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Pharmaceutical Dosage Form Design





YS Tanwar
A Sharma

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CHAPTER

4

Quality Management in Pharmaceutical Industry

INTRODUCTION

Quality management plays a key role in the pharmaceutical industry. To ensure that products are safe and effective, manufacturing processes are subject to strict legal conditions. National and international authorities constantly monitor the manufacturers' adherence to regulations. The directives and procedural instructions for validation require companies in the industry to document the entire logistics chain in full - from goods inwards to delivery, and from the development of new preparations to the maintenance of mixers and packaging lines.

Drug regulatory authorities (DRAs) must play a leading role in any quality assurance (QA) effort. A good QA system has many interlinked components, which must be applied in concert to be effective. The major challenge for many resource-limited countries is priority—how best to allocate limited resources to accommodate the greatest needs in both technical (e.g. registration, laboratory testing, inspection, etc.) and managerial (e.g. laboratory management, documentation, training, etc.) areas of regulation.

- **Quality:** The total set of characteristics of a product or services that affects its ability to satisfy a customer's stated or implied needs.
- **Quality system:** The organized structure, responsibilities, procedures, processes and resources for implementing quality management.
- **Quality assurance:** It is the sum total of the organized arrangements with the objective of ensuring that products will be of the quality required for their intended use.
- **Good manufacturing practices (GMP):** It is that part of quality assurance which is aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use.
- **Quality control:** It is that part of GMP which is concerned with sampling, specification and testing, documentation and release

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procedures which ensure that the necessary and relevant tests are performed and the product is released for use only after ascertaining its quality.

QUALITY CONTROL AND QUALITY ASSURANCE

The pharmaceutical industry is one of the most regulated activity sectors, where regulation includes specific quality systems such as good laboratory practice (GLP), good clinical practice (GCP) and good manufacture practice (GMP). The principles of many of these practices mainly cover the formal quality aspects of a procedure and do not evaluate the technical aspects in depth. The challenge is, therefore, to develop quality systems, compatible with various principles, that not only cover formal quality items, but also ensure good scientific and technical performance.

Medicines must be pure, safe and effective. That's why research, development and production are inextricably linked to compliance with global and local rules for the pharmaceutical industry. Pharmaceutical companies must satisfy the GMP directives. Good manufacturing practices (GMP) ensures that pharmaceutical products are made consistently and inspected in accordance with quality standards. GMP gives guidelines for production facilities, personnel, procedures and documentation. In order to fulfill the strict criteria, companies constantly invest in quality management at their chemical and pharmaceutical production facilities. Concern for quality is the thread from R and D, through the various phases of clinical research, to large-scale production. Quality management is essential for safe products, reliable processes and satisfied customers.

Quality Control

Quality is defined as the totality of feature and characteristics of a product or service that bear on its ability to satisfy stated or implied needs. Quality control (QC) covers all activities and practical techniques for securing quality of the manufactured product. These include design analysis, statistical sampling with inspection for defects, etc. as well as evaluation of raw material and finished products with adequate documentation before release.

Quality control is basically checking or testing, that specifications are met, or the regulatory process through which the industry measures actual quality performance, compares it with standards, and acts on

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the difference. According to ISO 9000 quality control is "the operational techniques and activities that are used to fulfill requirements for quality."

The quality control department can monitor production process and indicate where the process is deviating from control standards, supply statistical data and constructive comments and help in producing quality product. Thus the job of quality control department is to take samples at every step during production and evaluate them for desired specifications. QC performs the following functions:

- It should approve specifications and testing methods for active ingredients, raw materials, intermediate and finished products, packaging material; sampling procedures; reprocessing procedures for recovered materials or rejected batches; review production records and related to quality of products.
- It should ensure the stability of active ingredients as well as excipients
- Approval or rejection of components, products, containers and closures, packaging materials
- Instructions regarding sanitation and hygiene.

Quality control is of crucial importance to the pharmaceutical industry, and for this reason numerous checks are made at every stage of production to ensure that quality is not compromised and that the code of good manufacturing process is adhered to quality control procedures include:

1. **Sampling of raw materials:** All incoming raw materials are initially quarantined, and samples are taken and tested to ensure that the material meets strict purity guidelines. This testing involves both microbiological and chemical testing, as is laid out in the relevant pharmacopeia.
2. **In-process checks:** The manufacturing staff carries out checks on such things as tablet weight and size at frequent intervals. At hourly intervals the quality control staff takes samples to check for contamination and to ensure that composition is as expected.
3. **Final product checking:** Checking similar parameters to those measured during production.
4. **Monitoring cleaning:** When a batch of a certain drug has been made, all equipment that has been used must be cleaned. When the next pharmaceutical to be made on that line is going to be different, this cleaning must be particularly thorough to prevent contamination. In this instance, after cleaning the quality control staff takes swabs off each piece of equipment, and tests them to

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see if they can detect the presence of the active previously used. Only when the equipment is so clean that the previous active is undetectable can the production of the next pharmaceutical commence.

