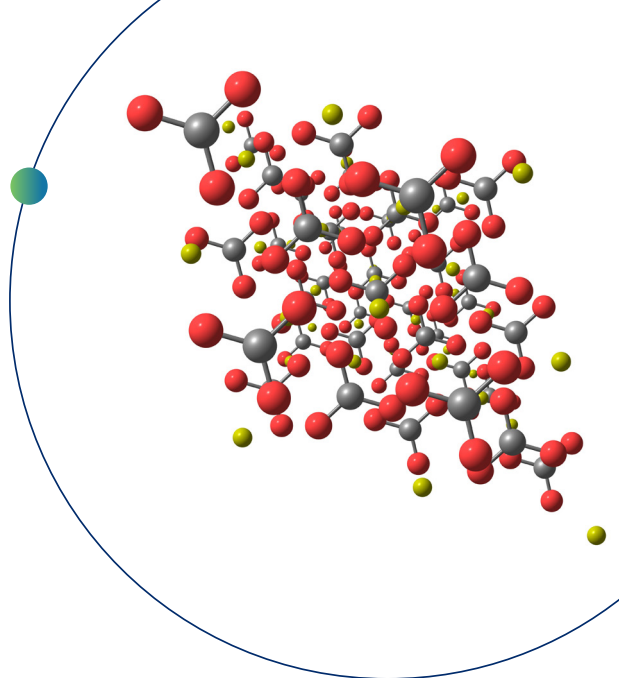


Case Study

Product development in
a challenging IP landscape



Project challenge:

Identification of suitable chiral reagent for chemical resolution, process validation, desired polymorph.

Solution design:

Often API development is bound by IP constraints. In order to develop a scalable and robust process to address IP challenges, the following approach was adopted by the CPS team.

- Non-infringing route to circumvent IP barrier was proposed
- Screening of chiral resolving agents and solvents to yield the maximum efficiency in terms of yield and highest desired enantiomer
- Polymorph screening with different solvent systems and a range of temperatures furnished the requisite
- Process developed in lab was demonstrated in plant by performing three process validation batches yielding the product with desired quality and culminating in regulatory filing

Robust process to address IP challenges

Conclusion:

Our team has demonstrated the ability to develop processes for commercial API that are already in the market with restrictions in IP and enable the submission of a regulatory filing

Thank You



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