

Application note:



Pharmaceutical Analysis

In this app note:

- See how Dragonfly's deep learning segments different phases in a pharmaceutical product
- See how deep learning overcomes image artifacts to make analysis possible
- See particle size analysis of two active ingredients
- See wall thickness applied to capsule

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The case study: a vitamin C capsule

X-ray imaging by computed tomography (CT) allows the quality evaluation of pharmaceutical products. There may be specific measurements of interest e.g. capsule thickness distribution, ingredient particle size distribution, or homogeneity of the ingredients. It may also be important to check for unexpected flaws such as cracks or inclusions / contamination. In this application note, we showcase the pharmaceutical capsule segmentation and analysis capabilities using Dragonfly 3D World software. Segmentation using deep learning is particularly useful here.

Requirements

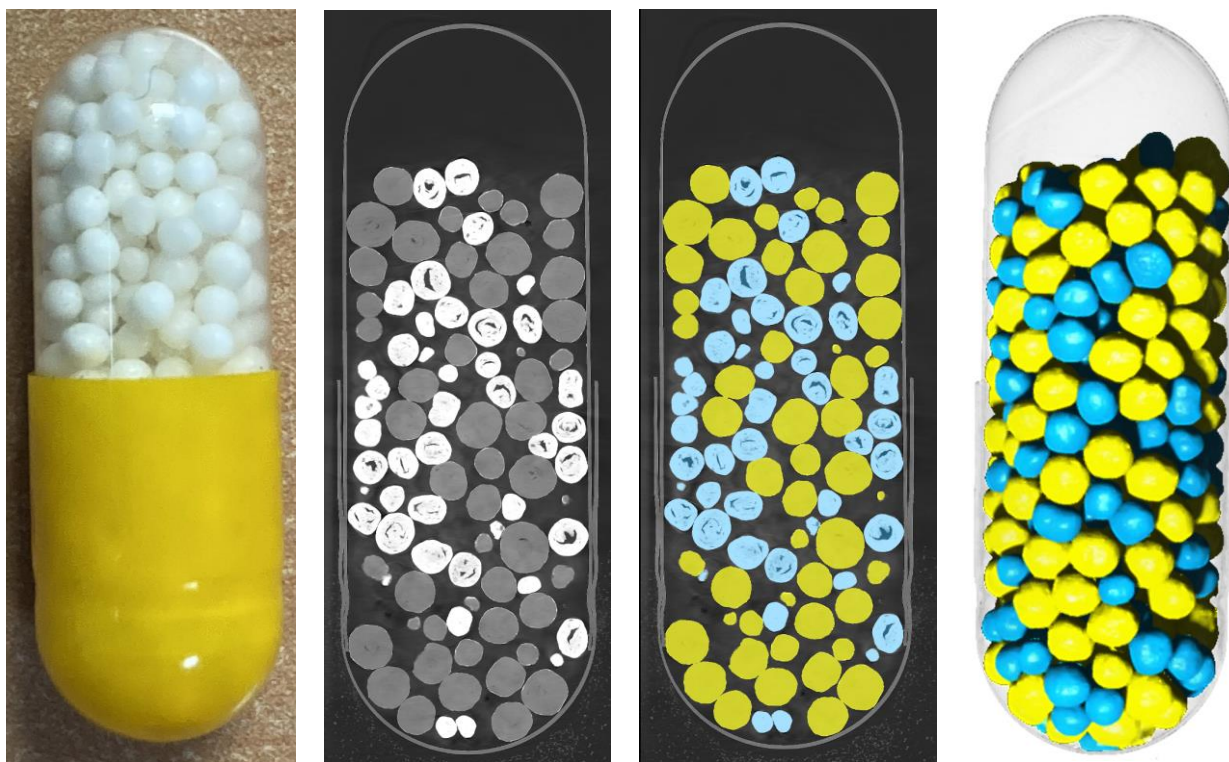
A high-quality CT scan of the capsule is needed, typically using a laboratory X-ray micro-CT instrument. Image analysis is fully digital and a computer with Dragonfly 3D World software is needed. The data can be any format as long as the voxel size is known (typical is a stack of 16 bit tiff images representing the full volume). The part in this example was scanned using the **Comet Yxlon FF35 CT in transmission mode at 60 kV and 70 μ A**.

Typical outputs

- Cross sectional images and videos of the capsule to visualize the internal contents and their distribution
- 3D images and videos highlighting different phases
- Volume and sphericity analysis of particles, and volume fraction evaluation
- Wall thickness distribution of capsule wall

