VERANOVA™

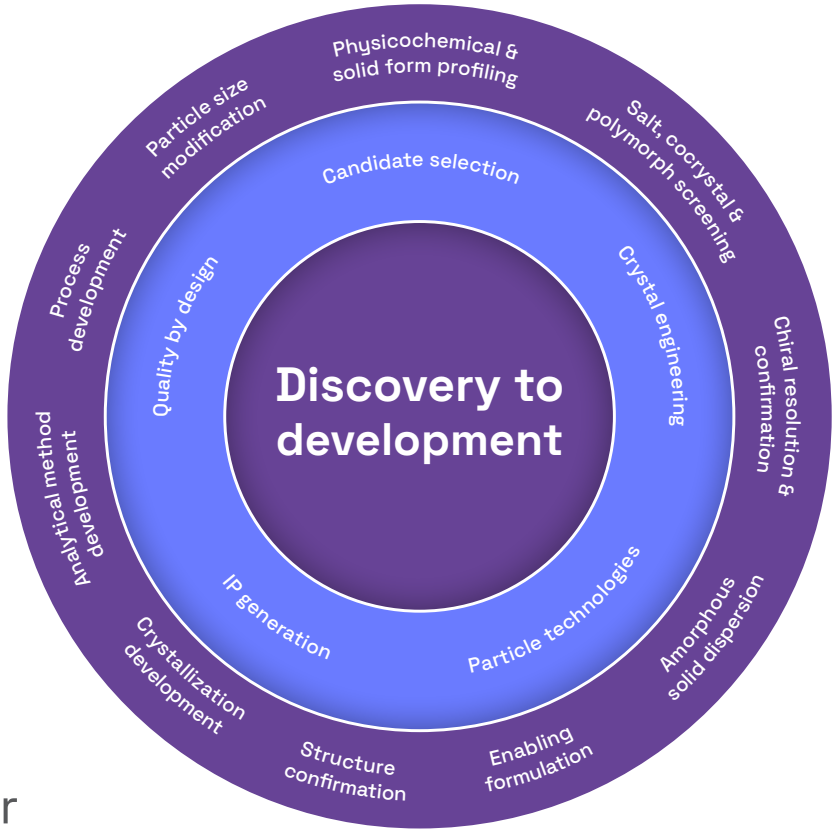
Pharmorphix®
Solid form and particle engineering

Under our Pharmorphix brand, we have a proven track record of delivering excellence for customers in early drug development. By applying our world-leading understanding of solid form sciences, we can improve the properties and success rates of drug candidates for the pharmaceutical industry.

We are a trusted and experienced partner, having completed over 2,000 customer projects on a wide range of structurally diverse and complex APIs. Our scientists have a unique understanding of how best to support customers to progress their compounds through the drug development process.

Our state-of-the-art facility based in Cambridge, U.K., offers one of the most comprehensive arrays of integrated solid form, pre-formulation, particle engineering and chemical development capabilities available to the pharmaceutical and biotechnology industries. We have the flexibility and breadth of expertize to adapt to your project's evolving needs.

Since 2014, our technology has benefitted nearly 1 in 5 of FDA approved small molecule drugs



Helping you overcome development hurdles and accelerate your speed to market

Candidate selection

The early characterization of candidates within a series of structurally similar molecules can reveal critical insights into their developability, allowing you to make informed decisions. We can gain a significant amount of knowledge through solid-form and physicochemical characterization that help direct screening strategies with small material quantities.

Crystal engineering

Crystal engineering is our understanding of how an API can pack in the solid-form resulting in different molecule arrangements or (non-solvated) polymorphs and via the inclusion of water or solvent to form hydrates and solvates. Understanding the interrelationships and intrinsic properties of these solid forms is crucial in establishing their developability and scalability. Moreover, physical property modification via the formation of salts/cocrystals may improve specific physical properties, rendering an API developable, whereas it was not in the free form.

Particle technologies

Particle technologies are a wide range of techniques and capabilities which facilitate API modification, including particle shape, size and surface area, ultimately tuning the properties of the API. Building upon crystal engineering and crystallization development strategies where the “same particle” each time is the goal, frequently additional processing is required to achieve the “right particle”.

