



# OWEN MUMFORD

## Pharmaceutical Services

# FROM DESIGN TO DISPOSAL: ACHIEVING SUSTAINABILITY IN MEDICAL DEVICES

In this article, George I'ons, Head of Product Strategy and Insights, Owen Mumford Pharmaceutical Services, discusses the onus on the device design industry to move towards sustainable practices, including what this entails, how it might be achieved and what benefits sustainability may bring.

*Based on the article "Three perspectives on how sustainability is being achieved in the medical device market", which first appeared on Owen Mumford's Web Page in August 2020.*

As our society becomes increasingly concerned with environmental protection, medical devices that are strictly single-use and disposable are a glaring issue. The medical device industry is under pressure from regulators, hospital systems, governments and consumers alike to seek more responsible and sustainable solutions. From a commercial point of view, developing sustainable medical products that continue to protect patients and healthcare workers from infection comes at a very real cost. However, companies that do not take the initiative to become more environmentally responsible risk losing access to markets around the world.

### WASTE REDUCTION VERSUS INFECTION CONTROL

While reducing waste in the healthcare system is an important objective that must not be neglected, safety in healthcare environments is a critical priority. According to the European Centre for Disease Prevention and Control, healthcare-associated infection (HAI) rates run between 5% and 8% of patients in most developed countries.<sup>1</sup> These rates are unacceptably high, and may be exacerbated by the spread of antimicrobial resistance.<sup>2</sup> A further consideration is the need to prevent avoidable infections from needlestick injuries amongst healthcare workers. These

safety concerns have led to strict one-use regulations around many invasive medical devices, along with mandatory legislation in the US and Europe on the use of products for needlestick injury prevention.

This tension between sustainability and infection control could not be more topical, as efforts to contain the coronavirus pandemic continue. An immediate concern for healthcare systems is to provide sufficient personal protective equipment (PPE) to frontline healthcare workers, which is frequently made of plastic material and tends to be single-use only. In fact, from

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February to July 2020, 2.3 billion items of PPE have been distributed to health and social care services in England, equivalent to that distributed in the whole of 2019.<sup>3</sup> This proliferation of demand, and a wider awareness of the issue due to the pandemic, may however prove to be an impetus for an urgent review of plastic waste management methods in the medical industry.

## THE STATE OF PLAY

Healthcare systems currently have a sizeable environmental footprint. Taken together, the healthcare sectors of the US, Australia, Canada and England emit an estimated 748 million metric tons of greenhouse gases each year, which, if ranked alongside whole nations, would come in as the seventh largest greenhouse gas emitter in the world.<sup>4</sup> In Europe, legislation has helped to manage the situation by significantly altering manufacturing processes, labelling requirements and disposal restrictions, and creating instructions for end-of-life management and recycling. Although many medical devices are currently exempt from these regulations, several directives, including the Waste Electrical and Electronic Equipment Directive and Restriction on Hazardous Substances Directive, are in the process of being reviewed and could be applicable in future. In addition, as medical products become more “connected” in our increasingly digitalised world, they will also fall under the purview of legislation for devices with electronic components.

## SUSTAINABILITY CHALLENGES

Currently, approximately 90% of medical device waste consists of disposable, one-time-use products or components. Efforts to reduce the volume of disposable components are constrained by the need to maintain safety standards, as discussed previously. Additionally, it is critical to ensure security of product supply; considering that in many cases, disposable products may generate the bulk of a manufacturer’s revenue, the transition towards greater sustainability must be commercially viable. The risks associated with hazardous medical waste and biological contamination, as well as the high cost of product sterilisation and reprocessing, have historically prevented businesses from moving away from disposable products towards something more sustainable.

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Traditionally, incineration has been used to reduce the volume of medical waste and destroy biohazardous materials. This process releases nitrous oxide, as well as known carcinogens including polychlorinated biphenyls, furans and dioxins.<sup>5</sup> Exposure to these compounds has been linked with damage to foetal and adult body function as well as the acidification of land and ocean. Replacing incineration with recycling would therefore tangibly benefit society, by reducing damage to both people and the environment. Where incineration cannot be avoided, European regulation sets strict emission limits for incinerators dealing with clinical waste.<sup>6</sup> Furthermore, sophisticated filtering systems are now being installed to prevent toxic fumes from polluting the atmosphere.

Sterilising devices for reuse may seem like a feasible alternative. However, it is often environmentally unsustainable, as well as being costly, as the sheer amount of energy required to carry out cleaning processes often outweighs the energy needed for the manufacturing and disposal of single-use devices. Moreover, several of the sterilisation methods which are well-established in healthcare, such as the use of glutaraldehyde and ethylene oxide, are not only harmful to the environment but also tend to be regulated by strict disposal rules. As a result, many hospitals and medical device companies are adopting less toxic methods, such as hydrogen plasma.<sup>7</sup>

A further obstacle to reuse is that a recycled device would be subject to the same level of scrutiny as a brand-new one under the EU Medical Device Regulation. However, manufacturers can expect further developments in this area, following the European Commission’s 2019 consultation around the safety and performance requirements for single-use device reprocessing.

