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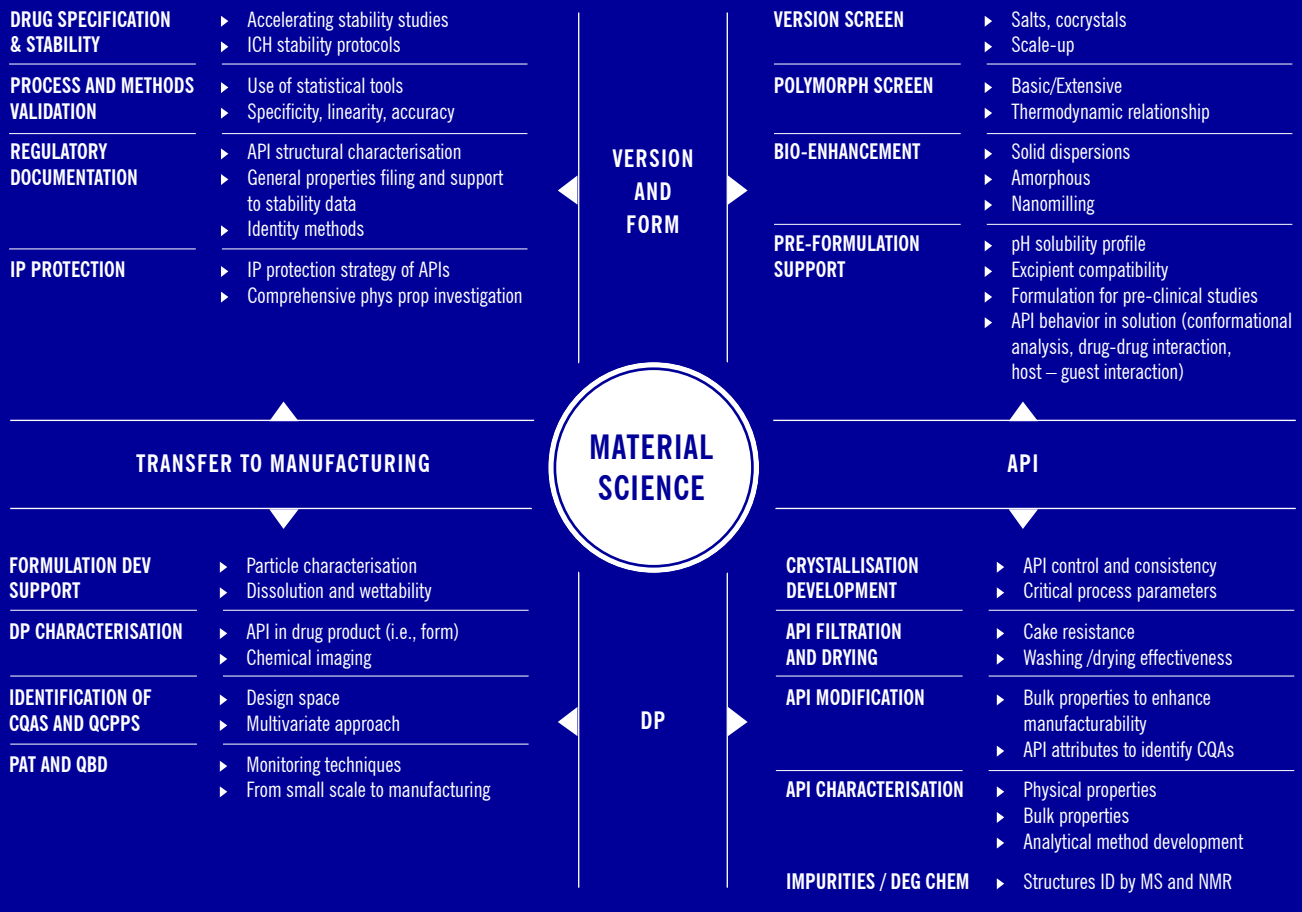
#RESEARCHNEVERSTOPS

MATERIAL SCIENCE: ENHANCING QUALITY OF API AND DRUG PRODUCT

- The solid form matters: deep understanding on how solid form influences API and Drug Product development
- State of the art instrumentation for physical properties characterisation and solid state chemistry with integrated expertise and facilities
- Proven expertise with troubleshooting attitude and recognised reputation in the pharmaceutical material science areas



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Materials Characterisation

- State of the art solid state analytical technologies and recognised expertise including spectroscopy (FTIR, Raman, NMR), diffraction (XRPD, also non ambient and 2D), SAXS, thermal analysis (DSC, TGA, TGA-IR), microscopy (PLM, ESEM+EDX), micromeritics (particle size, surface area, DVS, pycnometry, powder rheology, wettability)
- Method development and cGMP validation: qualitative or quantitative methods on both API and Drug Product (DP)
- Investigational studies: content uniformity, performance determinations (dissolution, bioavailability, flow properties), assessment of materials in troubleshooting investigations (*i.e.* batch-to-batch variability), presence of unknown particles (focusing on API, DP, or delivery devices)
- Strong and close cooperation with external partners for particular solid state techniques, *i.e.* ssNMR, single crystal XRD, synchrotron radiation based x-rays diffraction

API Version/Form Selection and Control

- Salt/Co-Crystal Selection to improve drug performances and enhance physicochemical properties
- Polymorph screening (abridged or extensive) to reduce the risk of failure during development, to meet regulatory requirements and to strengthen Intellectual Property
- Forms thermodynamic-kinetic relationships, relative physico-chemical stability, key properties differentiators, phase diagrams
- Amorphous Dispersions Development to increase solubility and bioavailability
- Crystallisation development to identify and control critical quality attributes of the final API (*i.e.* crystal form, particle size, particle morphology, chemical purity) with a Particle Engineering approach and PAT tools (*i.e.* FBRM, Raman)
- Both robotic screening of solid form and multi-parallel reaction stations on discrete samples

Key points

- Integrated expertise and facilities for both Solid State Chemistry and Physical Properties: same team is following the project from API to DP
- Possibility to serve as analytical service as well as support group to API and DP (stand alone and integrated projects)
- Transfer knowledge from API to DP manufacturing influencing the critical quality attribute and the choice of the final formulation
- High performance and flexibility (adaptable to any turnaround time for data production)
- Focus on data reliability, quality and integrity