

# Versatile use of X-Ray micro CT in the Pharma Industry

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## Aims

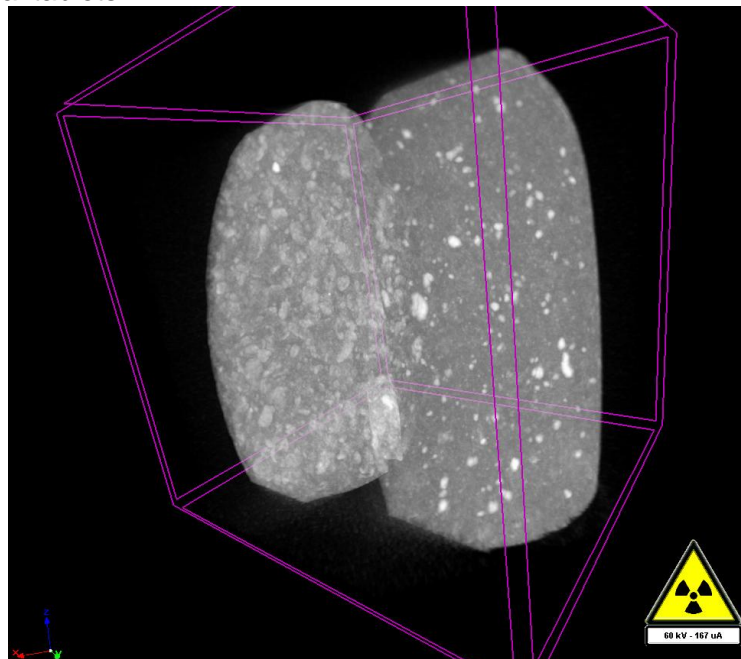
This presentation is to give an overview of the applications of X-Ray micro Computed Tomography (X-Ray micro CT) in the pharmaceutical industry. It shows how this technology allows a faster and more focus root cause findings in development issues..

## Method

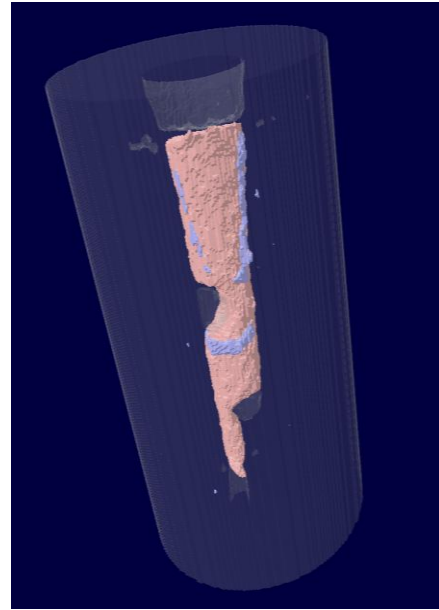
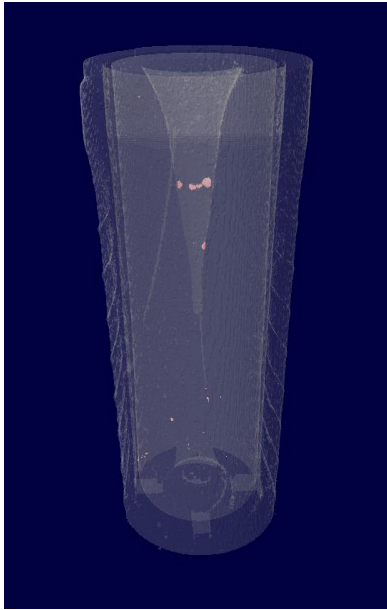
X-Ray micro CT is a completely non-invasive technology when employed for the analysis of pharmaceutical samples. It allows to have a precise image of the product before this one is used in different destructive tests such as dissolution for example. Having this image allows understanding which parameters of the product and the process may influence the dissolution or more generally speaking the performance of the product. X-Ray micro CT is also very flexible considering that many kind of sample can be analyzed. Form raw material to final drug product ( most often coated tablets) can be imaged. F. Hoffmann-La Roche implemented a Skyscan 1172 in November 2008 in the analytical development department. It is since then not only used for galenical development but also for drug substance, for packaging question and device analysis.

