

Understanding a Complex API Process

CASE STUDY



The challenge

Our customer had a complex API forming step including 4 isolations, a reverse anti-solvent addition and micronisation. In addition, the polymorph in development was metastable. The above aspects were considered high risk for the manufacturing process. Therefore, simplification of the process was deemed necessary.



How?

A thorough gap analysis and risk assessment were conducted, evaluating the four distinct API steps using the Blazemetrics probe alongside XRPD, TGA, DSC, and PLM. Solubility measurement and Dynochem process modelling were employed to optimise the process.



The achievement

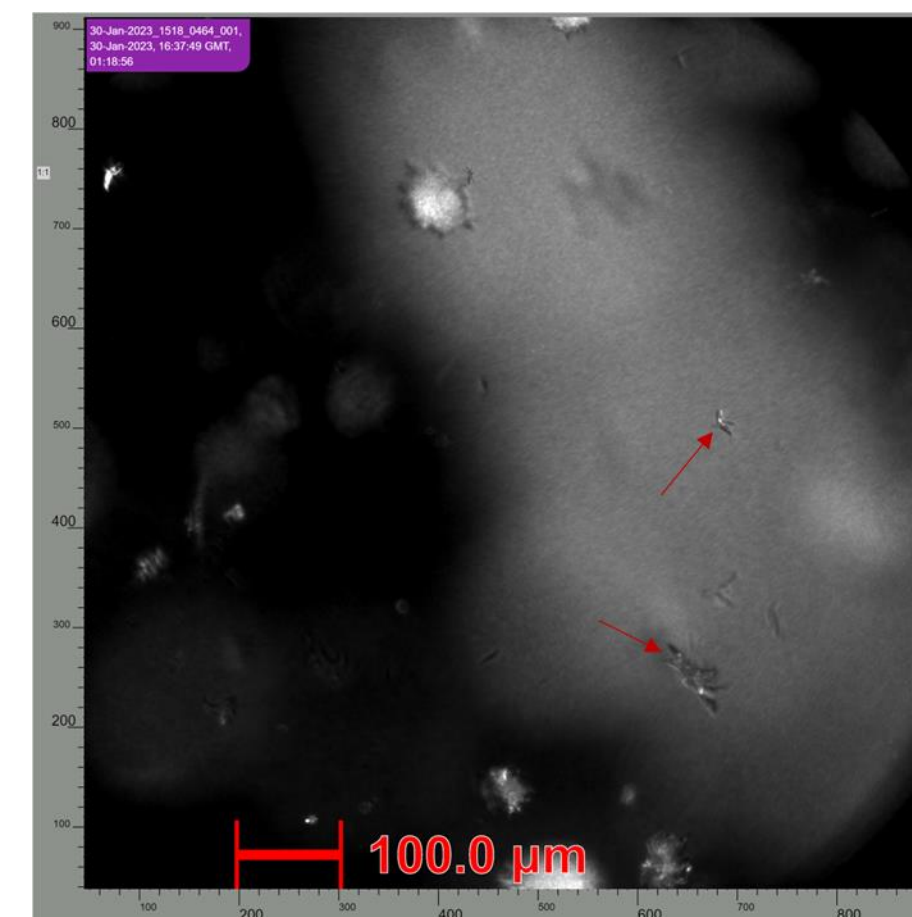
Through CatSci's risk assessment and process evaluation work:

- A number of significant risks were identified.
- The role of each isolation step was elucidated.
- Key processes occurring throughout the crystallisation process, such as agglomeration, attrition, and crystal growth were identified. A mitigation plan was proposed ensuring that the process was ready for manufacturing

