Intelligent Inspectors: Solid Metal Detection With a Twist

A new breed of products is offering manufacturers a range of added-value benefits in addition to sensitive detection. Here's a look at what's available.

Customers are placing high demands on pharmaceutical manufacturers to produce sensitive, cost-effective, and regulatory compliant inspection technology. This article examines how metal detection equipment suppliers can combine forces with manufacturers to provide state-of-the-art inspection systems, giving particular consideration to cleaning processes and regulatory issues.

Manufacturers do not need reminding that in today's litigious and safety conscious climate, a solid metal detection process is crucial. As they strive for greater automation and uptime, compliance with legislation and good manufacturing practice (GMP), manufacturers want a metal detector that does more than just prevent contamination. Proactive suppliers have responded by conceiving metal detectors capable of performing multiple functions. Enabling efficient cleaning and changeover, data control, and regulatory compliance, this new breed of intelligent inspectors offers a range of added-value benefits in addition to sensitive detection. Let's look at ways in which changing customer demands have had an impact on inspection technology, confronting issues such as washing-in-place (WIP), Dust Tight, 21 CFR Part 11 compliance, and the relentless push for heightened sensitivity.

Keeping It Clean

Today's metal detectors are capable of functions that enable efficient cleaning and changeover, data control, and regulatory compliance.

Traditionally, product changeovers for highly active pharmaceutical ingredients

(APIs) involve a time-consuming cleaning process. A machine operator in climatized, ventilated clothing enters the cell room and rids the tablet press of any visible powder residue. All components in contact with APIs, such as the tablet press rotor and metal detector reject, are then removed, dismantled, cleaned, and replaced. This accrues costly downtime, compromises the flexibility of the production process, and incurs high personnel costs for adverse working conditions. In a drive for higher quality from the Medicines Control Agency (MCA) and employee protection for health and safety legislation, cleaning-in-place (CIP) and WIP systems are now becoming commonplace. But although technology for WIP tablet presses is fairly advanced, until very recently metal detectors still had to be dismantled for cleaning because their aluminium construction meant they could not withstand the rigors of cleaning in situ. Fully sealed stainless steel metal detectors with reject systems that can be connected to a tablet press or deduster are now available to allow all contact areas to be WIP. Furthermore, integrated WIP systems containing a tablet press, deduster, and metal detector can also be built. These integrated systems operate by pumping water at pressure through the tabletting system to remove in place traces of dangerous ingredients from the press and metal detector. An operator in normal pharmaceutical clothing can then strip the machines and take the rotor and other removable components outside the press for cleaning. In the meantime, production can continue because the rotor can be exchanged immediately. This approach eliminates the need for bulky "space suits," reduces cleaning and inaccessible time, and assists companies in production planning. It also ensures dust-free connections. Although dedusters rid tablets of most dust, they are not capable of removing 100 percent. Sealed connections between the dedusters and the detector prevent dust from escaping at these points, creating a dust-free production environment.

Combining Forces

Line space is an important consideration for pharmaceutical manufacturers. Historically, machinery suppliers have faced problems producing machinery that is compact enough to fit into the limited cell room space available. Forward-looking suppliers are developing combination systems that overcome space constraints and perform multiple functions. However, co-ordinating the interfaces of different machines requires detailed electronic and mechanical engineering. A wide variety of metal detector configurations is needed to enable compatibility with the various types of tablet presses and dedusters on the market. For example, metal detectors can be fitted with a height/angle adjustment facility for integration with different tablet presses. Metal detection equipment suppliers can work with pharmaceutical manufacturers to integrate the metal detector, deduster, and press to reduce the overall footprint and save valuable line space in the non-sterile manufacturing area. By deploying a combination metal detector and deduster at this point, companies gain the dual benefits of alleviating excess dust and checking for metallic contamination before the final stage of blister packaging or bottling. It is also possible to configure the metal detector to transmit feedback signals to the tablet press. So, in the event of a metal detector fault, the press stops producing tablets and an alarm alerts the operator to the problem. This prevents product wastage and blockage and guards against contaminated product passing through undetected.

Real-life Contaminants

Leading suppliers run performance tests using real-life contaminants to show that their metal detectors can handle any type or shape of metal.

The industry standard for validating and calibrating metal detection equipment is to pass spherical balls of varying sizes and metal types through the detector. However, in reality, contamination is more likely to be in the form of metal slivers or short lengths of wire or swarf. These will produce differing signals in the metal detector, depending on their alignment to the detector's aperture. This is known as the "orientation effect." Leading metal detector suppliers now run performance tests using real-life contaminants, such as stainless steel sieve wire rather than spheres, so that customers are confident that the detector can handle any type or shape of metal.

Pure, high-resistance, non-magnetic stainless steels, such as 304 and 316, still cause problems for metal detectors because they go undetected at anything other than extremely high frequencies. It is difficult to design high-frequency machines for a pharmaceutical plant because of interference from the external environment and the detector hardware. Metal detector manufacturers have responded to this issue in two ways. First, they have developed detectors with smaller apertures. This improves sensitivity but reduces product throughput rates. Second, they have reduced frequency to 800 kHz. This eliminates interference but reduces sensitivity. Removing electronics from the head of the detector can achieve 1 MHz frequency and stability. The use of a larger aperture maintains a high rate of product flow while the high frequency ensures unparalleled sensitivity levels &#151 even for the most elusive stainless steel contaminants.

Regulatory Compliance

Pharmaceutical companies are facing mounting pressure to comply with 21 CFR

Part 11, which was introduced by the FDA in 1997 for controlling electronic records and signatures in validation and GMP. Metal detection is now subject to risk assessment to determine whether it falls within Part 11 compliance &#151 a decision that lies with each individual. Leading metal detection manufacturers have developed software according to GMP guidelines that allows equipment to be Part 11 compliant. The software implements all security access controls, user identification, audit trails, electronic records, and electronic signatures. As a result, in the event of contamination, batches can be fully traced and accounted for.

Generation X Detectors

Metal detectors has come a long way since the balanced coil principle was registered as a patent in the 19th century. The transition from analog to digital, the advent of information technology, and the upgrade to powerful microprocessors have been among the technological milestones to date in its evolution. Now, as detector performance reaches a peak, limitations are imposed by the boundaries of physics. Technology has entered a new era, with customer requirements determining the direction of the latest generation of intelligent inspectors.

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