

## ORGANIZATION OF MEDICINE QUALITY CONTROL IN PHARMACEUTICAL MANUFACTURING ENTERPRISES

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**Abstract:** The quality control of medicines produced by pharmaceutical manufacturing enterprises is of paramount importance. Given the significant impacts medications can have on human health and well-being, it is imperative that strict quality standards are established and diligently enforced throughout the entire production process. This ensures medications are both safe and effective for their intended medical purposes. To organize effective quality control, pharmaceutical enterprises must implement a robust organizational structure and procedures. At the top of this structure should be a Chief Quality Officer or similar senior executive role dedicated solely to overseeing all aspects of quality assurance. This individual is responsible for developing comprehensive quality policies and protocols, as well as monitoring compliance to safeguard patient safety. Reporting to the CQO should be multiple quality control managers who supervise quality inspectors, analysts and technicians working in production and testing facilities. This article will explore the system of quality control in pharmaceutical enterprises.

**Keywords:** Quality control, system of drug business, medications, serious ramifications, guarantees.

**Introduction:** Quality control is one of the key parts of the drug business. It is fundamental in guaranteeing the security and adequacy of medications, as well as keeping up with the trustworthiness of the production network. In an undeniably globalized world, with complex stock chains and developing interest for prescriptions, the significance of value control couldn't possibly be more significant. The expected results of lacking quality control in the drug business are sweeping and can have serious ramifications for the two patients and the business overall.

Unfortunate drug quality control can prompt the creation and circulation of inferior quality meds. These can cause destructive secondary effects, treatment disappointments, and even passing. Likewise, the presence of fake or inadequate medications can harm the standing of drug organizations, prompting loss of purchaser trust and monetary difficulties.

The effect of low quality control on patients can especially demolish. Patients depend on the security and adequacy of the medications they consume to keep up with or work on their wellbeing. At the point when the quality confirmation of these drugs is compromised, not just the wellbeing of individual patients can be hurt yet in addition trust in the medical services framework all in all. Besides, this can bring about loads on the medical care framework because of the need to treat intricacies emerging from the utilization of horrible score medicine.

At last, low quality control can have more extensive cultural ramifications. The spread of medication safe diseases, for instance, can be exacerbated by the utilization of unacceptable or fake anti-infection agents. This can make it more moving for medical services suppliers to treat contaminations and eventually lead to expanded dreariness and death rates over the long-term. Pharmaceutical natural substances are the structure blocks of the medications that patients consume.

They assume a basic part in deciding the wellbeing, viability, and item quality. Just while these structure blocks are of the ideal quality could the severe norms for patient security at any point be met.

Inadequate unrefined components can bring debasements or foreign substances into the last medication item, which can present critical dangers to patient wellbeing. Additionally, the utilization of sub-par unrefined components can bring about drugs with decreased power or soundness, possibly prompting treatment disappointments or antagonistic responses in patients. Thusly, quality control methodology and essential and pertinent tests on unrefined components are expected for the development of both protected and compelling medications

A viewpoint that ought not be ignored is that globalization has significantly expanded the intricacy of the drug store network. With providers situated in different nations, each with its own administrative structure and quality control norms, guaranteeing the nature of unrefined components can challenge.

This makes it considerably more basic for pharma organizations to lay out standard working strategies and quality administration frameworks and work intimately with their providers to guarantee the nature of the unrefined components they procure. The drug industry uses different kinds of natural substances in the creation of medications, including dynamic drug fixings (APIs), excipients, and bundling materials. How about we unload what takes cover behind every one of these terms [5,6].

#### Dynamic drug fixings (APIs)

Dynamic drug fixings (APIs) are the essential parts answerable for the significant capability of remedially dynamic plans. The nature of APIs is indispensable to the security and adequacy of the eventual outcome. The immaculateness, power, and strength of APIs should be thoroughly tried to guarantee they meet the necessary details.

For instance, in the event that a Programming interface has debasements or a lower strength than determined, it may not give the ideal impact, or it might cause surprising secondary effects. To guarantee the nature of APIs, drug organizations should comply to severe rules and direct in-process testing and completed item testing.

A few notable instances of APIs are acetaminophen and ibuprofen that large number of individuals overall require consistently for relief from discomfort.

#### Excipients

Excipients are the dormant fixings utilized in drug definitions to help with the assembling system, upgrade solidness, and work on the appearance or taste of the completed items. While they don't make an immediate helpful difference, the nature of excipients is fundamental to guarantee the general security and viability of the restorative specialists.