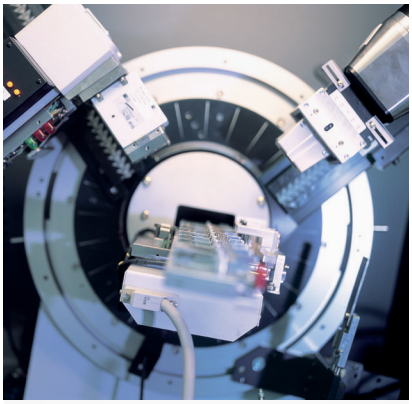
Broadly techniques can be described as top-down, e.g., milling/micronization, or bottom-up, e.g., amorphous dispersions, routinely scaled using spray drying. Multiple technologies and solutions can be assessed at Pharmorphix and starting at relatively small scales and maximizing the chance of success.

IP generation

Much of the work we conduct generates IP by investigating novel solid forms of an API. Solid form screening studies conducted early and rigorously is a well-established approach to either ensure robust protection from future market entrants or potentially extend patent lifespan, limiting generic competition. There are also opportunities to secure IP through novel engineered particles and particle processing such as spray drying. Process IP is also available during the development of a crystallization process that can demonstrate how a hydrate, solvate or anhydrous form is selectively isolated directly from the process.

Quality by design (QbD)

QbD starts with a thorough understanding of the product before developing an optimal process to deliver it. We apply our excellence in material science to understand an API’s intrinsic properties and use a structured development approach that includes design of experiments (DOE), computational modeling, and process analytical technology. Supported by comprehensive analytical development, we can understand the process design space and continually refine our model as we scale up.



Pharmorphix services

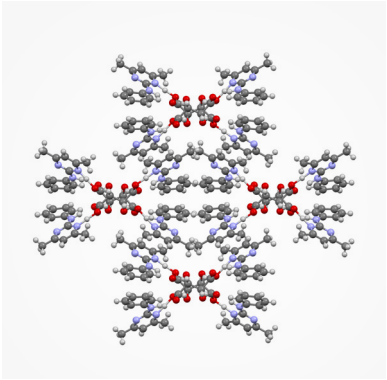
Physicochemical & solid form profiling

Physical and chemical analysis is used to assess the performance of novel crystaline forms, design appropriate salt and cocrystal screens and investigate alternative drug delivery routes. Our physchem data packages provide comprehensive physicochemical characterization for your compound, helping you make informed data-led decisions on how best to progress a candidate, even when material is limited. The insight provided by the combination of physchem with solid form characterization is powerful at all stages of development.

Salt, cocrystal & polymorph screening

Selecting the optimal solid form of an API during early drug development can mitigate the risk of failure later in development. This can be achieved through salt, cocrystal and polymorph screening.

- Salt screening is an approach to quickly identify and assess the salt forms of an API. This allows drug developers to modify the physical properties of an API while preserving the benefits of a crystaline solid form.
- Cocrystal screening can identify and assess the potential cocrystal forms of an API. It provides an alternative approach to modify the physical properties of an API where salts do not achieve the desired performance or are not an option.
- Polymorph screening aims to identify all relevant forms of an API, investigate their properties and choose the optimal crystaline form. Polymorph screening is a regulatory requirement whether a salt, cocrystal or free form compound is chosen for development.



Chiral resolution & confirmation

We offer a classical resolution screening service to identify diastereomeric salts that are effective in the separation of racemic compounds into their single enantiomers, as often required for chiral API and chiral intermediates. For non-ionizable molecules, a separation via the formation of cocrystals could also be explored. Robustness testing and scale-up are supported in-house. The absolute stereochemistry is confirmed by single crystal X-ray diffraction internally by our experts.

Amorphous solid dispersion

Developing a non-crystaline API is an approach that can improve the apparent solubility and oral bioavailability of a poorly water-soluble API. In order to stabilize an amorphous form, the API is combined in a single-phase amorphous mixture, amorphous dispersion, with a polymer to inhibit crystallization over the shelf life of the drug product.

Enabling formulation

By understanding the intrinsic properties of the drug substance, we are able to develop prototype formulations that improve the biological performance of a drug candidate and maximize the chances of success in preclinical toxicology studies.

Structure confirmation

Single crystal X-ray diffraction (SCXRD) is a powerful method that allows us to assign the absolute stereochemistry of chiral centers and determine the structure from the smallest of crystals. Our in-house expertize and state-of-the-art equipment facilitates a standalone service if desired but importantly a capability that runs in parallel with other solid form activities.

Crystallization development

Developing a robust crystallization process to isolate the optimal solid form of an API or intermediate is an essential step in development. Identifying the crystallization approach, solvent system(s), controlling form, crystal habit and delivering a consistent uniform particle size distribution from a single process step can be challenging. Our expertize in solid form, process analytical technology (PAT) and computational modeling underpin our development of crystallization processes, allowing us to deliver the best outcome at the required scale. Existing crystallization issues such as oiling out, isolating the wrong polymorphic form or extended filtration/ drying times can also be addressed.

