

Comprehensive cGMP Approaches: From Quality Management to Global Harmonization

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Abstract: *Current Good Manufacturing Practices (cGMP) serve as the foundation of pharmaceutical manufacturing, ensuring that medicines are produced with consistent quality, safety, and efficacy. This review outlines the major components of cGMP, beginning with Quality Management, which integrates Quality Assurance, Quality Control, and Quality Risk Management to establish a strong framework for product reliability. Supporting elements such as Product Lifecycle Management, Product Quality Review, Validation, Sanitation, and Hygiene play a vital role in sustaining compliance and continuous improvement. The system also gives importance to Complaints and Recall Procedures, enabling quick corrective measures to protect patients in case of product defects. Furthermore, well-trained Personnel, properly designed Premises, and comprehensive Documentation, including the Site Master File, are essential to maintain transparency and regulatory readiness. Finally, alignment with Global Standards and Harmonization ensures uniform practices across international markets. Together, these aspects highlight the dynamic role of cGMP in protecting public health*

Keywords: Current Good Manufacturing Practices (cGMP), Quality Assurance (QA), Quality Control (QC), Quality Risk Management (QRM), Product Lifecycle Management

