



Origin Outsourcing White Paper Series
The Cleanroom Advantage



The Cleanroom

Advantage:

**Sustaining Competitive
Advantage in the UK Hi-Tech
Manufacturing Industry
through Improved Cleanroom
Management**

Executive Summary

In spite of increasing globalisation based competition over the last decade the UK manufacturing industry has managed to remain competitive through shifting to the production of high value, hi-tech products such as microelectronics, medical devices and pharmaceuticals. Competing on this basis alone is unlikely to be sustainable however. The emergence of new challenges such as rising energy costs, potential economic downturn and climate change based social and legislative demands mean that firms will also need to drive down operating costs and reduce energy consumption.

The UK's shift to hi-tech manufacturing has come with a greater need for specialised manufacturing facilities and capabilities. This has resulted in an increasing reliance on cleanrooms, rooms in which airborne particles need to be kept to a minimum to prevent the contamination of highly specialised manufactured products such as microchips, medical devices and injectable drugs.

Adequate cleanroom management is vital in the prevention of manufacturing inefficiency through product damage and process downtime, both of which can negatively impact operating margins. This white paper identifies two specific areas of cleanroom facility operation where the application of new technologies and new management paradigms can be used to improve efficiency. These areas include the management of cleanroom garments and optimised vacuum pump maintenance systems.

To improve the management of cleanroom garment systems, manufacturers should work to improve their monitoring of garment user compliance, damage repairs and wash cycle sufficiency. Garment usage lifecycle should also be closely monitored as overuse can risk contamination whereas underuse adds unnecessary cost. The ability to adequately monitor garment use is becoming ever more possible with the introduction of

new, hi-tech tracking systems and reporting systems. The next step is the introduction of real-time, online monitoring to enable full and automated garment system control.

The maintenance of vacuum pumps, integral components to a number of cleanroom manufacturing processes, provides another opportunity to improve efficiency. This is through the introduction of Condition-Based Maintenance (CBM), the monitoring of pump machinery using advanced techniques adopted from other industries in order to pre-empt when pumps need to be serviced. CBM has the advantage over currently used vacuum pump maintenance practices in that it enables streamlining of maintenance resources, reduced unscheduled downtime and improved vacuum pump functional efficiency. This will in turn reduce cost, product waste and energy consumption.

Together the adoption of these two practices in cleanroom based manufacturing has the potential to help maintain the UK manufacturing sector's competitive advantage. The margin based cost saving of adopting improved garment system and vacuum pump maintenance techniques will improve the industry's ability to withstand competition and economic downturn whereas improved pump efficiency, energy consumption and reduced product waste will work towards meeting climate change based social and legislative demands.

Table of Contents

- Background 1
- The Cleanroom..... 2
- Cleanroom Management..... 5
- Garment Management 7
- Cleanroom Garment Systems in the Pharmaceutical Industry..... 9
- Environmental Control and Vacuum Pump Maintenance 10
- Vacuum Pump Maintenance..... 12
- Condition Based Maintenance..... 14
 - Vibration Analysis 14
 - Thermal Analysis 14
 - Lubricant Analysis 15
 - Visual, Aural and Tactile Inspection 15
- The Application of CBM to Vacuum Pumps..... 16
- Summary 17

