

RMC Offers Bolt-on CMC[®] Services



What is Bolt-on CMC[®]?

Bolt-on CMC support provides integrated, team-based management of Chemistry, Manufacturing and Control activities. This includes oversight of such areas as process, analytical and formulation development; quality control and quality assurance; GLP/GMP manufacturing of API and drug product; and packaging/ distribution. Our multi-functional team of experts represents a drug sponsor in coordinating CMC projects across all development stages, from pre-IND to post-approval. We don't simply make recommendations; we actively work to make your project a success.

Why hiring contract manufacturing and testing services is not enough

- Individual CMC contract service organizations only provide pieces of the package
- Information from a range of sources must be smoothly synthesized into a regulatory submission
- CMC activities need to be integrated into the broader project plan, coordinated with other departments such as clinical and regulatory
- Requirements and priorities change over the product lifecycle—RMC's integrated CMC project management ensures appropriate staging of activities as well as incorporation of new information into ongoing decisions
- Sponsor must retain ultimate responsibility for the quality of the product and program

RMC's team advantage

- Our ready-made CMC teams bring together cohesive, multi-functional technical expertise with integrated project management
- RMC's team of CMC professionals gives you easy access to a wide and deep knowledge base
- Efficiency is gained by using RMC's document and project management templates
- RMC's team operates under a single quality management system and philosophy
- Team composition can be tailored to fit each particular project and development stage

How a drug developer benefits from Bolt-on CMC[®]

- Structure the organization rapidly and flexibly by "bolting on" a single interlocking CMC department to oversee and integrate all related activities
- Gain comprehensive coordination of activities performed at all CMC contract services providers
- Develop consistent, stage-appropriate Quality Systems within the company
- Advance early-phase products to a more value-added stage by building and executing a comprehensive CMC strategy

To learn more about RMC's CMC services, contact Tim Joy at (303) 725-7216 or tjoy@rmcpharma.com. You can also visit our website at www.rmcpharma.com for more information.

Testimonial: "RMC has provided us excellent service in the areas of manufacturing advice and supervision, analytics and presentation to potential investors (successfully!) ... They have proven to be very responsive to our requests and easy to work with." - Woody Emlen, President of Taligen Therapeutics