As the bulk properties of a drug substance can have enormous impact on the downstream processing properties (filterability, dryability, flowability) or formulation (bulk density, impurities), the development of a robust and scalable crystallization process is an essential step in drug development.

A crystallization process is also the most frequently used technique for purifying solid drug substances. Irrespective of whether the chemical or chiral purity needs to be enhanced, a specially designed crystallization process is the best choice for processing.

Solvias offers a seamless approach to design and optimize a robust and scalable crystallization process together with kilogram supply of API under GMP, if required.
Polymorphism Investigation
• Determination of relevant polymorphic forms
• Evaluation of polymorphic transformations
• Identification of thermodynamic most stable form
• Identification of hydrates and solvates

Form Selection & Process Design
• Determination of temperature-dependent solubility of relevant polymorphs
• Identification of metastable zone width
• Evaluation of different crystallization techniques (cooling, seeding, addition of antisolvent, pH shift, salt formation, azeotropic distillation)
• Variation of solvent systems (solvent quality, solvent class)
• Determination of proper stirring time and speed
• Assessment of changes in substrate concentration
• Process development in terms of crystal design (size, shape)
• Comprehensive analytical testing (HPLC, headspace GC, X-ray powder diffraction, particle size distribution, microscopy, etc.)

Crystallization Process Optimization
• Systematic variation of relevant process parameters (cooling profile, stirring profile, seeding process, spiking with impurities, water activity)
• Optimization of process and bulk properties (space volume yield, batch cycle time, compression of final product, filterability)

Multigram to Kilogram Supply
• Proof of concept on 250g scale
• Delivery of seeding crystals from gram to kilogram scale
• Crystallization on kilogram scale under GMP or non-GMP
• GMP release testing
• Shipment of final product to customer
• Technical transfer of crystallization process

Our Contribution
The unique combination of Solvias expertise in solid-state chemistry, crystallization process development and kilolab production under GMP and non-GMP, supplemented with state-of-the-art instrumentation, enables us to tackle the majority of all drug development candidates.

Your Process
• Faster
• More efficient
• Safer
• More cost-effective