Background

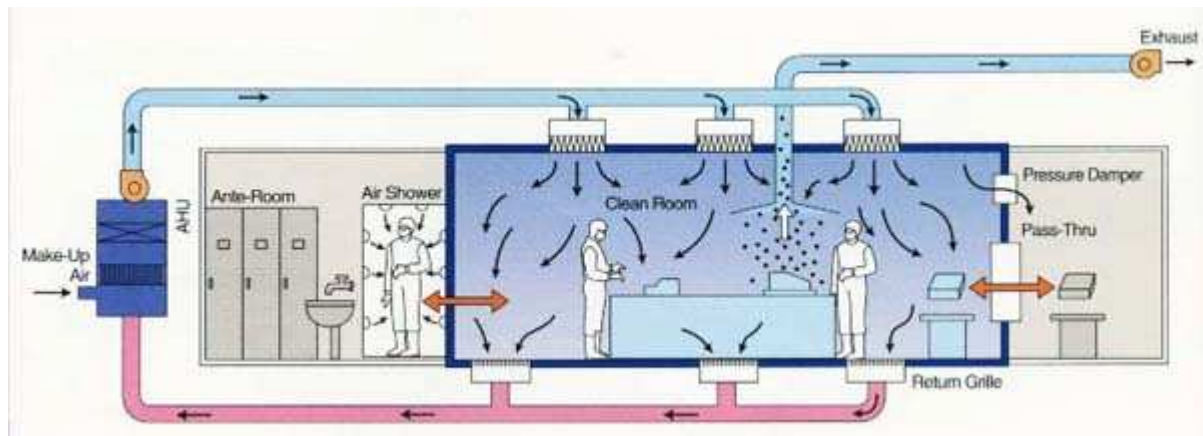
The ancient Chinese curse: “May you live in interesting times” refers to the difficulties of existing where your environment is constantly changing. The UK manufacturing industry is feeling the pressure of living in interesting times with increasing global competition, rising energy prices, credit crunch based economic uncertainty and climate change providing challenge in an already competitive industry.

The industry has a history of resilience however. Despite over a decade of overseas migration of low-tech, high volume manufacturing operations, such as the production of consumer white goods and textiles¹, the UK has remained competitive retaining its position as the sixth largest manufacturing country in the world². This has been achieved by a shift to the manufacture of more value added, knowledge intensive, hi-tech products such as, medical device, pharmaceutical, microelectronic and photonic based goods, all of which require sophisticated techniques and a highly educated workforce to produce.

Competing exclusively on this “value added” basis is unlikely to be sustainable however. Already the automobile part manufacturing industry in the UK has faltered as Chinese manufacturing sophistication has caught up.³ With this in mind, highly specialised UK manufacturers in these hi-tech industries need to take proactive steps to meet the emerging challenges they face. In addition to remaining at the pinnacle of value added manufacturing, companies also need to use technology and advanced knowledge to improve operational efficiency. This will work to reduce operating costs, energy consumption and wastage enabling resilience under economic uncertainty and contribute to the meeting of climate change based social and legislative demands.

The Cleanroom

The UK's shift to value added manufacturing has come with an increased need for hi-tech product fabrication facilities. This has resulted in a growing reliance on cleanrooms, specialised facilities where airborne particles (dust and bacteria for example) have to be kept to a minimum to prevent the contamination of specialised products. Cleanrooms can be up to 50,000 times cleaner than a standard hospital operating theatre and are vital in the manufacture of products such as microchips, medical devices, lasers, and injectable drugs.



Cleanroom manufacturing is a costly process. Facility design and setup alone can cost over \$6,000 (about £3,000) per square foot, a 25,000 square foot facility costing over £75m to build⁴. Furthermore, the energy required to run the systems needed to meet cleanroom manufacturing regulatory requirements can make them 20 to 100 times more costly to operate on a per-square-foot basis than conventional commercial buildings⁵.

The combination of such large capital investment and energy use means that cleanroom inefficiency can be a significant cost to a manufacturing company. In addition, any shortcomings in cleanroom contamination control can lead further losses in terms of operational downtime and product loss. According to reports by Epichem (Now part of Sigma-Aldrich Fine Chemicals), one day of high-

tech device fabrication cleanroom downtime can cost between €150k-€500k (£120k - £400k)⁶. Adding to this, Bob Predmore of A2C2 Magazine (now Controlled Environments Magazine) estimates that:

“A single interruption of [cleanroom] operations can have costs as high as \$1 million [£500k].”⁷

Cleanroom efficiency is difficult to achieve however. According to Kenny Gall, CEO of cleanroom specialists Origin Outsourcing:

“Cleanroom manufacturing processes are always under threat from downtime and inefficiency. This is because the intricate systems required to achieve standards are difficult to monitor and sufficiently maintain.”

This was illustrated in 2005 where a US Department of Energy led study found that some cleanrooms provide over six times the air-change rates of others within the same cleanliness classification, resulting in considerable capital and operating cost impacts (Figure 1).

