

## CASE STUDY

# SmartPath: API Risk Assessment & Tailored Mitigation Plan



### The challenge

A customer needed to rapidly identify and mitigate the risks associated with their early phase oncology asset to minimise delays in their accelerated clinical programme.



### How?

Our Director of Material Sciences, Dr Robert Dennehy worked with our customer to conduct a SmartPath risk assessment seeking knowledge on the following questions:

- What is known about the design intent for the product?
- What is known about the formulation and the process?
- What is known about the API and the formulation?



### The achievement

The customer received a tailored lifecycle plan and was able to advance their oncology asset with minimal impact to their development plan.



**The team**  
Dr Robert Dennehy

## Before SmartPath

- ✗ **The formulation blend had a propensity to stick to the tablet press.** This was related directly to the API properties.
- ✗ **There was chemical instability** in the proposed solvent system.
- ✗ **The asset was oiling** during the crystallisation step.
- ✗ **Poor control** over API bulk properties rendered micronisation problematic.

## After SmartPath

- ✓ **The team controlled the crystallisation,** which enhanced batch-to-batch variability. This also provided a more stable base for the formulation, which was then adjusted to reduce the danger of sticking.
- ✓ **The team measured the kinetics of degradation,** and the solvent ratio was optimised for yield, volume efficiency, and instability. This also provided an operating window for the process at scale.
- ✓ **Oiling was prevented** as the team worked out the optimal solvent composition to combat liquid-liquid demixing.
- ✓ **The client was encouraged** to critically address the need for micronisation.



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