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Quality Management System

Trupti Maloji Shelar[1], Shruti Narayan Jadhav[2], Pradnya Vijay Chavan[3], Sanika Chandrakant Deokate[4]

[1,2,3,4]Students, Late Laxmibai Phadtare College of Pharmacy, Kalamb

Abstract

Quality management in pharmaceutical industries is crucial as drugs are directly delivered to the customer's body system, requiring identity, purity, and appropriate product quality. ICH Guidelines aim to ensure uniformity in products worldwide, aiding in export and import of drug products. Maintaining quality in products is complex and requires adherence to guidelines like GMP and GLP. Quality assurance departments in all pharmaceutical industries ensure compliance with these guidelines. Quality auditing checks internal and external aspects to ensure proper functioning. This paper focuses on the Quality management system in the Drug industry and its elements.

Keywords: Quality Assurance, Quality Control, Quality Management system, GMP, Total Quality Management, ICH Guidelines, Quality by Design, NABL Accreditation.

1.Introduction-:

1.1 Quality Management [4]

A quality management system is a management technique that used to communicate to the employees what is required to produce the desired quality of product and service that Satisfied the need of consumer. An organization's primary business area requires a set of rules, processes, and procedures known as a quality management system (QMS) for planning and execution (production, development, and service). (i.e., areas that may affect the company's capacity to satisfy client needs.) An illustration of a quality management system is ISO 9001:2015. A QMS aims to provide a process approach for project execution by integrating the numerous internal processes inside the business. The ability to identify, monitor, regulate, and enhance the different key business processes that eventually improve company performance is provided by a process-based quality management system (QMS).

Purpose- [5]

1. To establish a vision in employees.
2. Build motivation with in company
3. Help fight resistance to change with the organization.
4. Help direct corporate culture.
5. Checking for adherence to the quality system
6. 6 .To provide guidelines and requirements
7. To implement manufacturing controls

1.2Quality Definition-[6]

ISO Define as the totality of features and characteristics of product of service that bear on its ability to satisfy implied needs.

Quality as it applied to an object is define as the degree to which as a set of inherent characteristics of object Satisfied a set of requirements.

The Latin word "qualis" that meaning "of what kind" is where the term "quality" first appeared. In other words, one approach to emphasize a subject's qualities and nature is through the subject's quality.

Quality as outcome assurance: When a producer has a quality system, also known as a quality assurance (QA) system, it is anticipated that the good or service will be delivered.

The system entails producing the good or service consistently and continuously.

That adheres to a given norm or requirement. Availability of QA systems

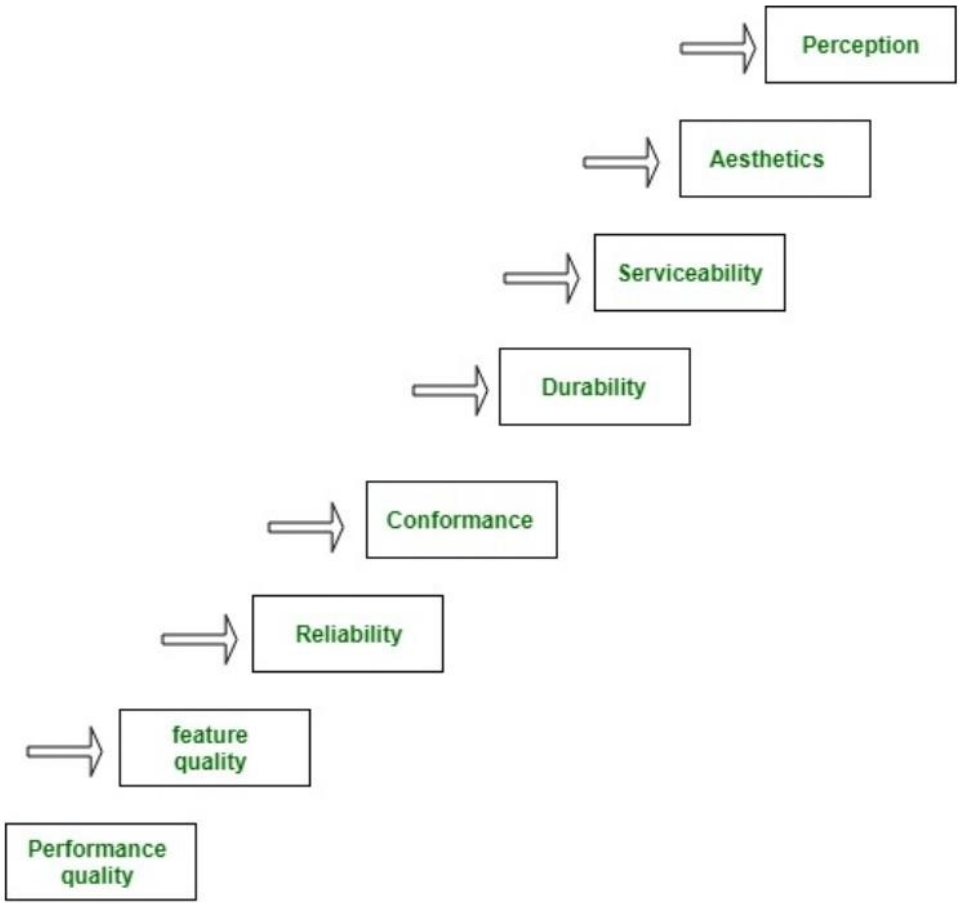
Guarantees that a certain service or product is "fit for purpose".