For example, an inadequately picked or polluted excipient may make the medication debase quicker, diminishing its viability, or may cause unfriendly responses in patients.

Accordingly, it is essential to perform applicable tests and guarantee legitimate quality control on excipients to guarantee they satisfy quality guidelines and are viable with the Programming interface and different parts of the medication definition.

Regularly utilized excipients are lactose, cellulose, dextrose and numerous others. Some of the time, individuals can be susceptible to excipients, despite the fact that they satisfy all security guidelines. That is the reason they are much of the time referenced unequivocally on the bundling of medications and in the patient data handout.

#### Bundling materials

Bundling materials, like compartments, terminations, and marks, assume a crucial part in safeguarding and saving the medication item all through its timeframe of realistic usability. Great bundling materials are important to keep up with the strength, intensity, and security of the medication and to forestall pollution or altering.

Bundling materials ought to be exposed to quality control techniques to guarantee framework reasonableness for the particular medication item, and they should agree with pertinent guidelines. For example, a few immunizations are bundled in vials that are golden in variety to shield the items from light.

Then again, drugs that are poisonous or represent a high gamble of mischief whenever ingested unintentionally by youngsters require kid safe terminations. For instance, remedy narcotics are normally bundled in bottles with youngster safe covers to forestall coincidental ingestion by kids.

#### Other helper materials

Notwithstanding these essential classifications of unrefined substances, the drug business likewise utilizes different helper materials, like solvents, impetuses, and process helps, which are associated with different phases of medication creation.

These materials should likewise go through quality control and follow administrative principles to guarantee they don't present debasements or in any case compromise the nature of the completed item. For example, ethanol is a regularly involved dissolvable in drug fabricating, particularly in the creation of fluid and semi-strong measurements structures like arrangements, suspensions, and gels.

Ethanol should fulfill quality guidelines to guarantee that it is liberated from pollutions, for example, methanol, which can be poisonous whenever ingested. Moreover, the grouping of ethanol should be painstakingly controlled to forestall unfavorable consequences for patients, like liquor inebriation or disturbance of the skin or mucous membranes. The drug store network is a complex, multi-stage process that includes different partners, from natural substance providers to makers, wholesalers, and medical services suppliers. Quality control experts assume an imperative part at each phase of this cycle to guarantee the security, viability, and trustworthiness of the last medication item.

At the unrefined substance obtainment stage, quality control measures include investigating and testing the materials to guarantee they meet laid out details. This assists with forestalling the presentation of toxins, pollutants, or unacceptable materials into the assembling system.

Organizations foster powerful provider capability and reviewing cycles to confirm that their providers keep up with excellent principles and conform to significant guidelines. At times, this might include leading nearby reviews or mentioning outsider testing authentications for the unrefined substances.

During the assembling stage, QC offices supervise observing and controlling the creation cycle, approving gear, and confirming adherence to great assembling rehearses (GMP). By keeping up with severe quality control during assembling, the business can guarantee that the last medication items fulfill the necessary guidelines for wellbeing, viability, and pass soundness testing.

In-process item testing, for example, examine tests to gauge the strength of APIs or disintegration tests to survey the rate at which the medication is set free from its dose structure, can give significant data about the nature of the medication item and consider remedial move to be made if important.

Quality control likewise assumes a huge part in the bundling and naming phases of the drug store network. Guaranteeing that bundling materials meet quality necessities keeps up with the respectability of the medication item during capacity and transportation.

Precise marking is fundamental for furnishing medical care experts and patients with the right data about drug utilization, dose, and possible incidental effects. To guarantee the precision and consistence of marking, drug organizations should lay out and follow strong techniques for name configuration, survey, and endorsement.

At last, during the appropriation stage, preventive activities stop the invasion of fake medications into the inventory network and guarantee the legitimate dealing with and capacity of medication items. We will dive further into this in the following segment, where we will more deeply study the significance of administrative guidelines.

**Conclusion:** With a well-organized quality control system governed by clearly defined roles, responsibilities, procedures and competencies, pharmaceutical enterprises can reliably assure the consistent production of safe and effective medicines. This protects public health and upholds the reputation of the industry. Constant evaluation and improvement of the quality management system also helps enterprises comply with ever-evolving regulatory standards and meet rising quality expectations. Ultimately, such robust quality oversight enables enterprises to realize their goal of helping patients through the provision of high-quality medicines.

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