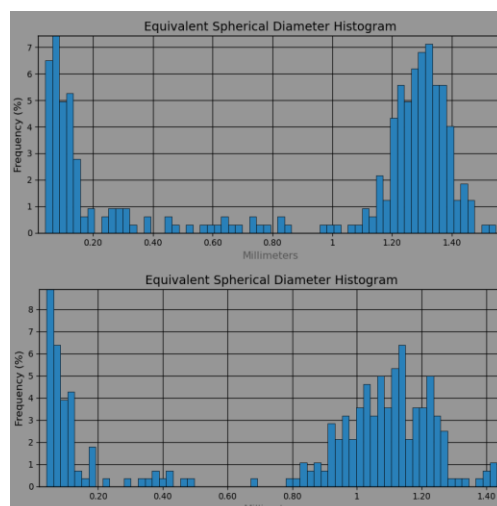
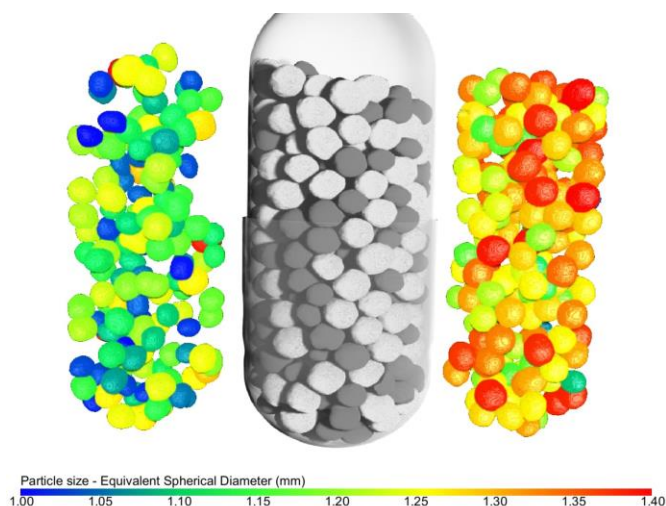
From image to analysis

In this case study, the CT data shows useful information in cross-sections without any further analysis required. There are two different particle types in the capsule, one of them with internal cracks. The next step is usually segmentation –to define which pixels in the image belong to which material phase. The segmentation step here is challenging due to touching particles and regions where different materials have similar grey values. Deep learning is ideal for this – Dragonfly’s deep learning was applied to segment the two types of particles and the capsule as three classes or phases.



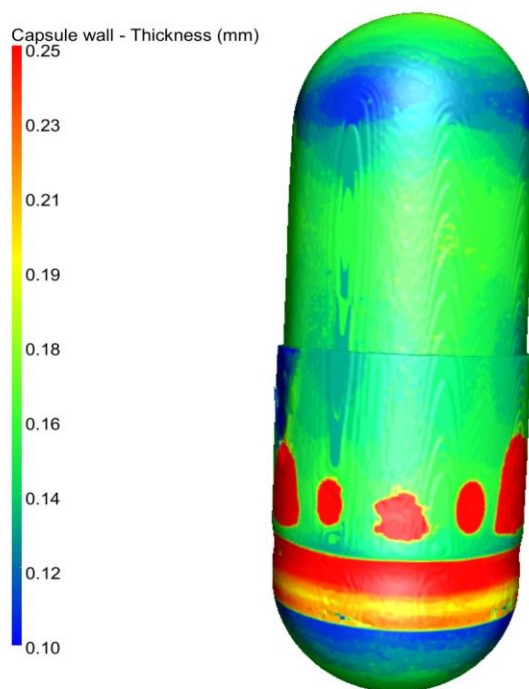
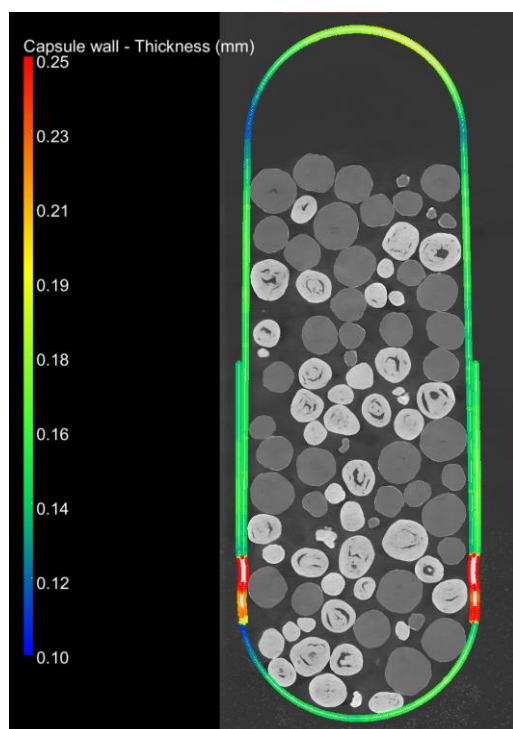
From left to right: the capsule photograph, CT cross sectional image, CT segmentation of two particle types in cross sectional image, 3D image of two particle types. Segmentation achieved using Dragonfly deep learning.

After segmentation, touching grains could be separated by the Dragonfly watershed algorithm, for each particle type. Each particle type is then analyzed for its size distribution which shows that one particle type is larger than the other in this capsule, with mean diameter 1.3 mm vs 1.1 mm.



Particle size distribution analysis is performed for each particle type in the capsule, they are visualized separately on the same color range showing the difference, with histograms containing statistical information on the size distributions.

