

CASE STUDY

FlowCam® for Continuous Improvement of Manufacturing Process

When this client realized that traditional microscopy was not effective at visualizing microparticles they they turned to the FlowCam to help.

They use the FlowCam to troubleshoot their manufacturing process by comparing old and new data sets allowing for continuous improvement.

THE CLIENT

This biotech company is headquartered in the EU and has 2 locations in the US. As a provider of high-quality solutions for customers, healthcare professionals, organizations and patients worldwide, they develop and bring to market innovative wound care and surgical solutions along the entire continuum of care, from prevention to post-acute settings.

THE CHALLENGE

Our customer manufactures a grafting product for treating burns and other partial skin loss injuries. One type of product is provided meshed (whereby the product is scored in a crisscross pattern which helps it expand to provide coverage over a larger area). The scoring process involves the use of stainless steel blades cutting against an Ultra High Molecular Weight Polyethylene (UHMWPE) product. This step in the process generates small pieces of plastic which could adhere to the patient.

As part of the client's continuous improvement process, this scoring step was investigated. Because the UHMWPE plastic is clear, small pieces are translucent and not visible using the standard microscopy tools available.



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Our client wanted to quantify the number and size of any sub-visible particles. They needed an instrument that could provide a clear edge gradient which could serve to isolate particles from the background and provide consistent counts and sizing.

ON TRIAL: TESTING FOR ACCURACY AND REPRODUCIBILITY

The Technical Product Manager of this company first became aware of the FlowCam in a prior employment with a biological corporation.

She came to Fluid Imaging Technologies (FIT) with her samples in July 2017 for a trial to see if the FlowCam would be successful in providing images and count/concentration. Using the FlowCam she could visualize, image and count any particulates associated with the sample, including the small, translucent plastic particles.

—Technical Product Manager

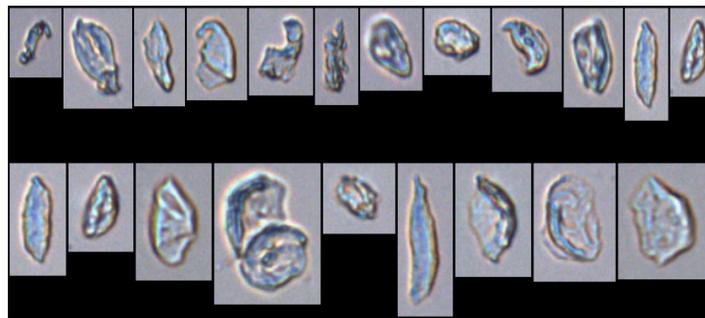
She visited FIT again in September 2017 after preparing a sample using a method referenced in the literature, and used the FlowCam to troubleshoot her protocol for the sample preparation. She was thrilled to see the FlowCam generate accurate and reproducible data for replicates and controls. “The FlowCam is so simple to use and understand. Not only the way it works, but the software that analyzes the samples is tremendously powerful.”

--Technical Product Manager

The FlowCam has provided this biotech firm with the ability to evaluate their current manufacturing process and, going forward, allows them to investigate engineering changes that will improve both process and product quality.

RESULTS AND FUTURE OUTLOOK

FlowCam allows this company to visualize small, translucent particulates that could not be seen with traditional light microscopy. Not only visualization, but quick quantification and replication.



UHMWPE plastic particles as imaged by FlowCam.

The digital images available from the embedded software (VisualSpreadsheet®) provide a record of data that can be analyzed, trended and manipulated.

Beyond a single point of use, FlowCam offers visibility at every step of manufacturing process. “The most exciting part of using the FlowCam is that it captures an image of every particle in your sample in real time so you can see the data right away. When you are looking for particles, having an image is critical when a particle description alone is not adequate.” – Technical Product Manager.

FlowCam provides a quick method of video capture to present findings to colleagues and share data. Additionally the FlowCam provides a means to run a single volume in a streaming sample without the need to run multiple smaller samples that would be less accurate.

They use the FlowCam to investigate, trouble shoot and contribute to improving their manufacturing process.

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