

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.



Take the SmartPath now