CMC TECH, LLC

CMC Tech, LLC is a BioPharmaceutical consulting company specializing in CMC development and manufacturing, spanning phase 1 through commercial products:

Startups

Process development and manufacturing strategy for Phase 1 through commercial stage. Execution of internal or external clinical supply development & manufacturing, including contractor identification, engagement and management.

Small pharma

CMC leadership, strategy, project management & execution for Phase 1 through commercial internal or external development & manufacturing, including contractor engagement and management.

Multinationals

Due diligence, CMC strategy & execution through commercial manufacturing including contractor engagement and management.

Investors

Strategy and due diligence.

Ken Ford PhD PE
Founder and
Principal Consultant
LinkedIn Kenneth Ford, PhD PE

Experience

Dr. Ken Ford has over 25 years of experience in product strategy, development, scale-up, submissions and tech ops support of solid dosage, sterile product (including vaccines, ophthalmics and lyophilized products), combination products and primary packaging development from pre-clinical through commercial manufacturing.

Previously VP of Manufacturing at Lyndra Therapeutics where he established the manufacturing division, constructed the GMP clinical manufacturing facility and helped move this start-up from an R&D organization to phase 3 pivotal and future commercial readiness.

Ken Ford led the Xiidra® development and manufacturing team at Shire through successful clinical phases to commercial approval and market supply utilizing a CDMO service. He led Xiidra® production divestiture from Takeda (formerly Shire) and incorporation into Novartis. Prior to this, he held product development and pilot plant positions at Merck for vaccines, sterile products, solid dosage products, combination products, primary package development and product stability prediction, including international projects in France and Singapore.

Ken Ford is an AIChE Fellow active in PD2M, PTF & AMPc and a former Section Chair. He serves on the NCEES CHE PE Exam Committee and the University of Rhode Island CHE Dept Industrial Steering Committee. Ken was the 2015 Delaware Valley Chemical Engineer of the Year, a 2009 AIChE Shining Star recipient, Shire CEO Award recipient and Merck Division Award recipient. He is an active mentor for early career talent in the biopharma industry.

Dr. Ford received his PhD in Chemical Engineering from Lehigh University, MSCEP from MIT and BS from the University of Rhode Island. He is also a licensed Professional Engineer.

Notable successes

Rapid, durable and cost-effective strategy and development of several commercial products, phase I through commercial, on aggressive timelines including Xiidra®, Gardasil®, RotaTeq®, Invanz® and Juvisync®, using both internal assets and managing CDMOs.

Establishment of a manufacturing division and 2MM dose/year internal manufacturing plant (during COVID) to move a start-up company from R&D through the clinical phases for multiple products utilizing a unique ultra-long oral dosage extended-release platform.

Multiple successful FDA face to face and written interactions including Type C meetings, Pre-Approval Inspections and presentations/facility tours for the CDER Emerging Technologies Team.

Face to face and submission interactions with international agencies including EMEA, MHRA, Health Canada, Swedish MPA, Mexico's COFEPRIS and others.

Commercial product due diligence, divestiture and aquired product implementation.

Contact

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