A NEW APPROACH TO PARTICLE MORPHOLOGY

CLAIRITY™ Particle Analysis Software Suite

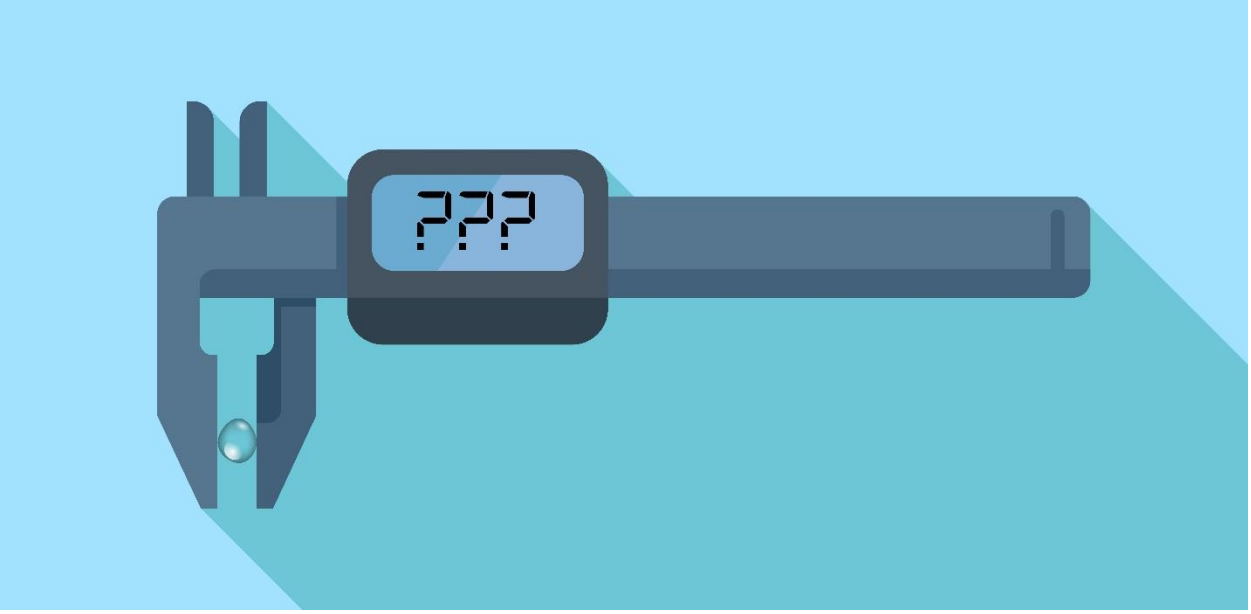
When developing a new pharmaceutical product, particularly where the delivery mechanism involves a dry power based active pharmaceutical ingredient (API), size is an important property to understand and control. The size of the API and excipients affects more than just the stability and appearance of the product. Particle Size can influence properties such as friability, dissolution, bioavailability, release rate, and can even influence manufacturing processes and parameters.

As important as particle size is, understanding and controlling particle shape or morphology is just as critical. A recent example of this importance was seen at a customer facility, where one batch of API was failing its bioequivalence test. Analysis of this API in comparison to a passing batch, using traditional methods including Laser Diffraction proved inconclusive, the particle size was the same. It wasn't until the product was analyzed using Image Analysis that the truth of the situation was found. The morphology of the particles clearly showed a change in aspect ratio, intensity, and area, pointing to a change in the milling and crystallization processes used early in the manufacture of the API.

Another important aspect of particle identification relates to quality control of pharmaceuticals. Visual inspection, covered by USP<790>, along with USP<787>, <788> and <789> which regulate the number of visible and subvisible particles in ophthalmic, and injectables all require the observation and count of particulate matter. In these cases, the presence of, size and morphology can additionally be used for forensic determination of the particulate source, be it intrinsic, extrinsic or inherent.

As pharmaceutical sciences move towards more advanced manufacturing and delivery technologies such as 3D printing, morphology of the constituents becomes more critical. Powder flow, and shape factors such as sphericity will need to be precisely controlled to ensure final product quality, content, and performance.

