Good Manufacturing Practice (GMP), which is fit for product manufacturing, can work alongside a complementary quality management system for clinical development.

**GMP FOR PRODUCT MANUFACTURING**

Many pharma/biotech manufacturing companies institute a Quality Management System (QMS) based on GMP. This “checks and balance” approach, known as ICH Q10, falls in line with GMP objectives and measures quality in terms of a product’s ingredients, purity and potency.

The need for precise and consistent product delivery is critical to avoid deviations from the manufacturing protocol that may lead to product rejection.

**GCP FOR CLINICAL DEVELOPMENT**

Unlike product manufacturing where a company uses a “one-size-fits-all” GMP QMS, clinical development requires a tailored, Good Clinical Practice (GCP)-related QMS that will be complementary to GMP, but is flexible to adapt to the nuances experienced in clinical development. Clinical quality centers on patient safety and data integrity.

**WHY A CLINICAL QMS IS ‘TAILOR MADE’ FOR CLINICAL DEVELOPMENT**

The TransCelerate Quality Management System Initiative has identified potential benefits that could be captured from the development of a proactive and flexible conceptual framework that can assist an organization with the creation of a QMS designed to better manage and navigate the complex clinical research environment.

**4 REASONS WHY A QMS DESIGNED FOR CLINICAL DEVELOPMENT IS THE BETTER APPROACH:**

1. **A CLINICAL QMS ACCOUNTS FOR VARIETY IN CLINICAL TRIAL TYPES:**
   No two trials are exactly the same. Because a clinical QMS provides for holistic oversight across trials, it must be flexible to account for this variability.

2. **A CLINICAL QMS FOCUSES ON ERRORS THAT MATTER:**
   In the clinical realm, regulators are focused on preventing and addressing those significant errors that have a material impact to patient safety and data integrity. Dedicating time and resources to minor deviations is inefficient and adds additional burden with little to no value.

3. **A CLINICAL QMS RECOGNIZES THAT RESEARCH TAKES PLACE IN THE CONTEXT OF CLINICAL CARE:**
   The clinical trials infrastructure is ever evolving, but at its core are patients and health care professionals. A clinical QMS provides appropriate oversight of clinical trials, while enabling clinical investigators’ medical judgment and respecting subjects’ rights, safety, welfare and autonomy.

4. **A CLINICAL QMS CAN ADAPT TO CLINICAL TRIAL SITES:**
   Trial sites participating in the diverse clinical trial research environment have different standards of care, staffing, infrastructure and local/regional regulatory requirements. This can have a profound impact on how a sponsor may design a clinical QMS.

As a result of the higher level of variability in a clinical development program, the level of control and scrutiny exercised in a GMP QMS cannot be achieved in the clinical setting. Hence the implementation of a more flexible, risk-based approach and judgment throughout clinical development trials, such as seen in a clinical QMS is needed.

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