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.

Before SmartPath	After SmartPath
The formulation blend had a propensity to stick to the tablet press. This was related directly to the API properties.	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.
There was chemical instability in the proposed solvent system.	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.
The asset was oiling during the crystallisation step.	Oiling was prevented as the team worked out the optimal solvent composition to combat liquid-liquid demixing.
Poor control over API bulk properties rendered micronisation problematic.	The client was encouraged to critically address the need for micronisation.

The team: Dr Robert Dennehy

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