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PMPS

Pharmaceutical Manufacturing and Packing Sourcer

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STARING INTO SPACE

Single-use temperature loggers could see us accumulate enough waste to lift us off

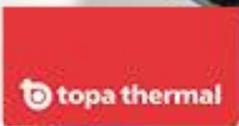
IN STARCH CONTRAST

Innovative pea starch technology is helping to meet the changing tide of capsuling

EXTRACTION POINT

Standardisation is demanding a more streamlined approach in extractables and leachables

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How Air Casters Benefit Continuous Manufacturing in Chromatography

Upgrading the pharmaceutical manufacturing world is never an easy task, and agencies across the world are working out the best way to improve efficiency and reduce costs

John Massenburg at AeroGo Inc

The goal of continuous manufacturing in pharmaceutical production is to consistently reduce human error, enable more flexible drug tracking and tracing, and optimise production efficiency. Now, this trend has extended to chromatography, and for good reason. The FDA, the US equivalent of the EMA, has identified chromatography as the last component of the pharma manufacturing industry that needs perfecting in order to bring the real potential of continuous manufacturing full circle. With true continuous manufacturing practices, biomanufacturing can produce drugs and other bioproducts much faster, more reliably, and at lower cost. Johnson & Johnson, for example, switched to continuous manufacturing for its HIV medicine Prezista (darunavir) and reduced production time from about two weeks to just three days (1).

Chromatography equipment, however, cannot operate continuously without regularly cleaning, repacking, and

frequent movement of columns. As experience has shown, traditional solutions, such as wheeled casters and tuggers do not lend themselves to continuous manufacturing processes. A better alternative is the integration of air caster technology, which increases the likelihood of seamless chromatography, improves potential for achieving EMA-approved cleanroom compliance, and fosters ergonomic goals to meet the needs of employee safety.

What Are Air Casters?

Originally developed for use in the aerospace industry, air casters are inflatable, doughnut-shaped bags that create a thin film of air capable of floating multi-ton loads. Once the bags have inflated, excess air escapes underneath and creates lift. This film of air, no thicker than a business card, reduces friction coefficient to around 1% so that air casters require only about one-tenth the force to move as wheeled casters.

The result is that operators can push chromatography columns around like pucks on an air hockey table. A 2.26 metric ton machine, for example, would need only 2kg to 11kg of force to move, something even a single operator can handle. A wheeled caster, by contrast, would require as much as 136kg of force to move across most floor surfaces.

The benefits of air casters become even more apparent with larger chromatography columns weighing upwards of 18 metric tons – a laborious weight and size that is inefficient to move by traditional methods. Since chromatography equipment must be regularly cleaned out and repacked, the labour and related inefficiencies can stack quickly; reducing productivity, throughput, and wasting time and labour.

Instead, in pharma cleanroom applications, air casters are compact and highly manoeuvrable. The following

case study illustrates these benefits. An engineer who was designing a new pharmaceutical production facility realised air casters required far less space than wheeled solutions. He was able to reduce the width of hallways through the environment by around six inches, which translated into millions of dollars in construction cost savings.

How Air Casters Facilitate Continuous Manufacturing Processes

Air caster systems are often customised and tailored to fit specific needs, but pharma manufacturers generally utilise one of two broad styles of air casters for use with chromatography equipment:

Option 1: Air Caster Transporter

For lighter chromatography equipment weighing only a few tons, a simple air caster transporter is enough. Functionally shaped like a pallet jack with two forks to accommodate the structure of the machine, the transporter slides under the column. The transporter fits almost entirely within the footprint of the column; it does not extend out to the sides at all. Since air casters can move omnidirectionally and rotate 360° in place, the operator uses a handle to manoeuvre the machine including the ability to back up and navigate even 90° turns with ease.

Option 2: Air Caster Drive System

Heavier chromatography columns might require more force than one or two operators can easily and safely provide. In this situation, an air caster system with a built-in throttle and drive enables operators to propel the column from



Air casters offer more manoeuvrability than traditional material handling or load moving equipment



point to point on air, without requiring muscle power alone to actually move the equipment.

Operationally, the drive system functions much like the human-powered transporter: it slides underneath the column and lifts it up. Even with the drive system incorporated, the air caster is not much bigger than the column itself and requires less overall space when compared to other solutions, like tuggers.

In either case, whenever a particular column needs to be cleaned and repacked, operators slide the transporter under the column, inflate the bags, and then navigate the machine through the corridors of the cleanroom to its interim destination. There, the air caster bags are deflated, and the column gently settles into its new position. Once is it ready to be returned to the production line, the air casters are re-inflated, and the operators simply push the machine into position. The omnidirectional movement inherent to air casters makes it possible to position the machine with extreme precision. Again, the air bags are deflated, and the air caster system can be tucked out of the way until it is needed again. In most cases, the actual machine

move requires only a few minutes of time and no more than an operator and a spotter or two.