The results of all of these tests are recorded on the batch records for the pharmaceutical, as well as the name and batch number of the pharmaceutical made immediately prior on the same production line.

In terms of laboratory testing, over the past 10 years there has been a major change in the equipment that is used. Ten years ago the laboratory was normally equipped with a ultraviolet-visible (UV-Vis) spectrophotometer, analytical balance, tablet disintegrator and analytical glassware. Nowadays pharmaceutical laboratories also include high pressure liquid chromatography, gas liquid chromatography, infra-red spectrophotometers, and dissolution testing apparatus as standard items.

Quality Assurance

Quality assurance (QA) refers to planned and systematic production processes that provide confidence in a product's suitability for its intended purpose. It is a set of activities intended to ensure that products (goods and/or services) satisfy customer requirements in a systematic, reliable fashion.

Quality assurance can be defined as the activity of providing evidence needed to establish confidence among all concerned that the quality function is being effectively performed. According to ISO 9000 QA is "all those planned and systematic activities implemented to provide adequate confidence that an entity will fulfill requirements for quality".

Two key principles characterize QA: "fit for purpose" (the product should be suitable for the intended purpose) and "right first time" (mistakes should be eliminated). QA includes regulation of the quality of raw materials, assemblies, products and components; services related to production; and management, production and inspection processes.

Quality assurance department is a broad based department, which is concerned with many quality related activities such as quality planning, quality control, quality improvement, quality audit, and reliability. Quality assurance involves "building-in" the quality into the product right from the raw material stage to the time, it is used by the patient. Quality assurance in pharmaceutical companies embodies the efforts to assure that products have strength, purity, safety and efficacy

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as intended. For new drug products, quality assurance has also become that effort which is needed to satisfy the doctor and patient and to achieve an established standard of excellence. The total effort requires that sound and safe working relationships be developed among the QA and R and D and production departments. QA is an integrated and economically sound activity involving quality planning; product and process development and a well-documented and validated system. The purpose of QA program is to devise and implement system and procedures that provide a high probability that each dose or package of a pharmaceutical product will have homogeneous characteristics and properties (within reasonably acceptable limits) to ensure both safety and efficacy of formulation. The following are the functions of quality assurance department:

- Products are designed and developed in a way that takes into account requirements of GMP and the defined quality attributes
- Manufacture and control procedures are clearly specified
- Managerial responsibilities are clearly defined
- Arrangements for manufacture, supply and use of correct raw material and packaging material are made (vendor control)
- All appropriate controls on intermediate products and any other in process quality control arrangements and validation have been carried out
- The finished product has been correctly processed and checked according to defined procedures
- Products are not sold or supplied, before the certification by qualified person that each product batch has been manufactured and checked accordance with requirements
- Satisfactory arrangements exist to ensure that the products are stored distributed and subsequently handled so that quality is maintained through out, the designated or expected shelf life
- A procedure for self-inspection and/or quality audit, which regularly appraise the effectiveness and applicability of the QA system
- To ensure that a valid formulation is assigned
- To qualify the process that will be scaled upto production size batches
- To assist in the design of validation protocol
- To manufacture bio-batches for the clinical trial
- To work with production and engineering to develop and carry out the qualification program for production equipment and facilities process systems

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- To develop validated analytical methods for raw material, packaging material, intermediates, finished product, and also for quality program.

Quality assurance is the activity of providing evidence needed to establish quality in work, and that activities that require good quality are being performed effectively all those planned or systematic actions necessary to provide enough confidence that a product or service will satisfy the given requirements for quality. QA introduces the rules 'fit for purpose' and 'do it right the first time'. It can be achieved by introducing appropriate standard operating procedures (SOPs) in-house. In real-world application, establishing SOPs is a very useful concept for managing quality aspects. Despite the need to improve on processes, as times change and things evolve, SOPs are considered by some as a business catchphrase used to describe the process of developing and following a standard way of doing things that multiple organizations can use for management, policy, especially quality systems.

1. **SOP:** An SOP is a set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Every good quality system is based on its SOPs.