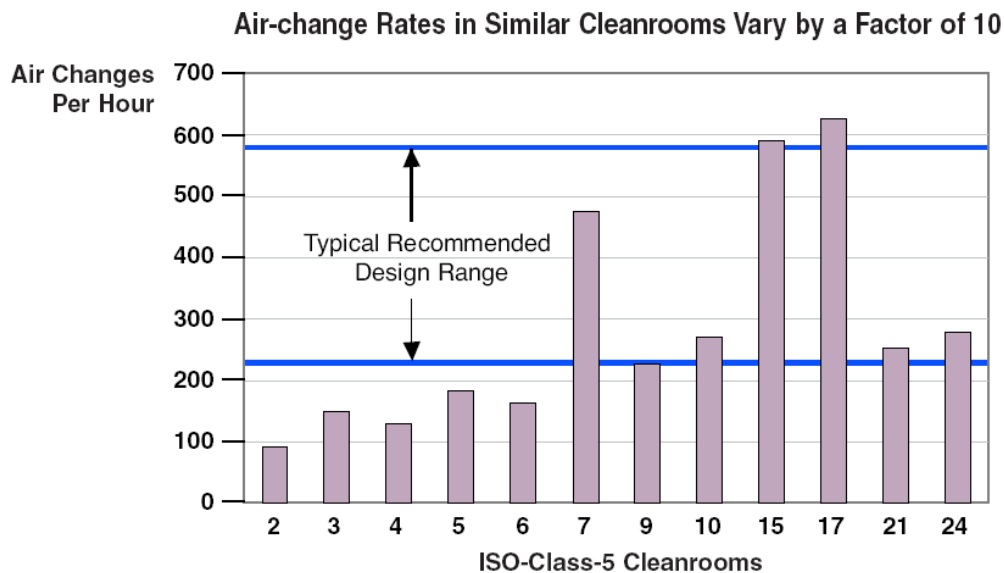


Figure 1: Source: Gary Shanshoian, Michele Blazek, Phil Naughton, Robert S. Seese, Evan Mills, and William Tschudi, "High-Tech Means High-Efficiency: The Business Case for Energy Management in High-Tech Industries" (November 15, 2005). Lawrence Berkeley National Laboratory. Paper LBNL-59127. <http://repositories.cdlib.org/lbnl/LBNL-59127>

In consideration of this, working to improve cleanroom operational efficiency is a way in which UK manufacturers can tackle the emerging industry challenges. Improving performance by ensuring that cleanroom contamination prevention systems are functioning optimally will reduce costs through minimising facility downtime, product waste and energy use. This in turn will increase margins enabling companies to remain competitive and resilient in times of economic downturn.

Cleanroom Management

To understand areas where there is opportunity to enhance cleanroom operational efficiency, the processes involved in cleanroom environment maintenance need to be understood.

The threat of contamination is by far the biggest risk to a cleanroom manufacturing operation's efficiency. Contaminants, most commonly in the form of particles and microorganisms, can come from people (the shedding of skin cells for example), walls (or surfaces), or from machinery and packaging located inside the cleanroom. Contaminants can also be brought from adjacent areas into the cleanroom by workers on entry or through inadequate prevention of outside air entering the room. Figure 2 illustrates the potential sources of contamination.