The ability to continually "meet or exceed customer expectations" is a sign of high quality for a good or service.

Value for money in terms of quality: A product's level of quality is strongly tied t

The product's economics. This is about offering premium goods at affordable prices.

Quality is an essential parameter which helps organizations outshine their competitors and survive the fierce competition.



Garvin's Dimentions of Quality

1.3 Quality control-An correct tool.

Quality control is a part of GMP which is concerned with sampling, specifications, testing with organization documentation and release procedure which ensure that the necessary and relevant test are carried out and that material are neither released for use nor product release for sale or supply, until their quality has been checked and judged to be Satisfactory.

A well-known and pioneering quality concept, quality control refers to the identification and rejection of either components or the finished product that do not meet the standard. It guarantees that only those parts or goods are released from manufacture.

That adhere to an established standard or specification. Alternatively put, the act of

The goal of quality control is to identify faulty goods. It is important to understand that quality assurance Is a "after-the-event" procedure, and the staff that worked on its creation In most cases, the quality control procedure does not include components or the product itself.

For this reason, a lot of businesses have upgraded or altered their quality control procedures.

Using techniques for quality control and management that entail integrating quality during production.

1.4 Quality Assurance-An analytical tool. [7-8]

Quality assurance can be divided into major areas like

- Development

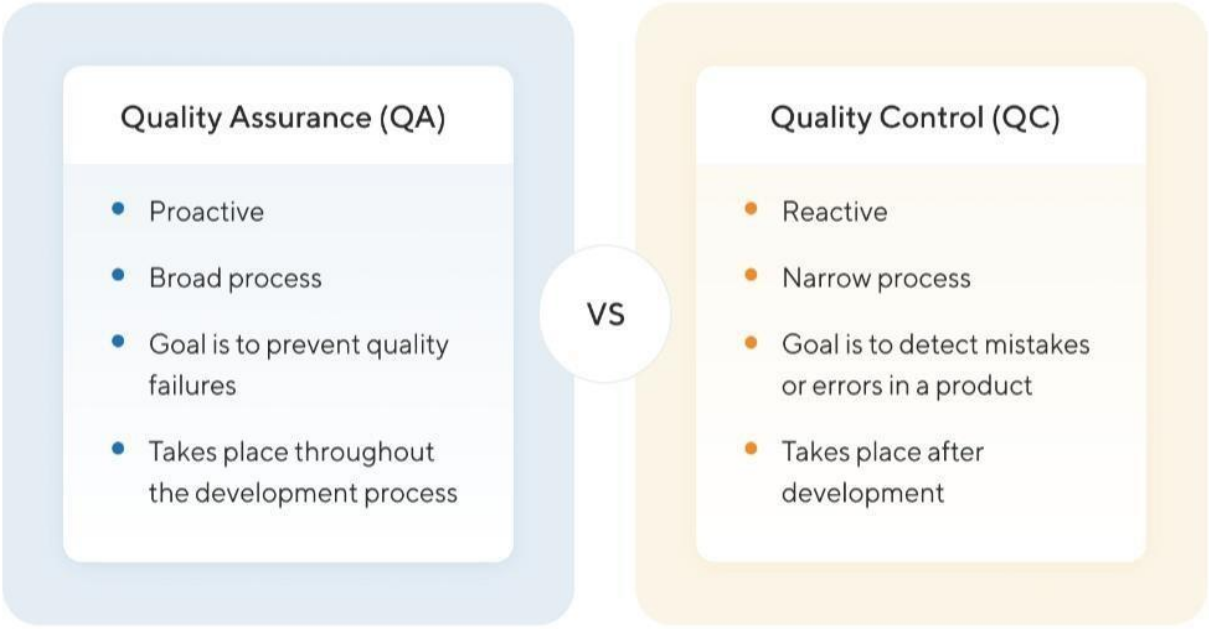
- Quality control
- Production
- Distribution
- Inspection

