company has two lead products: "Cancer patients undergoing chemotherapy frequently get nauseous and sick, and one of our products, Candex, helps alleviate that. This allows patients to continue with the treatment. The other product, Cannafen, will help with neuropathic pain, which is also a side effect of cancer treatment. Over 300,000 people in the United States and Europe are suffering from these conditions."

Gleeson adds: "In America, studies have shown that 50% of patients undergoing cancer treatments can't complete it because of the side effects - including nausea and neuropathic pain. If we could help alleviate those conditions, it means more people could complete the treatment process, leading to better clinical outcomes and a better quality of life. There's also a lot of money being lost when expensive treatments cannot be completed".

The underlying technology, developed by the company's CEO Alex Hearn, is a breath-operated inhaler. Demonstrating how

**"One of the things I've always enjoyed is setting up effective business-focused quality systems"**

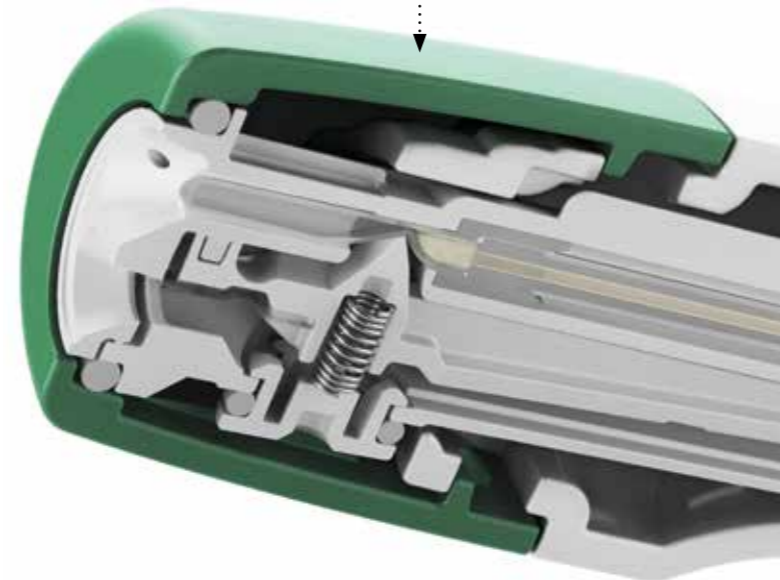
it can be used during our interview, Gleeson showed how a patient can administer the medicine without any assistance. "Most inhaled medicines reach the upper part of the lungs but because of the small molecule sizes in our formulas the medicine delivered by our inhalers reaches the lower lung (alveolar system) and, in pharmacokinetic testing,

**The technology**

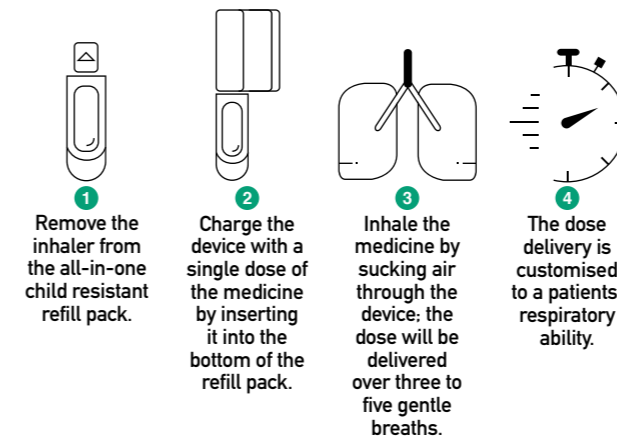
Dronabinol inhaler



Senzer's Systemic Inhaled Drug Delivery platform (SIDD) has been designed for speed and efficiency. The inhaler uses pressure to generate a vapour for inhalation.



**How to use the inhaler:**



the technology has been proven to deliver the Cmax (concentration maximum) in under two minutes," Gleeson says. "This provides relief very quickly. As an added benefit, the amount of medicine required is also much less. If you take tablets however, the medicine can take a few hours to get into your bloodstream and have an effect."

Senzer, working with its pharmaceutical partner in America, has commenced clinical trials on its product in accordance with the Food and Drug Administration's (FDA) guidelines. With changes in legislation to the use of medicinal cannabis in the UK, Senzer has now consulted with the UK's Medicines and Healthcare products Regulatory Agency (MHRA) to agree on the route to bring the medicinal product to the UK via prescription as unlicensed medicines - as defined by the MHRA.

**Quality ingredients**

Having spent the past 32 years working in the medical devices industry, Gleeson sought new challenges in the pharmaceutical world. "I was looking at the pharma world because of the interesting developments and medicines now becoming available. When the opportunity came along to join Senzer,

which allowed me to marry my medical device expertise with

the pharma world, it became a very interesting proposition. One of the things I've always enjoyed is setting up quality systems, designing them, implementing them and improving them. At Senzer I have set up the quality system to meet the requirements of ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes, as well as EudraLex Volume 4 - Good

**"Senzer's quality management system underpins everything we do as a business"**

Manufacturing Practice (GMP) guidelines. We are working on a programme to get our product approved in America through the FDA submissions process and CE marked as a medical device in Europe."

As the quality director, Gleeson focuses on three areas that are important to the business. The first is to maintain an efficient and compliant management system. The second is to ensure the company produces safe and reliable quality products that meet customer requirements and the organisation's specifications. Finally, Gleeson is responsible for providing a high degree of customer satisfaction when delivering Senzer's products and services.