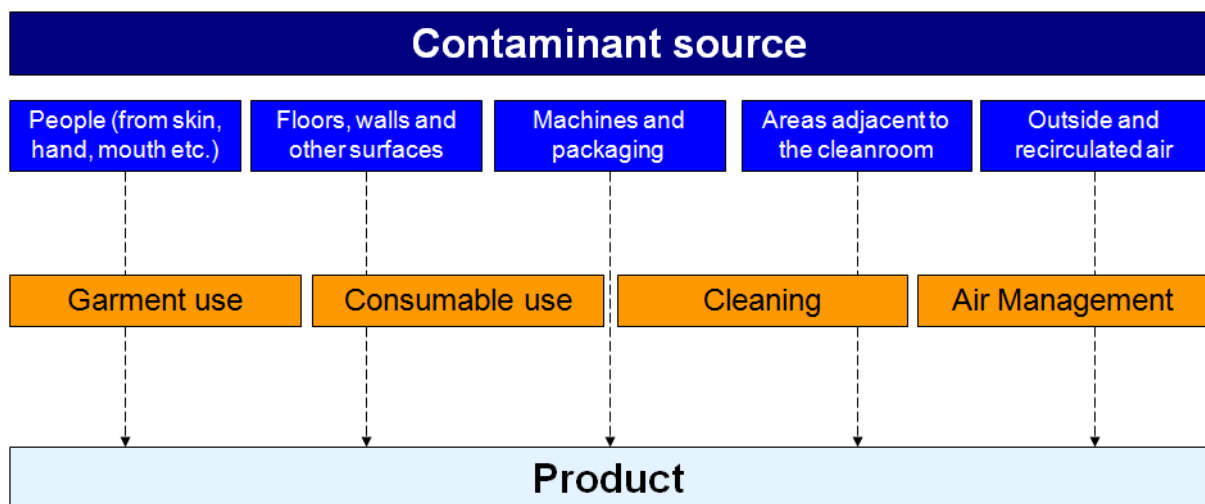


Figure 2. The four simplified preventative measures required to prevent product contamination in the cleanroom environment (adapted from Whyte 2001⁸)

To maintain consistent cleanroom cleanliness standards throughout the manufacturing industry, cleanrooms are classified according to the number and size of particles permitted per volume of air. In the UK, these standards are set by the International Standardisation Organization (ISO) and in most cases, especially in microelectronics manufacturing, are used as general guidelines to protect against product damage.

For manufacturers of pharmaceutical products however, standard adherence is considered far more important to facility manufacturing process efficiency. This is because when products that are manufactured under aseptic conditions fail, the whole product lot may have to be rejected (unlike microelectronics, pharmaceuticals can rarely be reworked to correct impairment). Additionally, loss of the product may only be the beginning of the financial loss. In the UK, medical product manufacturing standards are regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA). If manufacturing standards are not achieved, the MHRA can request internal investigations requiring cleanroom downtime and possible staff retraining.

There are four protocols used to prevent cleanroom contamination. These are adequate garment use by cleanroom workers, the use of specialised consumables that do not contribute to contamination (such as cleanroom specific gloves, wipes and chemical detergents), frequent and thorough cleaning and air quality management systems.

The high cost of maintaining garment and air quality management systems, as well as the potential risks to manufacturing efficiency if they are not maintained, make them integral to manufacturing efficiency. It is therefore these areas of cleanroom management that need to be investigated in order to examine ways to reduce operating costs, energy consumption and wastage.

Garment Management

Reports estimate that between 40 % and 80 % of contamination can be traced back to human cleanroom operatives⁹. According to Berndt et al., cleanroom operators are the most likely to cause cleanroom contamination. The group describe them as:

“...broad-spectrum particle generators[...]capable of generating and releasing chemical and biological aerosols to the surrounding environment together with potentially destructive electric charges.”¹⁰

Considering this, it is vital that cleanroom garments act as an adequate barrier to contamination at all times. This involves ensuring that cleanroom operators adhere to garment use guidelines and the garments are kept in a condition where they provide sufficient contamination protection. To achieve the latter of these objectives requires that garments are of adequate type and quality to prevent particulate leak in accordance with the sought regulatory standard. Just as important however is the regular and sufficient cleaning of garments and cleanroom worker adherence to garment use protocols, such as swapping out damaged garments and adherence to laundering schedules.

The cost of a quality garment system can make up a large portion of the cleanroom operational budget. As reducing the laundry cycle or re-wearing hairnets, gloves and shoe covers are not viable approaches to operational cost control however, other cost saving activities should be considered.

One viable activity lies in optimal garment utilisation to maximise garment lifecycle. According to Jan Eudy, Corporate Quality Assurance Manager for Cintas Cleanroom Resources:

“...cleanroom garments should be functional over six years of typical cleanroom use providing the employees

wearing the cleanroom garments are consistently adhering to accepted cleanroom protocol.”¹¹

Adherence to protocol is not the only way to improve garment use efficiency however. According to Keith Findlay, Director, Garment Services at Origin Outsourcing:

“Garment management is often inefficient as there is little control and measurement of garment overuse - risking contamination, or underuse - adding unnecessary cost”.

