CASE STUDY

Biotech Firm Chooses FlowCam for Quality Analysis

FlowCam® allows for easier, more accurate, and more informative subvisible particle analysis.

“We demoed a couple particle analyzers and we decided on the FlowCam because of the flexibility in choosing objectives, ability to detect particles in the 5 µm range or less, and it provided real-time data analysis including particle count and shape” - David Rhodes 
Formulation and Analytical Group, Protein Sciences Corporation

THE CLIENT

Protein Sciences Corporation is a biotech firm based in Meriden, Connecticut. Their mission is to “save lives and improve health by responding to the changing world through the creation of innovative vaccines and biopharmaceuticals.” They produce vaccines, therapeutics, and gene therapy products for clients and partners, and supply product development and manufacturing services to the scientific community.

THE CHALLENGE

Prior to the FlowCam, David Rhodes, a member of the formulation and analytical development group at Protein Sciences, and his team used two methods to analyze the stability and subvisible particle content in their drugs: light obscuration and manual microscopy. Light obscuration inaccurately counts and sizes amorphous and transparent particles, and manual microscopy is time-consuming. “Neither of these methods are very informative,” said Rhodes. “For example, when we characterized samples known to contain particles, we weren’t able to adequately characterize the sub-visible particulate. We knew [subvisible particles] were there but we didn’t know how many, how big they were, or anything else.” Rhodes was anxious to have something that analyzed subvisible particles faster, captured more information, and quantified more easily and accurately.
WHY CHOOSE THE FLOWCAM?

After doing some research on the available instruments on the market, Rhodes determined that the FlowCam imaging particle analyzer would provide the assessment of product quality he was looking for. The FlowCam provides information on particle size, concentration and appearance, and it also can characterize agglomerates that are transparent and therefore not detected by light obscuration devices.

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PRODUCT QUALITY WITH THE FLOWCAM

Protein Sciences Corporation has improved overall product quality with the FlowCam. Their prior particle analysis methods of light obscuration and manual microscopy failed to provide them with enough accurate information and were too time consuming. By incorporating the FlowCam into their formulation development, quality analysis, and stability studies, they have created a methodology that not only saves time and money, but results in superior products.

STABILITY STUDIES WITH THE FLOWCAM

The FlowCam is now used at Protein Sciences for routine testing for subvisible particles in bulk drug substances and drug products. When they have a new formulation or process and want to do a stability study, they include the instrument as part of the testing at each point. This analysis characterizes the potential degradation pathway of a product. “We’ll monitor [the drug] at one week, two weeks, or a month [in storage] to determine the progression of particle counts and particle size,” said Rhodes. “With the FlowCam, we get to see the particle morphology instead of just counts, and that really helps facilitate the debugging process if we encounter any issues during the development of new products.”