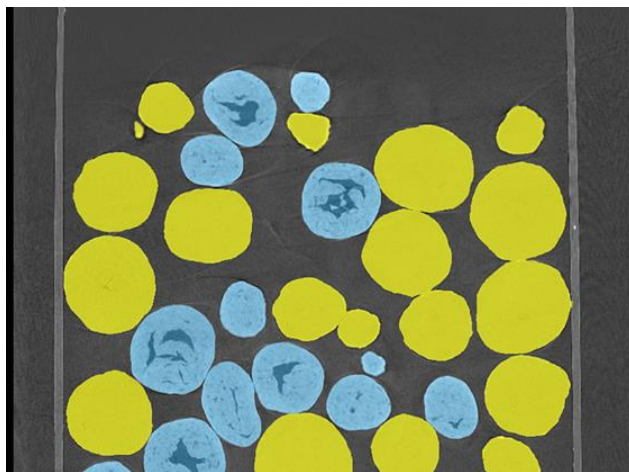
It is not only internal contents that are important, also the capsule walls need to be analyzed. The capsule wall thickness analysis shows regions of varying thickness. The main quality check involves the smallest values, e.g. the blue regions near the top – it is important that these are not too small which could lead to failure or premature release of the active ingredients.



Wall thickness analysis of the capsule shows regions with small thickness values near the top

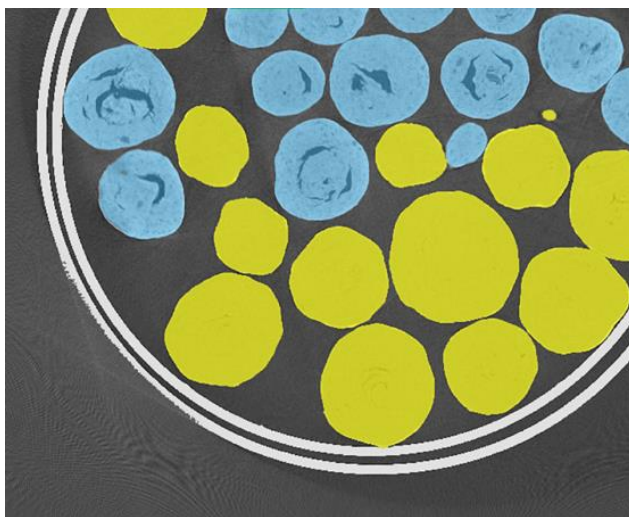
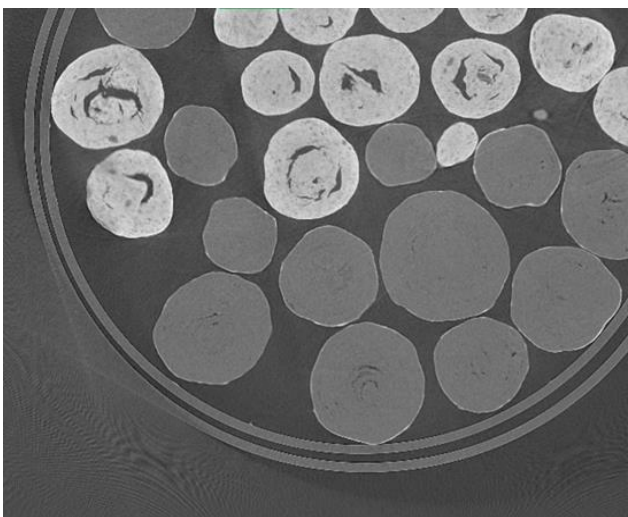
Advanced

This application note demonstrates the analysis of a single vitamin capsule. Deep learning was key to the segmentation here, not only due to the challenging data as is usual for pharmaceutical sample types, but also due to some image artifacts and unique aspects to the data, which could be resolved by using deep learning. Firstly, the one particle type had cracks inside which could be easily included into one of the phases or classes of the model, to reduce the chance for segmentation of “broken” particles, as shown below.



An example is shown here of the challenge with manual segmentation and grey values which are similar, making any manual/traditional segmentation approach problematic. For comparison, the deep learning result is shown on the right, including the cracks inside particles into the phase of that particle.

Secondly, another benefit of deep learning is here demonstrated: the ability to overcome image artifacts. Due to the large magnification used with too few projection angles in the scan, some part of the capsule is not clearly visible on the left bottom of the image below. The model could be trained in this region to make a reasonable estimate, as shown on the right, to allow further analysis to be performed.



A deep learning model could be trained to overcome image artifacts resulting in lack of capsule information in one region. The model could make a reasonable estimate here, to allow further analysis to be performed.

The benefits

The benefits of Dragonfly 3D World for improving your Q&A process is knowledge of the quality of your samples, using a reliable software for data analysis. The workflows in Dragonfly 3D World are fully customizable and open to the user, there are no hidden algorithms or question marks surrounding data analysis. Customization and reporting tools allow faster and better decisions to be made for improving manufacturing processes and in quality control and qualification efforts. Unlock a new world of quality inspection of pharmaceutical products using Dragonfly 3D World!

Further information

Get Dragonfly 3D World today on a 30 day trial at: <https://dragonfly.comet.tech/en/free-trial-dragonfly-3d-world>
And get in touch with our sales team sales.dragonfly@comet.tech to set you up with a full license with support plan included



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