To enable improved control over overuse and underuse, Keith suggests the use of new technologies:

“To add efficiency in garment system management newly available tracking technologies can provide real-time feedback on user wash protocol compliance, over or under-use of garments, repair requirements and garment life-cycle. This level of management will lead to better understanding of the company’s situation and therefore better management of garment systems. The next stage will be to provide customers with online garment management systems allowing full control over garment stock and circulation”

Cleanroom Garment Systems in the Pharmaceutical Industry

Enabling more control over cleanroom garment systems in this manner may be specifically cost effective in the pharmaceutical manufacturing industry. Often facilities opt for disposable garments rather than a managed service as they believe it will simply be easier to monitor and attain the stringent aseptic conditions required¹². This paradigm may be changing however.

According to David Hobson, president of the Uniform & Textile Service Association:

“Today's reusable products and laundry services... offer an attractive option worthy of consideration for many pharmaceutical cleanroom operations. And making sense of reusable system options and services is easier than ever.”¹³

The new cleanroom garment system monitoring technologies available today may therefore provide pharmaceutical companies with the confidence of improved garment control, creating an avenue for potential cost saving.

Environmental Control and Vacuum Pump Maintenance

Manufacturing processes in the cleanroom need to be both free from contamination and controlled for quality if product wastage is to be avoided. On the macroenvironmental level sophisticated heating, ventilating, and air conditioning (HVAC) systems are used to ensure air is circulated and filtered to the appropriate ISO level. Perhaps more importantly however, control of the product microenvironment is also required, especially in the microelectronics industry where many processes are dependent on controlled, localised vacuums. For this reason, one of the most important components of cleanroom operation is the vacuum pump.

Vacuum pumps are involved in a number of cleanroom manufacturing processes. In microelectronics manufacturing for example they are used to create vacuums to evacuate waste gasses and debris from small, product enclosing manufacturing process chambers and then to ensure the even spread of specialised coatings onto the product. Breakdowns can therefore result in product damage, quality failure and/or downtime with processes halting until the pump is fixed or replaced.

The potential negative impact of vacuum pump faults on cleanroom operation efficiency is one of the dominant issues for cleanroom facility managers. According to Lisa Laurin from US based semiconductor industry marketing consultancy ClearTech:

“The costs of maintaining vacuum processes in a semiconductor [microelectronic] manufacturing facility exceed most other maintenance costs. Pump failures, clogged or sticking valves, and clogged exhaust lines are

some of the catastrophic failures that cause lost yield, high downtimes, and high labor[sic] costs.”¹⁴

Considering the need in the UK manufacturing industry to reduce operating costs to protect against economic downturn and increasing competition, there is often pressure to reduce maintenance spend. This is difficult to achieve in the cleanroom however as compromising pump maintenance increases the risk of pump failure resulting in the inflated cost of downtime and product loss. Other cost saving solutions are therefore required.

Vacuum Pump Maintenance

There are four main approaches to vacuum pump maintenance: Breakdown Maintenance (BM), Planned Preventative Maintenance (PPM), Contingency Planning and Condition Based Maintenance (CBM) (Figure 3).

Pump Maintenance Methodology	Description	Benefit	Cost
Breakdown Maintenance (BM)	Running pumps until they develop a fault. The fault is then corrected	Pumps are run for full lifetime	Highest risk of unscheduled downtime Higher pump repair costs Highest risk of product loss
(time) Planned Preventative Maintenance (PPM)	Pumps are replaced after a period suggested by the OEM	Can schedule pump swap out reducing operational disruption Eliminates pump failure by setting frequency well below statistical norm	Pumps likely to be underutilised Pump system costs unnecessarily high Increased operational costs from excessive pump changes
Contingency planning	Having auxiliary cleanroom chambers or pumps on standby	Can significantly reduce the risk of downtime and interruption to overall process flow	Costs associated with creating and maintaining a contingency plan
Condition Based Maintenance (CBM)	Monitoring of pump performance on a regular basis to identify potential problems	Focus of maintenance resources (reduces maintenance costs) Allows preventative maintenance Prolongs pump life	Cost of pump monitoring Monitoring expertise required Overall cost of ownership can be reduced Saving on energy costs with more efficient pumps