The answer to this challenge however is not that simple. Current technologies for measuring particle size and morphology such as laser diffraction, dynamic image analysis, scanning electron microscopy, static image analysis, and microflow imaging all report different modes of size and shape. For example, laser diffraction reports volumetric size, dynamic imaging a cord length, static imaging a max length, and microflow imaging a Feret length, to name a few. Some techniques report statistical average data, others report number-based data, and others don't report enough information for statistical relevance at all.



The consequence of all this is that it is becoming increasingly difficult as a particle scientist to compare results between techniques. Especially as you increase the number, and complexity of competing and complementary technologies into the manufacturing process. All measurements provide correct results, but these results can be biased, and which result the most relevant to your application? To compound those issues, only a subset of techniques provides morphological data along with size, and the number of parameters reported varies by method.

The ultimate outcome is putting the jigsaw puzzle of information together can be a slow, tedious, and laborious process. This process requires a detailed knowledge of each technique's capabilities, along with their strengths and weaknesses relative to the application. Requiring scientists to become experts in the range of analytical techniques applicable, or companies to recruit expert consultants to help wade through the myriad of information.

With the introduction of CLAIRITY™, a new software product from ImageProVision, Inc., there may be a simpler way to help solve this conundrum. CLAIRITY™ is aimed to be a lower priced alternative to the traditional instrumentation in this space. Offering access to these essential measurements, with a smaller capital outlay, whilst improving the performance of the

technology at the same time. CLAIRITY™ offers big insights for a small investment in the world of particle size and morphology.

The CLAIRITY™ Particle Analysis Suite is a software package that offers a unique twist on measuring particle size and morphology. Where traditional instrumentation offers limited compatibility for comparison or interpretation of alternative measurement technologies, CLAIRITY™ steps in. Not only does CLAIRITY™ offer the ability to directly integrate with virtually any microscope, offering direct acquisition and analysis of particle size and morphology. CLAIRITY™ also offers the unique ability to import and process images from virtually any source.

This ability facilitates the direct comparison of data in a single software platform, whilst utilizing a range of reportable parameters that allow direct comparison of data to other techniques. For example, results such as spherical equivalent volume (SEV) allows for the comparison of laser diffraction data, and the reporting of 5 different length measurements, means that previously incomparable image analytics data can now be directly compared.

Take for example the data obtained from traditional Static Image Analysis platforms in the market today. One manufacturer report's size according to the USP<1776> definition, which is the longest distance between two points on a particle's axis. Another manufacturer reports size according to the Feret definition, which is a caliper base measurement of the maximum distance across the particle. For irregularly shaped objects these two measurements can result in very different outcomes, making the results incomparable.

Another example of CLAIRITY's™ unique capabilities is the comparison of Flow Imaging (FI) data to static image analysis. A typical FI analysis can result in tens of thousands of images being generated for a single sample, few of which contain actual particles. Comparison of these datasets between manufacturers can be quite challenging, and options for re-analysis of the data limited due to the number of images. CLAIRITY™ offers the ability to import, and re-analyze the entire image set, expanding the information available from the measurement, and providing directly comparable data to complimentary techniques.

What CLAIRITY™ brings to the table is the ability to process and interpret particle data within a single platform. Providing greater comparability, transparency, and repeatability between results. CLAIRITY™ almost sits as the referee between techniques, offering unique insights and comparisons into data that were previously quite laborious to achieve. Add to this capability to extend CLAIRITY™ to incorporate Artificial Intelligence, Machine Learning, and Deep Learning into the acquisition, image processing, data analysis, and data interpretation phases of the measurement this software package can provide analytical insights into the data, trends, and outliers that are currently not possible from traditional technologies.

CLAIRITY™ is big on performance, and small on investment in an application space which has seen little improvement in technology and capability over the last 10 years. While the functional

limitations of image base analysis remain, integration of new technologies and capabilities for data interpretation and analysis brings greater insights into once incomparable data sets. Offering a unique, unified approach to data collection, analysis, and review for particle size and morphology measurement. In turn this data can provide actionable insights and establish functional relationships between Critical Material Attributes (CMAs), and Critical Process Parameters (CPPs) to confirm Critical Quality Attributes (CQAs) or a pharmaceutical product

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