

# Pall Launches Sterile, Pyrofree Vials Product Range

*Platinum Press offers serialization-ready printed components*

Pall Corp. has launched the Pyrofree vials product range for filling processes with ready-to-use pyrogen-free vials, depyrogenated and sterilized according to industrial operations methods applied in vaccines, pharma and biopharma industries, and in hospitals. The packaging is designed for the processing of small batches such as clinical and technical lots, orphan drugs or personalized medicines.

A pyrogen is defined as any substance that can cause a fever, such as endotoxins. The injection of endotoxins into the blood can cause severe hazard to a patient and in worst case, lead to septic shock. Depyrogenation, or the removal of pyrogens, is therefore a crucial need in the aseptic filling process of parenteral drugs. Primary packaging of injectable drugs is particularly controlled for the absence of pyrogens and any chemical agent that can alter drug substances properties and stability. In this case, sterilization of primary packaging (e.g. by ethylene oxide sterilization) represents a risk of introducing chemical agents into drug substances.

The Pyrofree vials product range aims to address these needs with its packaging technology, allowing sterilization and depyrogenation of the vials by dry heat in their primary packaging under vacuum. According to the company, the Pyrofree process results in ready-to-use pyrogen-free vials that can be used for the filling of injectable drugs without using washing and depyrogenation equipment from the filling line.

The Pyrofree vials product range consists of Type I clear glass pyrogen-free vials of 2 mL, 5 mL, 10 mL and 20 mL, supplied with grey stoppers of 13 mm and 20 mm diameters, made of bromobutyl with Fluotec coating.



The product line is compliant with EP2.9.19-Test 1B and USP <788> (particles contamination); EP2.6.14 and USP <85> (bacterial endotoxins); and EP2.6.1 and USP <71> (sterility test). According to the company, Pyrofree packaging technology can be also offered for other type of vials depending on the scope of application.

*More info: [www.pall.com](http://www.pall.com)*

## Platinum Press Offers Serialization-Ready Printed Components

Platinum Press, Inc. (PPI), a provider of healthcare packaging solutions for the pharmaceutical, medical device and animal care sectors, offers a new variety of serialization-ready printed materials to apply final track and trace data onto packaged pharmaceutical products.



The company supplies a variety of substrates and printing options for track and trace compliance, and its serialization service employs the equipment and technology to help pharma companies comply with the Drug Supply Chain Security Act (DSCSA)'s current and approaching serialization mandates.

By 2017, pharmaceutical packagers must include Data Matrix and human-readable track and trace codes at the unit level. The U.S. will require all Rx products to have a serial number and all homogeneous cases to have a serial number. Full aggregation and supply chain data exchange providing traceability will be required by 2023.

Platinum Press offerings include DataLase and Laser Ablation technological capabilities to produce materials for final serialization. The company has also invested in coding and marking equipment suited to the 'parent-child' aggregation of pharmaceutical products, and offers multi-factor authentication using both overt and covert anti-counterfeiting measures for track and trace marking at both the unit and aggregate levels.

"Platinum Press has the equipment, knowledge and experience to make healthcare packaging the first line of defense against counterfeiting and supply-chain diversion," said Andrew Vale, senior

vice president of Corporate Strategy and Development.

More info: [www.platinumpress.com](http://www.platinumpress.com)

### Thermo Scientific Launches Next-Gen Bioanalysis Solution

Thermo Scientific has launched its next-generation MSIA Streptavidin EVO microcolumns for large molecule bioanalysis. The fully automated affinity purification solution is designed to enable scientists to analyze large biomolecules, such as proteins and antibodies, with improved accuracy, consistency and simplicity, even at high throughputs, according to the company.

The MSIA Streptavidin EVO microcolumns have been designed to bring the mass spectrometric immunoassay (MSIA) affinity purification technology to Tecan's Freedom EVO series of robotic platforms that are equipped with a 96 multichannel arm (MCA96).