How Air Casters Increase the Likelihood of Seamless Chromatography

First, they are more manoeuvrable than tuggers. Air casters offer more manoeuvrability than traditional material handling or load moving equipment. Perhaps the most common load handling solution in a pharmaceutical environment is a wheeled system, such as an external tugger that attaches to the column and pulls it through the facility much like a trailer hitched to a car. That becomes an obvious challenge for operators who must manoeuvre a two-piece solution that pivots in the middle, particularly when backing up with the load. The air caster is simply more manoeuvrable. Operators can rotate the column around its centre within a much smaller envelope than available with an external pulling solution. Backing up is as easy as moving forward – an improved manoeuvrability that confers a secondary benefit: air caster systems complete the moving process faster than the alternatives and are easier for operators to intuitively move in a safe manner.



1. The red air hose feeds into a base module (orange) with an air caster (yellow) underneath. 2. Compressed air inflates the air caster and creates lift. 3. Excess air escapes the air caster, creating a film of air that floats the load like an air hockey puck.

Second, air casters keep the cleanroom clean. Most pharmaceutical operations utilising chromatography machines maintain cleanroom environments. The machines, the media within them, and the product being manufactured need to be protected against potential contamination. These cleanrooms are ideally populated by equipment that is clean and easy to sanitise, such as stainless steel and food-grade plastics.

While wheeled casters systems are a common choice, they are not ideal for the chromatography environment. They tend to attract dirt and debris, and they are harder to clean. Air casters are no more inherently sanitised than any other equipment, but if pristine surface finishes, cleanability, and EMA-approved materials are key, air casters will easily meet the requirements for keeping cleanrooms clean and meeting compliance regulations.

A Better Fit for Moving Chromatography Equipment

Ultimately, the advantages of air casters for pharmaceutical use are only as impactful as the outcomes they produce. Fortunately, air casters can power some notable process improvements and efficiency starting with fitting in the footprint of the equipment. Here's why:

1. They fit within narrower hallways:

Since moving chromatography columns with air casters requires less space on either side, pharmaceutical producers can increase productivity and/or reduce the expense of building and maintaining cleanrooms. Space within the cleanroom is expensive, with each square foot requiring significant resources to build and maintain. Material handling

solutions like tuggers with their large wheel size and structure require extra space that limits the facility's productive capacity. Even smaller chromatography columns necessitate large wheels, a body extending past the sides of the equipment and a hallway significantly wider than the chromatography machines. Reducing hallway width just by a few inches through air caster solutions can potentially save millions in construction and facility costs.

2. They fit under shorter doorways:

Cleanroom cubic footage is expensive, so maintaining the environment's cleanliness is costly. The total volume of air needs to be purified to meet specifications. Thus, many cleanroom environments are built with lower ceilings, shorter doorways, and other height limitations when compared to non-cleanroom production facilities. If operators plan to move a chromatography column via wheels, it is likely that they will need to raise the unit as much as eight to ten inches. Contrast that with air casters, which when fully inflated, typically rise only two to three inches. The film of air that floats the load is only 0.003 to 0.005 inches thick. The lower height is an ergonomic advantage for operators, making each load easier and safer to move.

3. They protect against vibration:

Chromatography columns, particularly when freshly packed, are very sensitive to vibration. Depending on the specific machine, vibration and load shocks during movement could potentially reduce the equipment's overall operational efficiency. That is because moving on wheels down a hallway will always transmit vibration to the load. Even

if operational degradation is only incremental, production inefficiencies could be significant. The inflated air caster, however, inherently provides suspension to isolate the packed column from vibration. Consequently, the media within the machine is either unaffected or less affected by the movement process and can perform at, or close to, optimum.

Air Casters Bolster Production Efficiency

The cumulative benefits of air casters translate into improved productivity and operational efficiency, and potentially substantial cost savings, especially when air casters are included in design planning. Air casters require less space than alternative solutions, so the facility can be more cost-effective and efficient in its operations. The quicker users get a column back into service, the better the utilisation, which is an ongoing benefit for efficiency and operational productivity.

Air casters are not just a better way to move machines from one place to another. They have proven themselves essential to operating a cost-effective, continuous manufacturing process in chromatography and pharma facilities.

Reference

1. Visit: www.biopharmadive.com/news/pharmas-slow-embrace-of-continuous-manufacturing/532811/



John Massenburg is President and Chief Executive Officer of **AeroGo, Inc.**, Seattle, Washington, US. AeroGo manufactures heavy load equipment utilising hovercraft technology for moving heavy, awkward, or delicate loads.



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