Figure 3. The four main approaches to vacuum pump maintenance in the UK hi-tech manufacturing sector. These maintenance strategies are used extensively in a number of other industries and are backed by research¹⁵

The predominant vacuum pump maintenance paradigm in the UK manufacturing industry is that of BM: pumps are run until they stop working or begin to exhibit obvious signs of malfunction such as oil leaks or abnormal noise or vibration. The BM approach can be highly inefficient however as pumps may provide sub-par performance before obvious signs of malfunction appear. In addition, pumps that crash often require significant refurbishment that incurs inflated maintenance cost and the risk of crashing adds significant risk of product loss.

Another preferred approach is PPM where pumps are simply swapped out on a predetermined, regular basis for overhaul or replacement. The “lifecycle” of the pump is usually determined by the Original Equipment Manufacturer (OEM)’s recommendations dependent on how the pump is used. Where this does have the benefit of being able to schedule cleanroom downtime to avoid process interruption, there is the possibility that pumps are underutilised, reducing efficiency and incurring unnecessary cost.

Another approach is to have contingency plans in place such as auxiliary pumps on standby or additional duplicate process equipment that can be used in the event of downtime. Where this will significantly reduce the negative impact of pump problems on manufacturing operations, there can be significant cost in creating and maintaining these contingency plans.

Condition Based Maintenance

A far more embryonic technique in the vacuum pump industry is the use of Condition-Based Maintenance (CBM). CBM was born out of operations management research suggesting that improvements in the cost effectiveness of maintenance can be achieved through the regular monitoring of machinery¹⁶. This works to identify incipient machinery faults before they become critical enabling the planning of scheduled and specific preventive maintenance actions (only the right action at the right time)¹⁷. The technique has been widely adopted in other sectors such as the oil and gas industry. Here, early research into its use estimates that downtime can be reduced from between 50% - 80%¹⁸.

There are three widely applied monitoring techniques used to implement CBM which are able to detect a range of potential machine faults. These are vibration, thermal, and lubricant analysis.

Vibration Analysis

Machines, such as vacuum pumps, with moving components generate forces that result in vibration. Excessive forces arising from damage or wear of pump shafts, bearings, rotors or housing or debris build up will change the vibration level of the pump indicating that the pump needs attention. Vibration is usually measured with an accelerometer, with the signal being measured by a hand-held system.

Thermal Analysis

Temperature gives information about system performance. In mechanical and electrical machines such as vacuum pumps, heat generation is usually an early sign of failure as motors are working excessively or abnormalities are causing increased friction. Temperature

can be measured by contact thermistors or more advanced non-contact infra-red imaging techniques providing the advantage of speed and wide area analysis.

Lubricant Analysis

Lubricant analysis can indicate excessive machine wear. By detecting the size and quantity of wear based particles in a machine's lubricant indicates damage and potential failure. In vacuum pumps however, this technique may only have limited application as many are lubricant free (dry pumps).

Visual, Aural and Tactile

Inspection

Although not technically a specific technique, many machinery problems can be detected by simply observing vacuum pumps visual inspection, or through listening to the sound it makes. This technique is not as precise as the other three mentioned and is highly dependent on engineer ability. It is therefore often used in conjunction with the above techniques.

The Application of CBM to Vacuum Pumps

If applied to vacuum pumps, CBM is likely to enable a focus of maintenance resources, reduce downtime and improved pump functioning. Where focusing of resources and a reduction in downtime will improve operating margins, CBM will also work to improve pump efficiency. This is because frequent monitoring will enable even small trend fluctuations in vibration and temperature to be identified and corrected. Pumps that are regularly maintained on this basis are more likely to remain efficient, leading to an improved grip on environment control and a reduction in energy consumption.