"Quality is the vital ingredient to ensure we are successful," he says. "We ensure our UK-based manufacturing and supply chain partners comply with ISO 13485: 2016 Medical devices, FDA 21 CFR Part 820 and the EU's Medical Devices Directive (93/42/EEC) and that facilities meet strict GMP, GLP, ISO 14644-1 Class 7 Cleanroom Classification Guidelines and ▶



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hold the necessary MHRA and Home Office licenses.”

Developing a strong quality culture through the organisation’s quality policy is integral to Senzer’s successful future. “We are a small team here at Senzer, but everyone understands that their actions and outputs all have an impact, which can be traced directly to the end user,” Gleeson says.

“As a small company it’s important to get the quality culture right because if we don’t take full ownership and look out for quality in all areas of the business, and if we don’t produce good quality products and devices, there’s no one else to do it. Quality is embedded all the way through the company. It’s in all of our training and procedures. Everyone does the training on all processes because we want them to understand exactly what it is that we do – such as, why we have to manage our suppliers, why we have purchasing controls, what we have to do in case there’s an issue with products, and the returns process.”

Gleeson says employees at Senzer understand that quality is a source of competitive advantage and is a fundamental

requirement that must be incorporated in everything they do. “Getting the right quality culture helps us to reduce cost and save time, increase customer satisfaction, reduce risk for both the business and product, improve the quality of product and services, be more efficient and reduce response times to our

customers, and finally, to adopt best practices to provide profit for sustainable growth. Having the right quality culture is especially important in the field of medical devices and pharmaceutical products – which is probably the most heavily regulated industry in the world.”

Senzer’s quality management system also plays a significant role as it allows the company to stay focused during the entire planning and design process. Gleeson explains: “Senzer’s quality management system underpins everything we do as a business. It is very important that the design, development and manufacture of our products is guided by our core quality principles at every stage. The quality management system is owned and maintained by Senzer’s employees who are empowered and encouraged to constantly make improvements. We start off the planning stage with the new device development process and we look at what we want to achieve and what our user requirements are. We then go through the design process and produce prototype models, agree on a design specification, and enter the production stage,” Gleeson explains.

Involved in this process is the selection of suppliers. Gleeson says regular meetings are held with third-party service suppliers to ensure they too are aware of the company’s commitment to quality and to establish a relationship that enables good



transparent communication. “The worst thing is to have a supplier that tries to hide problems from you, rather than working with you to solve them,” Gleeson says.

### Navigating a heavily-regulated industry

Senzer has recently transitioned to the ISO 13485: 2016 Medical devices standard. Gleeson says the starting point for this transition was to perform a gap analysis to understand which elements contained in the new version of the standard may not be covered in Senzer’s current quality management system. “I then worked with the Senzer functional leads to develop the current processes to incorporate the new requirements and formalise them in our quality procedures. Finally, we trained the whole organisation in the new process using our quality procedures.”

When asked if the company faced any challenges during the transition, Gleeson said: “I don’t think there were many challenges, because we set out our processes right from the start and asked, ‘what do we need in here to help us design good quality products, manufacture good quality products and deliver them?’ Our new device development procedure had all of the risk analysis and failure mode and effects analysis tools. It was already in place for us because we understood that by having this structured approach to design, we would anticipate all the areas that could fail later on and cause problems.”

Gleeson says the first half of 2019 will be spent on ensuring the company’s products meet other necessary industry requirements.

For example, the organisation is aiming to secure CE marking for its inhaler device against the new Medical Device Regulation (EU) 2017/745 by the end of March 2019.

### Driving continuous improvement

To help drive continuous improvement, Senzer holds weekly management meetings to realign the company’s priorities and explain to employees what everyone is working on. Gleeson says this allows an opportunity to communicate updates, for instance if a new supplier is needed or the company is about to embark on a new device design or an improvement to an existing device. “We have an opportunity to say, ‘we’re doing this,’ and explore what we have learned through the previous iterations and how to incorporate those into our new pathway. We have a great communication structure, everyone knows what’s happening, what the priorities are and that’s how we establish continuous improvement.”

Gleeson explains there are also weekly meetings with the company’s main suppliers and pharmaceutical partner. These meetings help the company acknowledge any problems their suppliers/partner may be facing and if they can help to drive improvements.

Establishing good communication channels with MHRA has also been vital to Senzer’s journey so far. “Seeking their guidance and help and telling them exactly what we’re planning on doing is something we’ve been very conscious of,” Gleeson adds. He says the company is aware of the role regulators play and their value, which is why Senzer is working to engage with them and meet their approval.

When asked what the future holds for Senzer, Gleeson is optimistic that the company has developed a unique product which has significant potential.

“We can further develop the technology and the small molecule formulation for other pharmaceutical products. It’s just a question of time and money,” Gleeson says. “We’ve got a very good baseline product and we just need some time to further develop it.” ■

### Gleeson's tops tips for quality professionals

Keep things simple. Really make sure you understand your business environment and your business requirements and ensure your QMS focuses on this.

Do the right things for the right reasons. Sometimes you’re going to have to convey bad news to senior management. Ensure you understand the issues and the governing regulations. Then find and propose a solution to the problem. Don’t just convey problems.

Pay attention to the details when transitioning. When new standards are released, go through them step by step and align your quality manual to the new standards. From there, you can then roll out your quality management system.



Scottish Daily Mail

Image: (Above left) In 2018, Charlotte Caldwell campaigned to allow her son, Billy, to be legally treated with cannabis oil for his epilepsy. (Above right) Karen Gray successfully campaigned for her son Murray to be treated with medical cannabis for his chronic epileptic seizures.