

Protein Sciences Corporation Chooses FlowCam for Quality Analysis

THE CUSTOMER

Protein Sciences Corporation, a Sanofi company, is a biotechnology firm based in Meriden, Connecticut, with the mission 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.

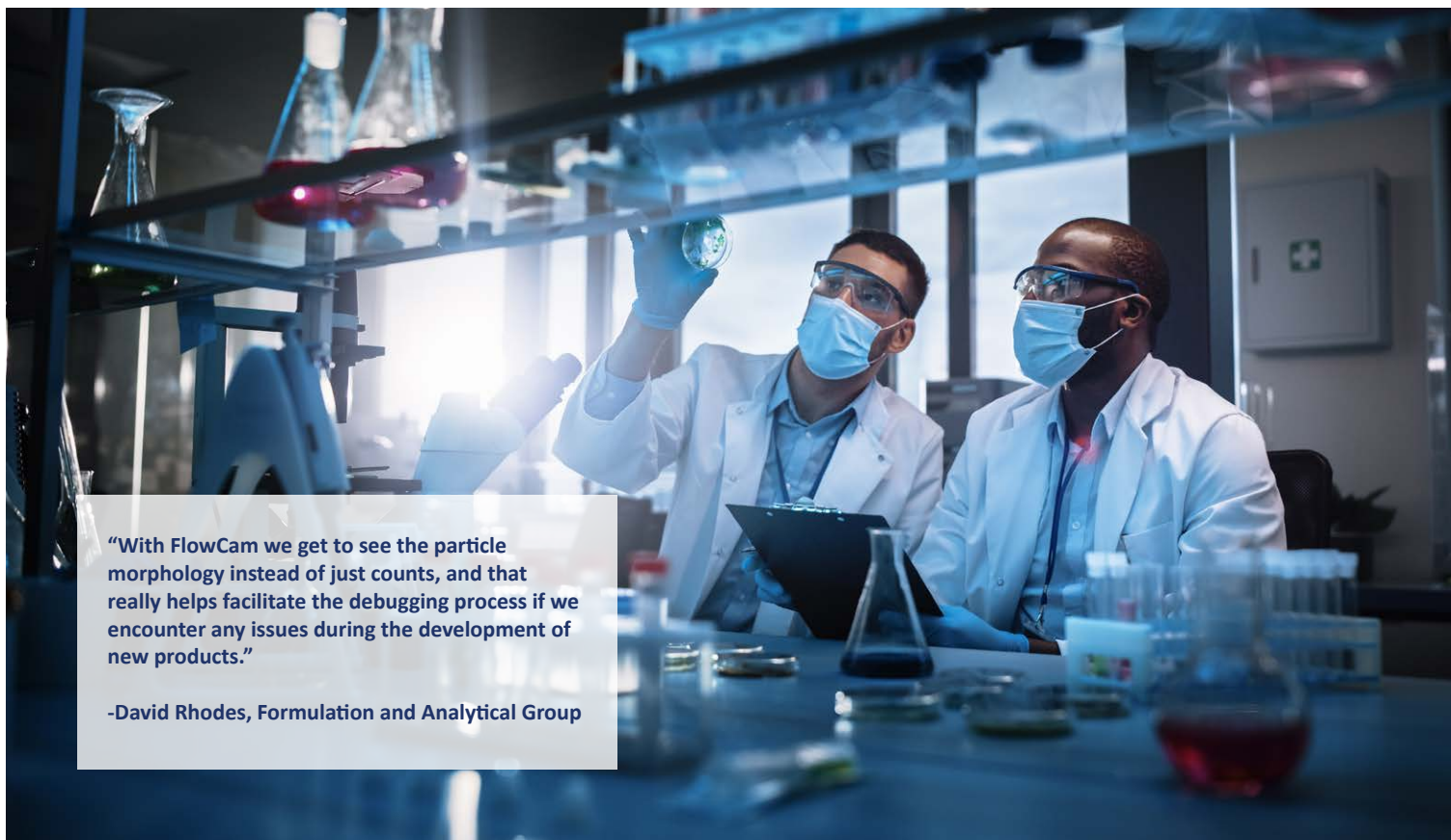
THE CHALLENGE

Prior to using FlowCam, David Rhodes and his team, the formulation and analytical development group at Protein Sciences, used two methods to analyze the stability and subvisible particle content in their drug formulations: 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 subvisible particulates. We knew [particles] were there but we didn’t know how many, how big they were, or anything else.” Rhodes was looking for technology that analyzed subvisible particles quickly and accurately, and provided more comprehensive morphological data.