Limitations of conventional affinity purification methods can present challenges for biopharmaceutical, translational, clinical and sports anti-doping labs performing high-throughput characterization of large molecules. These challenges can include low efficiency, inconsistent results, high background and carryover and the inability to standardize methods and transfer between labs.

When combined with the Tecan Freedom EVO robotic platform, MSIA Streptavidin EVO microcolumns are designed to enable fast and accurate isolation of target analytes from complex biological matrices, according to the company. Housed within a pipette tip, the monolithic columns are densely coated with streptavidin for analytical affinity purification of any biotinylated affinity ligand, even at low concentration, and users can analyze sample volumes as low as 10  $\mu$ L.

"The MSIA Streptavidin EVO microcolumn is an ideal solution for biologics and biosimilars discovery and development," said Preeti Saini, product manager for MSIA liquid handling consumables at Thermo Fisher Scientific. "It is particularly well suited to laboratories performing large molecule bioanalyses that demand high-quality, reproducible and unambiguous results with minimal background noise. Moreover, this solution is designed

to help scientists save both precious samples and time."

"Our combined solution will provide these laboratories with faster assay development, scalable sample processing and surety of data quality and consistency," added Rohit Shroff, product manager for Tecan. "By bringing together Tecan's well-established Freedom EVO workstations and Thermo Scientific MSIA technology, we can better cater to the high-volume bioanalytical research market."

The MSIA technology was previously available for use with the Thermo Scientific Versette Automated Liquid Handler and Thermo Scientific FinnpiPette Novus i Multichannel Electronic Pipette for high- and low-throughput applications, respectively. The MSIA Streptavidin EVO microcolumns have been designed to enable a broader community of high-throughput bioanalytical researchers to benefit from automated liquid handling for large molecule bioanalytical assay development.

More info:

[www.tecan.com/analyticalchemistry](http://www.tecan.com/analyticalchemistry)

### Flottweg Introduces New Solution For Separation Challenges

Flottweg has introduced new AC Separators designed reach higher speeds than other centrifuges, such as the decanter centrifuge, according to the company, and the design allows the centrifuge to achieve g forces of up to 10,000 g. Also, disk inserts provide a larger clarifying surface. According to the company, the combination of an expanded clarifying surface and the high g forces make it possible to separate the finest of solid particles or liquid mixtures efficiently.

The AC separators feature the Soft Shot discharge mechanism, where during discharge, part of the control water stays under the piston. That means that during ejection, the piston cannot strike the bottom of the bowl and the solid is ejected in a gentle, quiet manner, according to the company. Also, this hydraulic system offers adjustment options to adapt the machines to specific processes and increase product yields.

Also, Flottweg Clarifying Separators are used to separate solids from liquids to allow highly efficient clarification, according to the company. The disk stack in the bowl



divides the product flow into many thin layers, providing a large clarifying surface. Within the disk stack is where the solid is separated from the liquid. Due to the high centrifugal force, the settled solids migrate to the solids space in the bowl. The hydraulic actuation of the piston periodically ejects the settled solid at full speed, where it is discharged through a solids cyclone. The clarified liquid flows out of the disk stack to a gripper and guided over it at pressure.

More info: [www.flottweg.com](http://www.flottweg.com)

### Exco Intouch Launches Gather

Exco InTouch has launched Gather, a new product suite designed for all stakeholders within the clinical trial process: sponsors, CRO's, sites and patients. For CRO's, the Gather suite is designed to connect each section or module of a study within the clinical trial process, allowing CROs access to this data and providing greater visibility to monitor the progress of a study, access enrolment quotas, site metrics and other data at a glance.

Data can be accessed in real-time, providing visibility of any potential issues within the study, allowing CROs to address any problems earlier in the process. Visibility of data can also extend across multiple studies, giving a holistic view of several trials and their progress. Gather also allows CRO's to share data from individual or multiple studies across their organization.

The product is delivered through a user interface with intuitive reporting functions.

More info: [www.excointouch.com](http://www.excointouch.com) **CP**