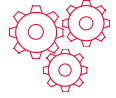


# The Blacksmith's Anvil



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## GOOD MANUFACTURING PRACTICES

Good manufacturing practices (**GMP**) build a common culture for avoiding: wasted time, wasted effort, and controversy. GMP helps ensure our products are safe, effective, and meet standards when assembled and operated using recommended practices and guidelines. GMP supplements QA manuals and industry standards for quality.

GMP requires continuing, consistent, control of production operations in a disciplined manner. Discipline is a keystone for manufacturing operations with insistence on performance within the control limits for all operations.

GMP strives for preventing product deficiencies, and reduces incidences of non-conforming products. It requires a formal corrective action system for fixing problems, including early detection of deficiencies. Corrective action helps maintain predictable manufacturing schedules and thus restrains costs by doing things right the first time.

GMP relies on educated, trained, and skilled personnel in each facility. Each manufacturing operation must have personnel who assure correct performance of the operations, as required by the company, for conducting its business. GMP requires remedial job instructions for employees whose performance produces non-conforming products so as to keep product with errors from mixing with good product. GMP expects appropriate design and installation of production equipment so the job can be performed correctly. Likewise the equipment must be inspected, adjusted, and operated correctly.

GMP expects buildings, where work occurs, will have safe, orderly space. The facilities should be designed and operated for preventing product mix-ups. Regulating plant environments prevents deterioration of manufactured products and allows control of materials. Materials must be segregated, including cleaning agents and other hazardous agents, to avoid corrupting end products. GMP requires receiving, storing, and handling materials for resale in a manner preventing damage, mix-up, contamination, or other adverse effects. GMP also requires receipt and issue of materials for resale must follow procedures including acceptance or rejection of the materials. GMP requires that materials for resale must meet product specifications and have records for traceability. GMP requires securing customer owned materials, identifying, and controlling them to prevent loss of identity.

GMP requires plant activities have clear, written, processing specifications, procedures, and control limits. These details help assure that products conform to the original design, or specific authorized changes in the design, when the goods are shipped to the end user.

Quality control and inspection equipment under GMP must be suitable for the intended purpose and operated so they produce correct results. Records must document periodic equipment calibrations as described in the quality assurance manual. GMP requires records showing results of specific lots of material moving through critical steps in the process. These documents are important certificates of compliance for the manufacturing plan.

Manufacturing novices often think GMP requires tough and unproductive steps. Their opinions change as losses occur from ignoring the GMP lessons learned by experience. GMP insists on good, cost effective, process control.

When you buy products from a facility with GMP, you have assurance the products have high quality.

**Good manufacturing practice is:** Orderly and controlled manufacturing for doing things right the first time. Professionally manufactured products using GMP avoid surprises for the end user and have high quality. The pharmaceutical industry is the largest user of GMP as a keystone of their quality program so that products are manufactured without error—and you appreciate these carefully controlled steps when your family needs health care. GMP helps us keep our jobs for the long run and provides security for you and me.