WHY CHOOSE FLOWCAM?

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



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-David Rhodes, Formulation and Analytical Group

“We demoed a couple particle analyzers and we decided on 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,” said Rhodes.

With its VisualSpreadsheet® software, FlowCam can record more than 40 different morphological parameters per particle and can capture particle images at up to 100 frames per second, allowing for high sampling efficiency and short analysis times. It sorts and filters particle data and immediately displays all similar-type particles.

“The testing process is a whole lot easier, quicker, and more informative, in some ways, than the USP <788> testing,” adds Rhodes. “It’s a question of taking 15 minutes compared to taking a better part of a day.” Rhodes estimates that this provides a 10-fold savings in laboratory costs for Protein Sciences.

STABILITY STUDIES WITH FLOWCAM

FlowCam is now used at Protein Sciences for routine testing for subvisible particles in bulk drug substances and drug products. When researchers have a new formulation or process and want to do a stability study, they include the instrument as part of the testing at each stage. 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 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.”

Figure 1 shows the results of a stability study where FlowCam revealed protein aggregate agglomeration through a combination of count, size, and image data - information that would not have been available through light obscuration alone.

Day One		Week Four	
Count	33470 of 33470	Count	13568 of 13668
Particles / ml	231866	Particles / ml	93754
Summary Stats	Filters	Context Summary	
Summary Stats	Mean	Max	
Area (ABD)	12.87	9040.76	
Area (Filled)	12.97	9267.54	
Summary Stats	Mean	Max	
Area (ABD)	35.06	13353.71	
Area (Filled)	35.81	13695.84	

Figure 1. FlowCam Stability Study Data. Note that overall particle count decreased after four weeks, and particle size increased overall when looking at mean and max.

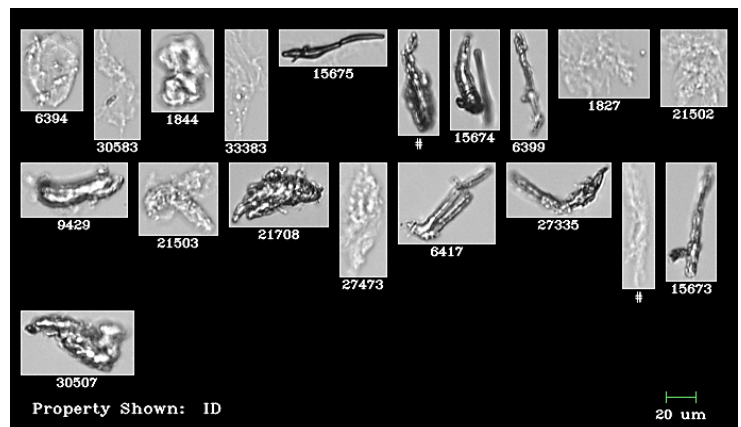


Figure 2. Protein aggregates as imaged by FlowCam on Day 1 of the study shown in Figure 1.

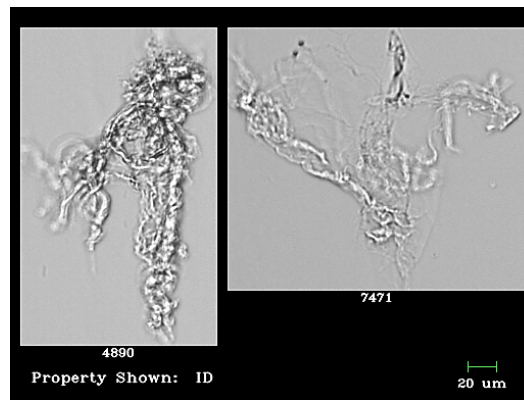


Figure 2. Protein aggregates as imaged by FlowCam after four weeks of the study shown in Figure 1.

PRODUCT QUALITY WITH FLOWCAM

Protein Sciences Corporation has improved overall product quality using FlowCam. 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 FlowCam into their formulation development, quality analysis, and stability studies, Protein Sciences has created a methodology that not only saves time and money, but results in superior products.