

Validation Projects for Solid Dose Products

Background

A mid-sized pharmaceutical company was challenged with a new project that required a new product launch, while also sourcing alternate equipment and completing a Site Transfer operation.

Objective

The primary objective was to provide project management guidance and provide a functional team to complete the validation activities prior to product approval in anticipation of product launch by bringing the new manufacturing line into a fully validated state.

Enhanced Compliance Engagement

Numerous consultants supported the launch effort with the following tasks and documentation activities:

- Master Validation Plans and Master Validation Reports.
- IQ, OQ, PQ, Process validation Protocols and Reports
- Master batch manufacturing records
- Standard operating procedures
- Technical reports and memos
- Non-conformance investigation reports
- CAPA

Additionally, the consulting team provided expertise with the following types of manufacturing equipment.

- Compression Equipment: Korsch XL 400, Courtoy R-100 & R-190, Manesty BB4, Kikusui libra.
- Encapsulation Equipment: Matic 120, MG Futura, Bosch/H&K 1500, Mocon & Precisa 12 Weight Sorter.
- Coating Equipment: Vector HC-170, 48" Accela-Cota
- Milling Equipment: Quadro/U20 Gral 600 & 1200, Quadro/U30 MP-7, Quadro/ 194S, Fitzmill, Glatt Quick Sieve.
- Fluid Beds: Glatt WSG-60 & GPCG 60/120, Niro MP-7.
- High Shear Mixers: Collette Gral 75/600/1200, Glatt VG-200
- Blenders: Bin Blenders, V-Blenders

Result

By applying the strengths of our project management team and engineering experts, the facility efficiently and cost-effectively were able to begin production in their new capacity on schedule, saving money, and most importantly, time.