



GMP FOR CLINICAL TRIALS

Do you know what is in your trial medicine?

Guide to early phase trials and importance of GMP for
Researchers & trial sponsors

The Imperative of GMP in Early Clinical Trials

What is Good Manufacturing Practices (GMP)?

GMP is not just a set of guidelines; it's a commitment to quality and safety. The adherence to GMP standards ensures that every batch of a drug meets quality specifications and is consistent with its intended use. It encompasses all aspects of production, from the starting materials and premises to the training of staff and record-keeping. In the context of early phase clinical trials, where the safety profile and pharmacodynamics of a new drug are not fully established, the margin for error is minimal. The utilization of GMP facilities provides a structured and validated methodology that significantly mitigates risks, ensuring that the clinical trial materials are free from contamination, accurately dosed, and consistently



The Perils of Non-GMP Compounding Pharmacies

While non-GMP compounding pharmacies may offer quicker and less costly solutions, the risks they pose can outweigh the initial advantages. Non-GMP facilities lack the stringent quality control and validation processes inherent in GMP-compliant facilities. This shortfall can lead to inconsistencies in drug formulations, potential contamination, and inaccurate dosing – factors that can compromise the integrity of clinical trial results and, more critically, patient safety. For example,

The absence of stringent cleaning validation protocols in compounding pharmacies significantly heightens the risk of cross-contamination, potentially leading to the adulteration of one

ASPECT	GMP COMPLIANT FACILITIES	NON-GMP COMPOUNDING PHARMACIES
QUALITY ASSURANCE	HIGH. COMPREHENSIVE QUALITY CONTROL MEASURES AT EVERY PRODUCTION STAGE.	VARIABLE. LACK OF STANDARDIZED QUALITY CONTROL.
SAFETY	ENHANCED. RIGOROUS TESTING FOR CONTAMINANTS AND PRECISE DOSING.	COMPROMISED. HIGHER RISK OF CONTAMINATION.
CONSISTENCY	HIGH. REPRODUCIBLE PROCESSES ENSURING BATCH-TO-BATCH UNIFORMITY.	LOW. VARIABILITY IN DRUG FORMULATION AND POTENCY.
REGULATORY COMPLIANCE	FULL COMPLIANCE, FACILITATING SMOOTHER REGULATORY REVIEW AND APPROVAL.	LIMITED OR NONE, POTENTIALLY COMPLICATING APPROVALS.
COST	HIGHER INITIAL INVESTMENT, BUT REDUCED RISK OF TRIAL FAILURE.	LOWER UPFRONT COSTS, BUT HIGHER RISK OF COSTLY ISSUES.
TIMELINE	LONGER SETUP TIME DUE TO STRINGENT PROTOCOLS.	SHORTER SETUP TIME, BUT AT THE EXPENSE OF QUALITY.

Table 1. Comparison of GMP with compounding pharmacy for the preparation of clinical trial material

product with residues from the previous, thereby compromising product purity and patient safety. This becomes risk increases exponentially when considering such sites may handle new chemical entities that have never been administered to humans and thus, have unknown toxicity profiles.

In stark contrast to the rigorous framework of GMP facilities, non-GMP compounding pharmacies conduct no quality control on the finished product. This glaring gap leaves a void of crucial information about the correctness of the dose, potential variability across a batch, and lacks essential data on product performance metrics such as dissolution, drug release, or deposition. This absence of validation and control not only elevates the risk of inconsistent therapeutic outcomes but also poses a significant threat to patient safety and the scientific validity of clinical trial results.

Beware of those who claim GMP but are not licenced.

Navigating the nuanced terrain of GMP-Ready, GMP-Like, or GMP-Light facilities carries inherent risks, as working with an unregistered manufacturer may lead to compliance uncertainties and potential quality compromises, overshadowing the assurance traditionally offered by fully GMP-certified entities. Ask yourself if they were truly 'ready' why have they not undertaken a registration process. The answer is usually simple, they simply do not meet the standards for GMP.

Risks to the participant, researcher & sponsor

In Australia, the responsibility for ensuring the safety and adherence to GMP standards during early phase clinical trials lies heavily with the sponsors and organizers of the trials. Although certain exemptions may be granted, these do not absolve trial sponsors from their duty to ensure product safety. The Therapeutic Goods Administration (TGA) underscores the importance of GMP compliance, particularly in the context of compounding pharmacies involved in clinical trials, to prevent issues related to dosage accuracy, stability, and contamination (TGA, 2021). The Australian Clinical Trial Handbook explicitly states that while exemptions for GMP compliance in early-phase trials are possible under specific conditions, the overarching responsibility for patient safety and product integrity remains with the trial sponsors (Australian Clinical Trial Handbook, 2018).

Conclusion

While the allure of cost and time savings may render non-GMP compounding pharmacies an attractive option for the manufacture of early phase clinical trial materials, the potential risks they harbor, highlight the imperative of adhering to GMP standards. GMP not only fortifies the foundation of clinical trials with robust quality assurance and safety protocols but also aligns with the ethical responsibility towards patient safety. To learn how Ab Initio can support your clinical trial contact us.

ABOUT AB INITIO PHARMA

Ab Initio Pharma, is a licensed GMP manufacturer (TGA Licence: MI-2012-LI-02662-3, APVMA Licence: 3016), specialising in formulating and manufacturing pharmaceutical goods. Ab Initio can take molecules from initial discovery to clinical trial products and commercialization.

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