   In drug development, the International Conference on Harmonization (ICH) defines SOPs as 'detailed, written instructions to achieve uniformity of the performance of a specific function'. SOPs are necessary for drug development-whether it concerns a pharmaceutical company, a contract research organization, an investigator site, or any other party involved to achieve maximum safety and efficiency of the performed clinical research operations. SOPs provide procedural information about what needs to be completed to fulfill the obligations of the regulations and provide auditors and regulatory authority inspectors a tool to monitor adherence.

   The presence of these quality documents is essential when inspections take place, since the most frequent reported deficiencies during inspections are the lack of written SOPs and/or the failure to adhere to them. The risk of non-compliance is high at organizations with a poor availability of drug development specific SOPs and also, if at all they are available, the staff or the people for whom they were written are not either aware of them or their need. It therefore becomes very important for the staff to train them on these SOPs so that they are actually aware of why and how SOPs

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can play an important role in fulfilling the ICH and other regulatory requirements.

2. **Inspections and audits:** Before any inspection or audit starts, it is customary for the inspector or the auditor to read the current SOPs for the relevant field. This is to judge the compliance of SOPs, as to how sincerely they are used by the related personnel, following ICH and other applicable regulatory guidelines.
   During inspection the inspectors generally ascertain that appropriate SOPs are available; edition numbers are correct and all obsolete editions have been withdrawn from circulation; distribution lists are still correct; SOPs are effective, not leaving parts of the working procedures uncontrolled; whether the SOP conveys a process that is effective in achieving compliance with requirements/ standards, whether the process that is described in the SOP is an efficient way of performing the task; can the requirements of the SOP be enforced; and whether the SOP training records for the staff are in place.
3. **QA paradigms:** One of the most widely used paradigms for QA management is the PDCA (Plan-Do-Check-Act) approach. In order to have the PDCA approach, SOPs may be tailored for--pre-clinical, clinical, bio-analysis and pharmacokinetics, regulatory affairs, pharmacovigilance/drug safety, project management, data management, quality assurance including inspections by competent authorities, external vendor management, crisis management (including product recall), supply chain management and change control procedures.

Quality Assurance versus Quality Control

- Quality assurance refers to the process used to create the deliverables, and can be performed by a manager, client, or even a third-party reviewer. Examples of quality assurance include process checklists, project audits and methodology and standards development.
- Quality control refers to quality related activities associated with the creation of project deliverables. Quality control is used to verify that deliverables are of acceptable quality and that they are complete and correct. Examples of quality control activities include inspection, deliverable peer reviews and the testing process.
- Quality assurance is an integrated function of assuring one and all the resources available (facility, equipment, personnel, services)

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and the processes procedures involved provides the quality attributes to the product the first time and every time. This is achieved by a well documented, validated, and audited system.

- Quality control is the regulatory process through which we measure actual quality performance, compare it with standards, and act on the difference. The testing involves probability sampling. It is basically control/check action carried out at different stages of manufacture.
- Quality control, the control function is an integral part of over all QA. QC function can be minimized and may be eventually eliminated by a well documented and validated system and procedures. This will ultimately lead to batch release without end product testing.
- Quality control is about adherence to requirements. Quality assurance is generic and does not concern the specific requirements of the product being developed.
- Quality assurance activities are determined before production work begins and these activities are performed while the product is being developed. In contrast, quality control activities are performed after the product is developed.

GOOD MANUFACTURING PRACTICES

Good manufacturing practice (GMP) is a term that is recognized worldwide for the control and management of manufacturing and quality control testing of foods, pharmaceutical products, and medical devices. An extremely important part of GMP is documentation of every aspect of the process, activities, and operations involved with drug and medical device manufacture. GMP requires that all manufacturing and testing equipment has been qualified as suitable for use, and that all operational methodologies and procedures (such as manufacturing, cleaning, and analytical testing) utilized in the drug manufacturing process have been validated (according to predetermined specifications), to demonstrate that they can perform their purported function(s).

Good manufacturing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use. These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective.

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GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix up, and errors. GMP regulations address issues including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling.

The World Health Organization (WHO) version of GMP is used by pharmaceutical regulators and the pharmaceutical industry in over one hundred countries worldwide. The European Union's GMP (EU-GMP) enforces more compliance requirements than the WHO, GMP, as does the Food and Drug Administration's version in the US. Similar GMPs are used in other countries, with Australia, Canada, Japan, Singapore and others having highly developed/sophisticated GMP requirements. In the United Kingdom, the Medicines Act (1968) covers most aspects of GMP in what is commonly referred to as "The Orange Guide", because of the color of its cover, is officially known as *The Rules and Guidance for Pharmaceutical Manufacturers and Distributors*.