Analytical method development

Our experts can develop and optimize analytical methods on a wide range of instrumentation and deliver methods for complex compounds throughout early research. These can be validated to GMP standards in line with ICH and FDA/MHRA requirements at our other development sites.

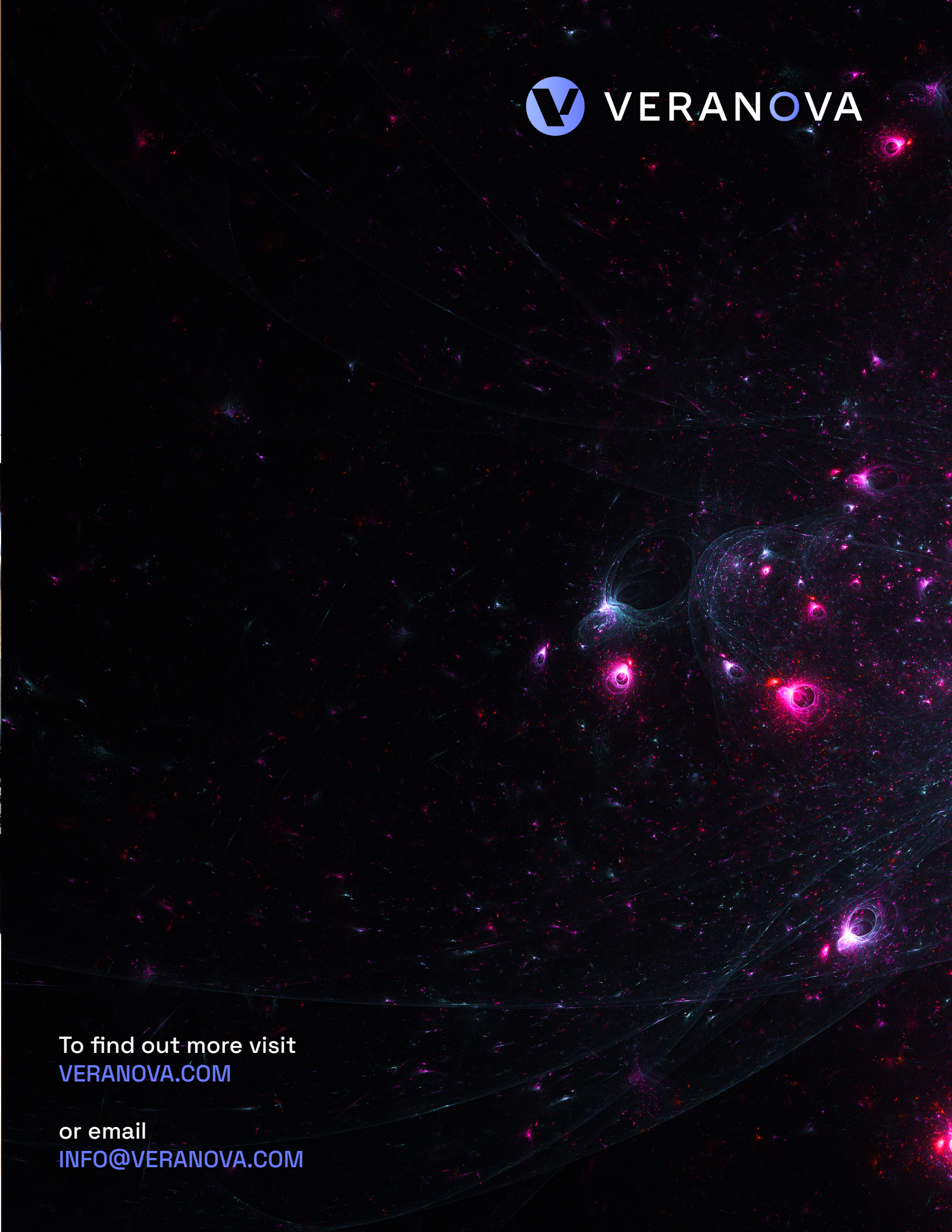
Process development

We carry out phase-appropriate process development from early medicinal chemistry routes through to GMP processes. By combining our expertize across a broad range of chemistries with state-of-the-art process modeling tools, we're able to accelerate development and scale-up.

Particle size modification

Controlling and modifying particle size is important for maximizing the performance of your API. We offer several ways to modify particle size and distribution, including controlled crystallization, spray drying, micronization and milling.

We are able to offer one or multiple services, worked in parallel, to meet your specific reqirements



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