

Recent CMC Focused Support

- Planning and oversight of sterile manufacturing at a CMO for a Phase 2/3 clinical program
- DP planning and support of a topical product and an ocular product
- Planning and support of DS, DP and analytical for a Phase 2 asset acquired by a small company from a major Pharma
- Formulation advice in the background to an internal CMC generalist as the client pursues a challenging bioavailability problem with a highly insoluble drug at a technically weak CMO
- CMC and supply chain Diligence of an entire therapeutic area portfolio of a major pharma. Assets ranged from pre-clinical to Phase 2. Supported formation of a newco and overall dev and org planning for the financial acquirer. Now supporting ongoing planning and execution of DS, DP, Tox QA function and DMPK within the new entity.
- DP formulation and manufacturing support for a challenging injectable at a CMO
- DP and QA auditing support for an IND-track ocular program
- Formulation support in the background, QA Auditing support and support of remediation of a CMO to support PAI
- Support of planning and execution of DS development and manufacturing at CMO
- In the background process chemistry advice to CMC team
- Backfill for internal development resources in late stage development of a biologic
- CMC support for oncology combination product including sourcing non-traditional actives, regulatory strategy and IND writing
- Planning and execution of DS as well as submission publishing for IND and P1/2 assets
- DS and DP problem solving, function as Quality Unit
- CMC Regulatory coaching and comparator sourcing
- Manufacturing strategy, planning and execution team for a difficult biologic and for a vaccine. Client is a small molecule company without that core expertise
- DP, CMC Regulatory and launch / supply chain planning for a Phase 3 non-opioid pain product
- CMC planning and execution of an IND track antibody
- CMC support to overcome stability and bioavailability problems with an antibody, Bioanalytical method development and vendor mgmt.