Since the 1999 publication of *GMPs for Active Pharmaceutical Ingredients*, by the International Conference on Harmonization (ICH), GMPs now apply in those countries and trade groupings that are signatories to ICH (the EU, Japan and the US), and applies in other countries (e.g. Australia, Canada, Singapore) which adopt ICH guidelines to the manufacture and testing of active raw materials.

The GMPs are enforced in the United States by the FDA; within the European Union, GMP inspections are performed by National Regulatory Agencies (e.g. GMP inspections are performed in the United Kingdom by the Medicines and Healthcare Products Regulatory Agency (MHRA); in the Republic of Korea (South Korea) by the Korea Food and Drug Administration (KFDA); in Australia by the Therapeutical Goods Administration (TGA); in South Africa by the Medicines Control Council (MCC); in Brazil by the Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency Brazil) (ANVISA); in Iran, India and Pakistan by the Ministry of Health.

Personnel

The ICH Q7 requires that there should be an adequate number of personnel qualified by appropriate education, training and/or experience to perform and supervise the production of intermediates and APIs. Training for personnel engaged in production and quality control of drugs is needed. For production personnel with direct contact with drugs, a physical examination should be at least annually

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conducted. In general, GMP focuses more on personnel hygiene in clean rooms.

The training received by an employee should be documented. It is important that personnel be trained in aseptic procedures. It is the ethical responsibility and human ethics that will play the important role in the attainment of GMP.

Number of personnel employed shall be adequate and in direct proportion to the workload. All personnel shall wear clean body coverings appropriate to their duties. Before entry into the manufacturing area, there shall be change rooms separate for each sex with adequate facilities for personal cleanliness such as wash basin with running water, clean towels, hand dryers, soaps, disinfectants, etc. The change room shall be provided with cabinets for the storage of personal belongings of the personnel.

The personnel handling Beta-lactum antibiotics shall be tested for penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall be periodically examined for adverse effects. These personnel should be moved out of these sections (except in dedicated facilities), by rotation, as a health safeguard.

Smoking, eating, drinking, chewing or keeping plants, food, drink and personal medicines shall not be permitted in production, laboratory, storage and other areas where they might adversely influence the product quality.

Building and Facilities

The factory building(s) for manufacture of drugs shall be so situated and shall have such measures as to avoid risk of contamination from external environmental including open sewage, drain, public lavatory or any factory which product disagreeable or obnoxious odor, fumes, excessive soot, dust, smoke, chemical or biological emissions.

Pharmaceutical companies should be located in a clean environment, e.g. the location/site with less industrial pollution. The general layout of the production, administration, living, and ancillary areas should be appropriately arranged. Whether buildings are appropriately located in accordance with the production process flow and the required air cleanliness classes, is considered to be one of the critical items during inspection for GMP certification. The walls and floors of the areas where manufacture of drugs is carried out shall be free from cracks and open joints to avoid accumulation of dust. These shall

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be smooth, washable, covered and shall permit easy and effective cleaning and disinfection. The interior surfaces shall not shed particles. A periodical record of cleaning and painting of the premises shall be maintained. The production and dispensing areas shall be well lighted, effectively ventilated, with air control facilities and may have proper air handling units (wherever applicable) to maintain conditions including temperature and, wherever necessary, humidity, as defined for the relevant product.

There must be adequate lighting, ventilation, screening, and proper physical barriers for all operations including dust, temperature, humidity, and bacteriological controls. The firm must provide adequate space for the placement of equipment and materials to prevent mix-ups in these operations-receiving, sampling, and storage of raw material; manufacturing or processing; packaging and labeling; storage for containers, packaging materials, labeling, and finished products; production and control laboratories. There must: be adequate blueprints, which describe the high purity water, HEPA, and compressed air systems. There are adequate requirements for clean rooms in GMP **(Table 4.1)**. Air supplied to the non-sterile preparation or formulation area for manufacturing solutions prior to sterilization should be filtered as necessary to control particulates. Air being supplied to product exposure areas where sterile drugs are processed and handled should be high efficiency particulate air (HEPA) filtered under positive pressure. Specifications for viable and non-viable particulates must be established. Specifications for viable particulates must include provisions for both air and surface sampling of aseptic processing areas and equipment. Cleanliness specifications or levels of non-viable particulate contamination must be established.

Table 4.1: Air classification

Clean Area Classification (0.5 µm particles/ft^3)	*ISO 14644-1 Designation*	*≥ 0.5µm particles/m^3*	*Microbiological Active Air Action Levels (Diameter CFU/m^3)*	*Microbiological Setting Plates Action Levels (Diameter 90mm; CFU/4 hours)*
100	5	3,520	1	1
1000	6	35,200	7	3
10,000	7	352,000	10	5
100,000	8	3,520,000	100	50

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The manufacturing premises shall be cleaned and maintained in an orderly manner, so that it is free from accumulated waste, dust, debris and other similar material. A validated cleaning procedure shall be maintained.

