Platform to Advance New Drugs from Solid State Science through Clinical Development to Commercial Brand Management

Partnership
TC&bCMC
TeraCrystal and BrylaCMC-Reg Consulting, LLC

The Partnership of TeraCrystal and Bryla CMC-Reg Consulting, LLC **(TC&bCMC**) consolidates a comprehensive range of combined research expertise spanning many aspects of solid state chemistry with consulting expertise in global CMC drug development of small molecules, peptides and monoclonal antibodies. The partnership of TC&bCMC is able to manage a rapid, risk-reduced and cost efficient progression of drug candidates from discovery through all phases of clinical development and product commercialization, having an edge over its competitors in regards to reliability, expertize, instrumentation, and prices. The main integrated research and consultancy services for drug substance (API) and drug product are described below:

Solid State Chemistry Research, Preformulation and Formulation

- Early-stage solubilization screening of lead candidates for PK studies
- Solid form screening (polymorph, salt, co-crystal) and crystal engineering; solubility enhancement
- Preformulation evaluation; Selection of optimal solid forms
- Drug-excipients compatibility studies for development of various dosage forms; Selection of lead prototypes
- Amorphous solid dispersion screening
- QTTP, QRM and CMC development plan (QbD); Regulatory status of solid state
- Formulation design for water soluble and insoluble small molecules, semisynthetic peptides and monoclonal antibodies (mAb)

Manufacturing and Quality Controls; Solid State Support

- Crystallization process development at lab scale
- Polymorphic purity confirmation in drug substance and drug product
- Detection limits of analytical methods for solid state characterization and control
- Estimation of the amorphous content in drug substance and drug product batches over shelf life
- Manufacturing process development, troubleshooting, scale up, validation and tech transfer
- Phase-appropriate analytical development and validation (physical/chemical-based techniques)

Other CMC and CMC Regulatory Affair Consultancy and External Services

- Drug development/pharmaceutical operations and CMC Regulatory Affair gap analysis
- Preparation and review of module 2/3 electronic regulatory submissions: INDs, IMPDs, NDAs, MAAs, master files and other documents; Expertise in all regional regulations and pharmacopeias
- QbD Quality Controls (CQAs, CMAs, CPPs and QRA), cGMP, 21CFR, batch record review and approval, QP release management
- Clinical supply chain management: packaging, labeling, and distribution
- Negotiations with regulatory authorities, starting materials, organic, inorganic and genotoxic impurities, setting specifications, dating period, and ICH stability programs for clinical studies and registration
- Project and outsourcing management, cGMP audits, due diligence
- Commercial launch preparation and post-approval changes
- Offer network of CMOs and CROs located worldwide to accommodate drug development needs

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TeraCrystal's main area of expertise and technological acumen is the understanding of the relationships between crystallization, solid-state form and properties of pharmaceutical solids. With the right combination of expertise, state-of-the-art equipment and resources, TeraCrystal is ready and well placed to solve the most complex solid state chemistry issues. Additionally, TeraCrystal's experience covers a broad range of analytical techniques including the determination of crystalline structure, able to provide important and rapid information regarding polymorphic purity, solid forms presented in drug product and designing desired solid forms (crystal engineering). The role of TeraCrystal in the partnership is to develop novel crystalline forms of lead compounds useful for further development into effective drugs and define CMC strategies that smooth the path to manufacture.

Bryla CMC-Reg Consulting, LLC, a recognized member of Worldwide Branding for demonstrating strong leadership and excellence in pharmaceutical drug development, complements TeraCrystal with multidisciplinary consulting services on global CMC drug development under cGMP, QbD, QbR and international regulatory requirements from conception of a lead through all phases of clinical development and commercial launch. The firm multifaceted experience and expertise encompasses the design and planning of all aspects of analytical, formulation and aseptic and non-aseptic manufacturing processes development, tech transfer, scale up, phase-appropriate validation, supply chain management, stability programs, assignment of dating period, specifications and impurities management, global CMC regulatory support including technical writing and facilitation of successful negotiations with regulatory agencies, and cost and time effective project management. The organization also leads development of various dosage forms for insoluble compounds and proteins and where appropriate it uses new technologies, which provide measurable increase of bioavailability.

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