## Results

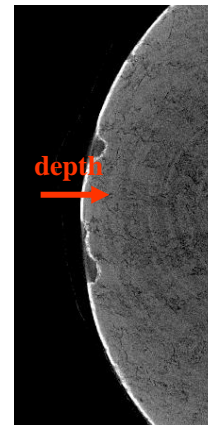
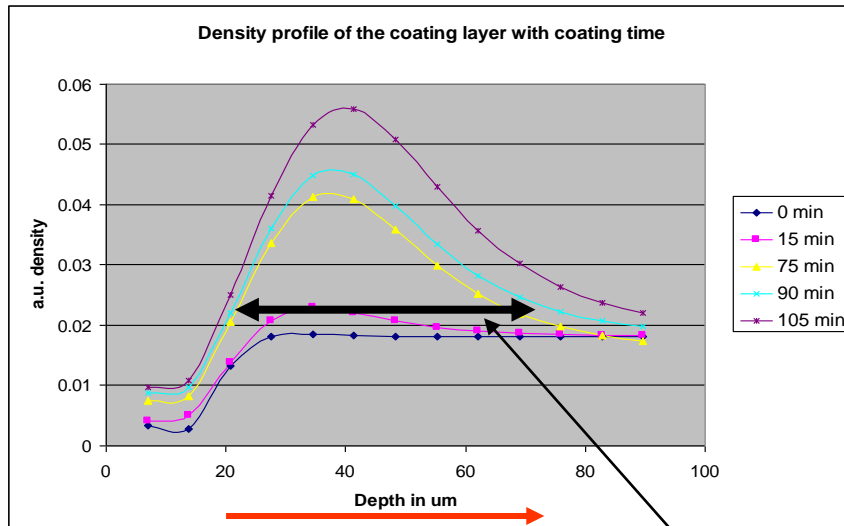
As shown in the following picture X-Ray micro CT may allow visualization of the influence of process parameters changes in the granulation step of the production of pharmaceutical tablets.



This technology may also be of use to analyze the trace left by the needle in the Rigid Needle Shield after removing this cap from a prefilled syringe.



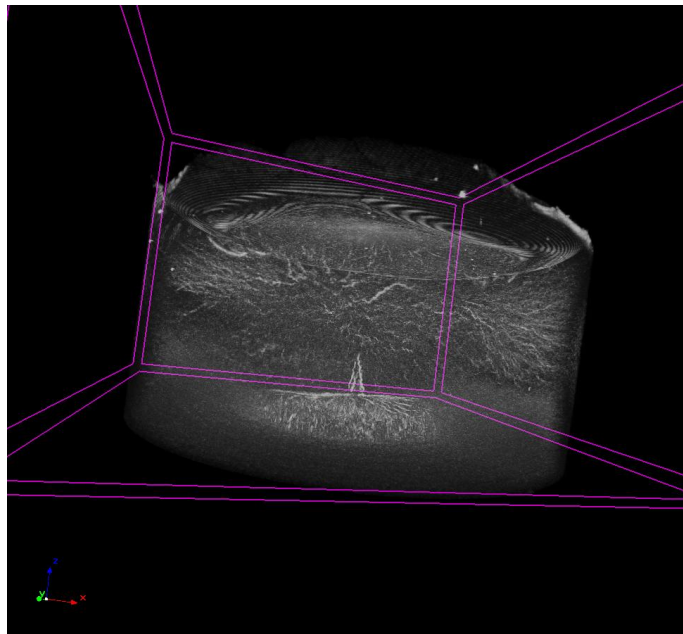
Determination of coating thickness as well as coating integrity can be achieved with computation and data analysis of the absorption profile. The influence of stability testing on tablets such as the variation of the volume of the tablets during this stress can also be precisely determined by X-Ray micro CT and this may help to understand the dissolution behavior of the final drug product after stability.



Coating Thickness



The formation of the lyophilized cakes of products may also be explained and the process of lyophilization as well as the formulation of the drug can be adapted according to the X-Ray micro CT findings, while no other technique allows such non invasive and 3D visualization of the cake.



### **Conclusion**

X-Ray micro CT is a high performing tool to identify the key parameters of a process during the drug development. Its non destructive ability allows very useful correlation between observed results from classical analytics and the images of the product before analysis.