Production Area

The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations. In order to avoid the risk of corss-contamination, separate dedicated and self-contained facilities shall be made available for the production of sensitive pharmaceutical products like penicillin or biological preparations with live microorganisms. Separate dedicated facilities shall be provided for the manufacture of contamination causing and potent products such as Beta-Lactum, sex hormones and cytotoxic substances.

Working and in-process space shall be adequate to permit orderly and logical positioning of equipment and materials and movement of personnel to avoid cross-contamination and to minimize risk of omission or wrong application of any manufacturing and control measures. Pipe-work, electrical fittings, ventilation openings and similar services lines shall be designed, fixed and constructed to avoid creation of recesses. Services lines shall preferably be identified by colors and the nature of the supply and direction of the flow shall be marked/indicated.

Material Management

According to GMP, the management systems for purchase, storage, dispatching, and use of materials used for production should be established.

- Changing the source of supply of critical raw materials should be treated according to change control
- Materials stored in fiber drums, bags, or boxes should be stored off the floor and suitably spaced to permit cleaning and inspection
- Sampling should be conducted at defined locations
- Materials should be re-evaluated to determine their suitability for use
- Full analysis should be conducted on at least three batches before reducing in-house testing.

Production Management

There are mainly four kinds of production management documents, e.g. master formula, job position instruction, standard operating

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Salient Features

- Provides latest and informative knowledge in academia and pharmaceutical industry with both basic and applied principles for the dosage form design.
- Also includes complete range of concepts of dosage form development applied in modern pharmaceutical sciences.
- Figures are used extensively to illustrate complex concepts and multifaceted processes.
- References are provided to enable readers to continue investigating a particular topic in depth.
- Up-to-date information on various aspects of excipients and its role on formulation development.
- Outlines an updated preformulation program for modern drug development issues that includes particle morphology, characterization, thermal analysis, drug excipients compatibility.
- Provides comprehensive overview of the major aspects of the prediction of drug degradation and shelf-life, presents up-to-date approaches to pharmaceutical stress testing.
- This text supplies new and must-have information regarding the good manufacturing practices (GMPs), standard operating procedure, validation procedure, ISO 9000, total quality management (TQM).
- Focuses on the application of dissolution testing to the quality control of drug products, practical issues in design of dissolution tests. It includes regulatory requirement of dissolution tests and in vitro-in vivo correlation (IVIVC) relationships.
- Breaks the subject down to its simplest form and includes numerous examples with latest advances in the use of polymers in dosage form.
- Addresses the applications and approaches of advanced drug delivery systems including transdermal, nanoparticles, liposomes, resealed erythrocytes, dendrimers, etc.
- Comprehensive overview of the role of packaging and labeling in the development and delivery of pharmaceutical and medical devices.

YS Tanwar PhD MPharm (Pharmaceutics) is Professor and Head, Department of Pharmaceutics, Bhupal Noble's College of Pharmacy, Udaipur, Rajasthan, India, with more than 16 years of teaching and research experience. He has supervised 72 dissertations and thesis of MPharm. He is the approved Supervisor for PhD programme at many reputed universities including Rajasthan University of Health Sciences, Jaipur; and, presently, eight students are working under his guidance. He has published 47 research papers and review articles in national and international journals of repute. He has completed research projects of Department of Science and Technology (DST). He is Editor-in-Chief of Journal of Global Pharma Technology. He is also reviewer and referee of many international journals. He is expert and advisory board member in many universities, institutes and organizations throughout India. He is Life Member of Association of Pharmaceutical Teachers of India (APTI) and former Vice-President of APTI-Rajasthan State Branch.



A Sharma PhD (Sub) MPharm (Pharmaceutics) is an Assistant Professor, Department of Pharmaceutics, Bhupal Noble's College of Pharmacy, Udaipur, Rajasthan, India, with 10 years of teaching experience. He completed his MPharm dissertation work under the guidance of Professor YS Tanwar. He has published 15 papers in national and international journals. He completed the Department of Science and Technology project on Nanostructural Constructs for Treatment of Amoebiasis.

He is also reviewer, referee and editorial board member of many national and international journal. He is the approved Supervisor in Rajasthan University of Health Sciences, Jaipur and Pacific University, Udaipur. He is Life Member of Association of Pharmaceutical Teachers of India (APTI) and Indian Pharmacy Graduate Association (IPGA).



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