## LEVERAGING PURCHASING POWER

On first inspection, the complex relationship between product sustainability, patient safety standards and commercial

viability may appear to create an impasse. However, there is much that can be achieved and much that is already being done. The purchasing power of healthcare systems is a significant tool that can be used to influence suppliers towards taking environmental factors into consideration during manufacturing. Evidence of this can already be seen in the industry. Many group purchasing organisations have appointed and empowered Senior Directors of Environmentally Preferred Sourcing who are successfully implementing the sustainable purchasing business case.<sup>8</sup> Additionally, tenders within the EU increasingly include requirements for environmental credentials. As a consequence, many medical device firms are proactively publicising their environmental record and sharing their progress in this area. When assessing how these medical device manufacturers are delivering on sustainability, while taking into consideration the significant regulatory and safety concerns, three key areas of activity can be identified:

- Recyclability
- Sustainable manufacturing
- Sustainability by design.

## RECYCLABILITY

As it has become clear that enabling device reuse is fraught with complications, another option is to reprocess and reuse its materials. PVC, the most widely used plastic material for disposable medical equipment, can be recycled several times without losing its critical properties. Equally, work has been done around the use of more easily recycled plastics, such as renewable polyethylene (PE) and polyethylene terephthalate (PET). For optimal gains, closed loop recycling systems must be put in place to recover waste material from hospitals and bring them into the recycling process. Considering that there is an estimated one million tons of clean, non-infectious healthcare plastic waste generated in healthcare facilities every year,<sup>9</sup> the benefits of these schemes would be considerable.

Further research could bring greater benefits still. Monomer extraction techniques in development enable recycled polymers to be broken down to their constituent monomers. If widely adopted, this could mean a virtually limitless recyclability of some polymers without loss in performance.<sup>10</sup> Finally, recycling should also extend to packaging. Manufacturers have already developed solutions such as decreasing packaging volume by favouring sealed trays instead of pouches or reducing the overall number of packaging components (Figure 1). However, they can also reduce energy consumption by assessing logistics during the design process and selecting optimum transport, especially if there is a need for controlled temperature.<sup>11</sup>

## SUSTAINABLE MANUFACTURING

Reviewing manufacturing processes plays an important role in reducing the impact of production on the environment. As well as optimising logistics, businesses can reduce water use, strengthen energy efficiency and reduce the use of polluting chemicals (Box 1). These initiatives can also help to reduce operating costs, which in turn, makes sustainability more commercially attractive. Moreover, reducing energy costs can help to finance sustainability programmes, producing further savings in the long term.

Newer generations of manufacturing technology are also likely to play a part in reducing waste, whilst simultaneously

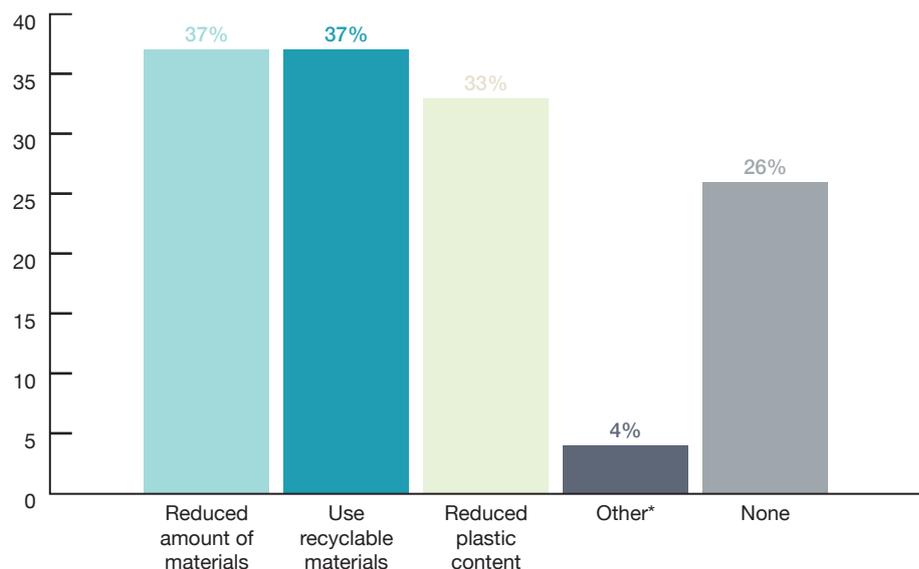


Figure 1: Responses to the question: "What changes have you already implemented to pharmaceutical packaging design and materials to provide a more sustainable alternative?"