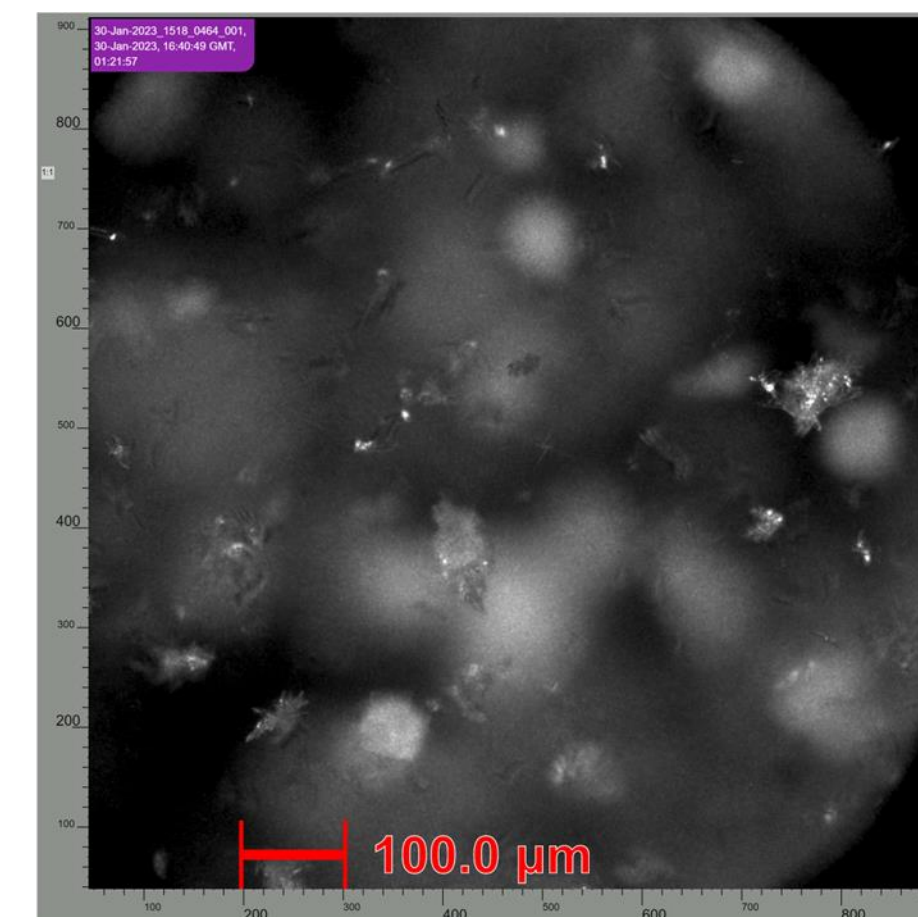


The team: Dr Philip Lynch & Dr Robert Dennehy

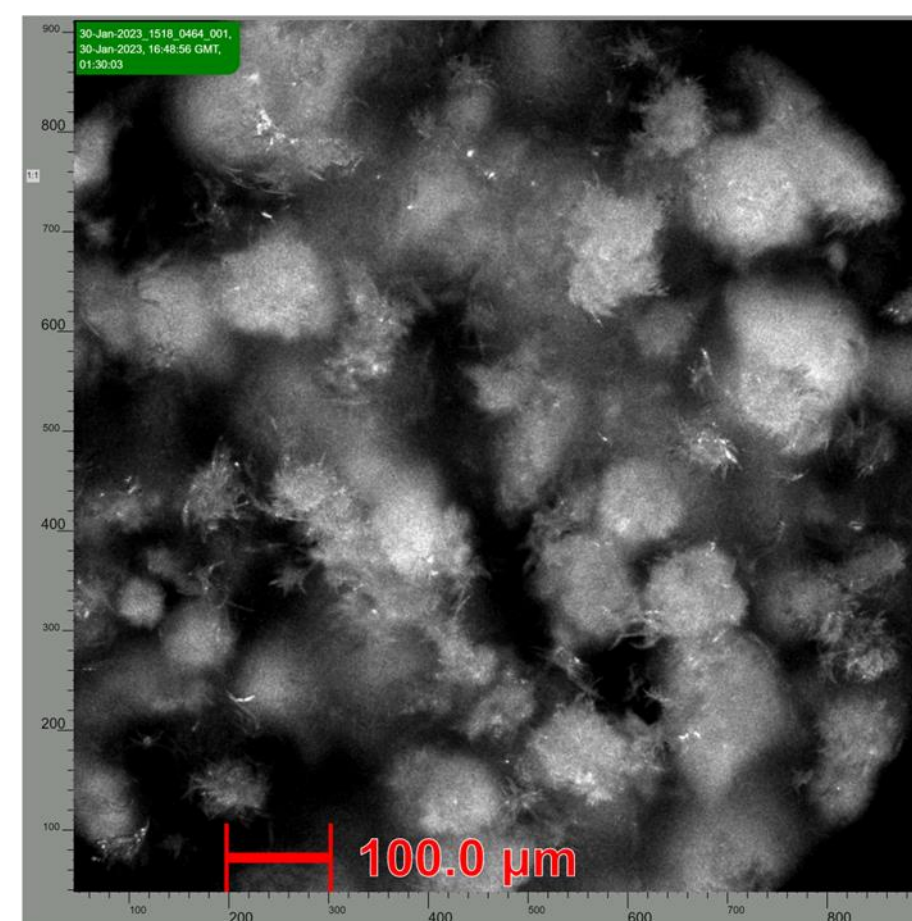
In-process images from the Blazemetrics probe, capturing nucleation, growth of agglomerates and attrition