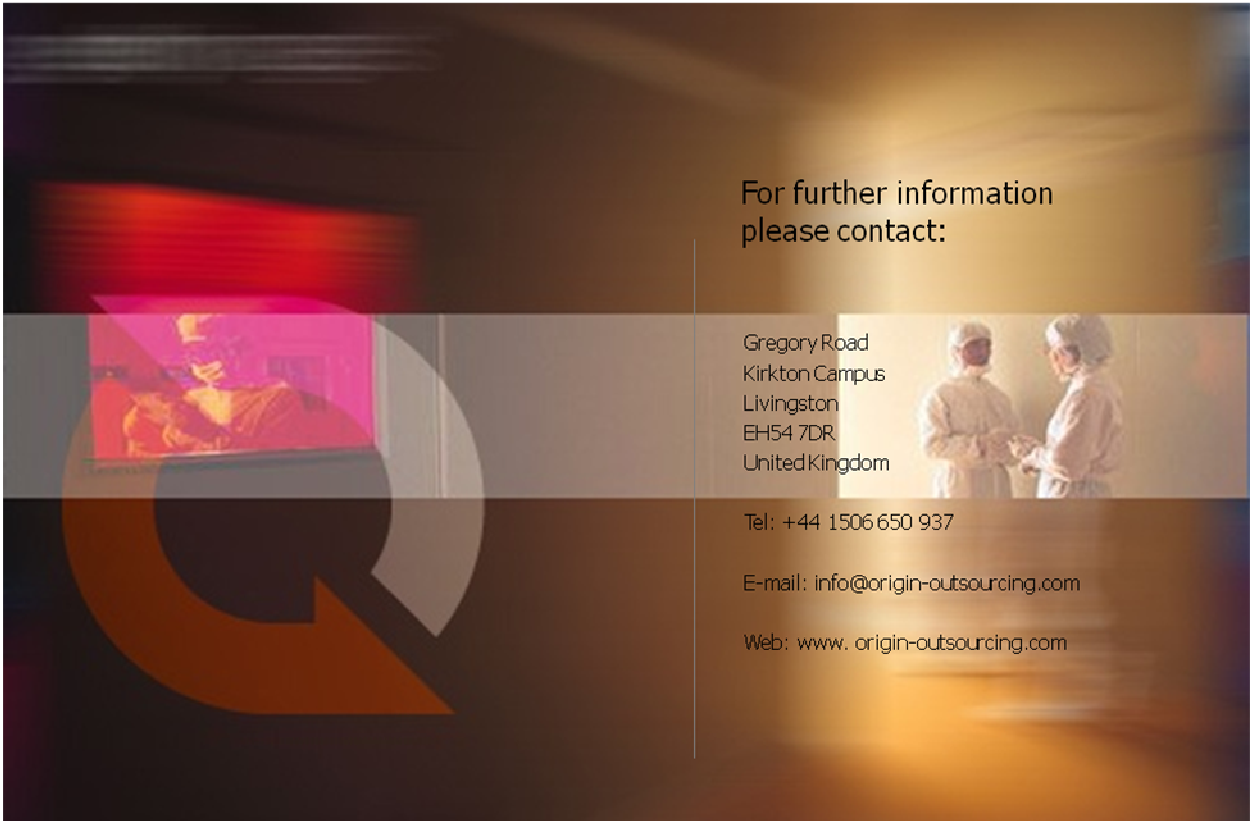
Regardless of the well established benefits, CBM's application in cleanroom vacuum pump systems remains difficult to implement. According to Kenny Gall at Origin Outsourcing:

“Executing CBM is difficult as it requires the ability to know what pump function parameter to use and how to correctly interpret changes in these parameters in terms of maintenance requirements. This expertise is still being developed in the vacuum pump industry with only a few service providers having the required equipment and capabilities.”

Summary

Improvements in cleanroom manufacturing operational efficiency are required to maintain the UK manufacturing industry's competitive advantage in times of increasing industry pressure. Closer management of garment processing as well as the adoption of CBM for vacuum pump systems are two actions which may be used to achieve the required efficiency improvements. The margin based cost saving of reducing downtime and product loss by adopting these techniques will improve the industry's ability to withstand competition and resist economic downturn. In addition, improved pump efficiency, energy consumption and reduced product waste also works towards meeting climate change based social and legislative demands.

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