Respondents were permitted multiple answers (n=166). \*Other includes: improved nonreactive materials; more reusable and biodegradable components; new way to administer; and training on critical thinking about sustainability with several groups of health professionals. Conducted by Owen Mumford Pharmaceutical Services in partnership with Pharma Intelligence.

producing a raft of business benefits, such as improved productivity and shortening time to market. A good example is the adoption of 3D printing to develop and test prototypes. These can help to develop optimum product moulds more quickly, fulfil usability testing outcomes and refine production parameters to minimise raw material volumes and maximise output productivity. In sum, further technological innovation aiming to get as near as

possible to "zero defect" manufacturing will, in all likelihood, produce inherent sustainability benefits.

## SUSTAINABILITY BY DESIGN

From the very beginning of the design process, manufacturers already take many factors into account around the whole lifecycle of a product, from concept development and material selection, to transportation methods and end-of-life disposal. Businesses must simply add sustainability factors to their existing design procedures, making sure to evaluate energy efficiency, environmental impact, material usage and recycling. There are already resources available to support this transition. For example, existing US FDA and EMA quality system requirements cover tracking, materials safety/efficacy and disposal. Similarly, lean manufacturing methodologies can provide sustainability benefits in several areas, such as overproduction, waiting time and inventory management.

In relation to product design and engineering, there are many elements that can support sustainability (Box 2). Optimising the size of a device design and reducing the number of components can simplify the manufacturing process, reduce waste and reduce transport impact. If a product has minimal components and is easy to disassemble, this will also facilitate

## BOX 1: OWEN MUMFORD & SUSTAINABLE MANUFACTURING

"Owen Mumford has adopted many onsite changes to ensure all our energy is coming from clean, renewable sources. We are also investigating a wide range of materials and additives which can reduce the energy required to process into final product. Bio-based materials can offset the carbon emitted during processing as the monomer source grows. A growing range of sources for bio-based monomers is available, such as wood pulp or sugar cane.

However, when assessing the most appropriate material for a part, the entire lifecycle of the product needs to be considered. For example: bio-degradable polymers can contaminate a recycling stream and emit methane when incinerated... and methane has a carbon emissions impact 25 times greater than CO<sub>2</sub>."

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Technology Development Group Manager R&D, Owen Mumford

recycling and make the process cheaper. An assessment of how raw materials and production methods can be better harmonised across different products may streamline the use of resources, while enabling greater task agility across production lines. Finally, for disposable products, manufacturers must review whether they could be using more environmentally friendly materials, which will reduce the level of toxic air emissions during disposal or incineration, as well as lower waste processing costs.

Most devices – especially parenteral or other invasive products – will continue to have a disposable component to meet regulatory requirements, and address safety and hygiene concerns. This does not mean that disposable medical products cannot be made more sustainable. There are many areas for improvement, such as increasing the recycling of materials, and introducing sustainability considerations in manufacturing processes and design. Additionally, device designers can look to produce products that incorporate the disposable component within a “shell” that is reliably reusable. In fact, digitally connected devices are already driving developments in this direction, as disposable electronic components would not be commercially viable or an acceptable option for the environment. Designers must therefore focus on creating a simple, repeatable interface between disposable and reusable components, without compromising device functions or efficacy.

## ABOUT THE COMPANY

Owen Mumford is a major healthcare company and device manufacturer that commercialises pioneering medical products in its own brand and custom device solutions for the world’s major pharmaceutical and diagnostic companies. Owen Mumford’s goal is to enhance access to diagnostics, encourage adherence to treatment and reduce healthcare costs, making a world of difference to a world of people.

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## BOX 2: OWEN MUMFORD & SUSTAINABLE DESIGN

“Device design considerations can have a large impact on the carbon footprint of therapies. Innovative approaches have been adopted by Owen Mumford Pharmaceutical Services to remove springs from our disposables; emissions related to the manufacture, processing and shipping of metals greatly exceed that of polymers due to the higher density and forming temperatures required. Furthermore, a reduction in the amount of single-use plastic associated to each treatment whilst maintaining safe and effective usability characteristics can be achieved with careful consideration at a design stage.”

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## ABOUT THE AUTHOR

George Pons is currently Head of Product Strategy and Insights at Owen Mumford having worked for the former Original Equipment Manufacturer and now Pharmaceutical Services division of the organisation since 2006. His current focus is on deciphering the rapidly changing pharmaceutical and biotech sectors in relation to their needs for combination products. In his previous roles in business development he worked closely alongside R&D to develop devices for a variety of global pharmaceutical and diagnostic clients. Prior to Owen Mumford George worked for Abbott (Berkshire, UK) in EMEA marketing roles in Germany, focusing on its diabetes business.



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