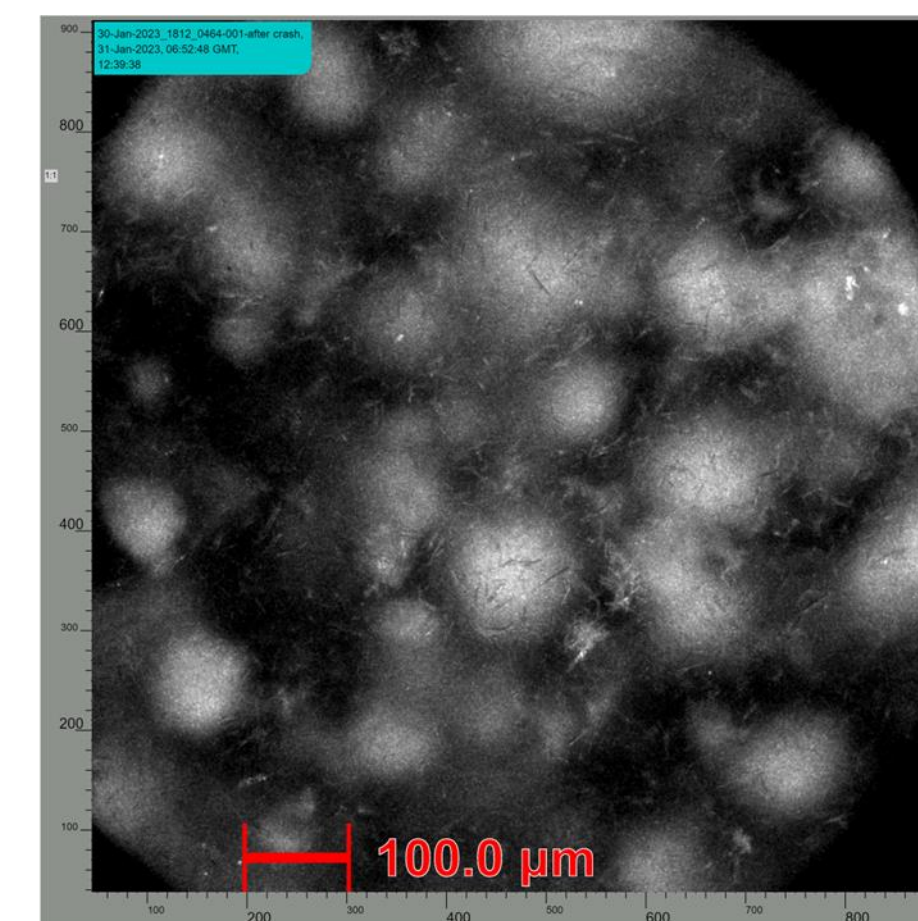
Initial nucleation



Initial nucleation + 3 mins



Initial nucleation + 12 mins



Initial nucleation + 16 hours