ISO 9000 define as part of quality management focus on providing confidence that quality requirements will be fulfilled.

It is sum of all activities and response ability required to ensure the medicine that reach the patient in safe, effective, and execrable manner.

Therefore, quality control may be considered a "before-and-during-the-event" procedure that aims to not only spot flaws but also actively stop them from happening.

Different from quality control, quality assurance focuses more on "consistently meeting Or "doing things right the first time, every time"



1.5 GMP (Good manufacturing practice) –[9-11]

GMP define aa a package of requirements and procedures by which the work methodology takes place under controlled condition and by which surrounding condition are created that allow production of hygienic and safe product.

WHO define as the part of quality assurance which ensure that the quality products are consistently produce and controlled to the quality standard appropriate to their intended use as required by making marketing authorization. It contains 5 principles of P-

- People- comprehend roles and responsibility.
- Product- clear specifications at every phase.
- Process- properly documented, simple and process.
- Procedures- guidelines for understanding critical process.
- Premises- cleanliness and equipment calibration always,

Objectives of GMP-

- To ensures safety and quality of product.
- To minimize the contamination.
- To eliminate the error.
- To improve use of natural resources.

Current GMP- Guidelines are prescribed by every country drug regulatory authority and according to WHO, GCMP state that-

1. All manufacturing process are clearly defined systematically reviewed
2. Qualifications and validation should be performed
3. All necessary resources are provide as given below- • Adequate qualifications and training personnel.

- Adequate premises and device.
- Appropriate material, container, and label.
- Appropriate procedures and instructions.
- Suitable storage and transport.

2 Total quality management- [12-17]

Total quality management is a management strategy aimed at embedding awareness of quality in all organizations process.

Total-Made up of whole.

Quality-Degree of excellence of a product.

Management- Act, art or manner of planning controlling and directing. It said to be art of management the whole to achieve excellence.

A management approach known as Total Quality Management (TQM) is focused on ensuring customer happiness while promoting quality as a business strategy. TQM is a strategy. When managing a company that seeks to increase an organization's Competitiveness via constant product enhancement, Personnel, processes, services, and environment. TQM is Functional management using a continuous improvement strategy Concentrated on enhancing quality so that their products adhere to

The level of excellence required of those serving in the implementation Of neighbourhood development. The idea diverges from Management as a method or sequence of tasks for integrating owned Resources, which must be combined with the escalating Putting management responsibilities into practice so that work may Realizing a high-quality production process.

Key of TQM-

- Focus on customer.
- Contentious improvement. 3. Employees involvement
- Team work.

Elements of TQM-

There are 8 keys as given below-

1. Foundation-

The foundation also consists of ethics, integrity, and trust.

The core principles of ethics, integrity, and trust serve as the cornerstones of the entire total quality management process. No matter their position or hierarchical level, all employees are involved in total quality management.

They move together and offers something different TQM.

It has 3 subtypes-

A) Ethics

B) Integrity

C) Trust

- **Ethics-** it is a discipline concerns with good and bad in any situation. Represent by organization and individual ethics. Individual ethics involved person right and wrong. Organization is ethics that outline the guidelines with their performance and work.
- **Integrity-** it implies honestly, morals, value, fairness, adherence facts and sincerity.
- **Truth-** trust is a by product of integrity and ethical conduct. Without trust framework of TQM cannot be built. Trust builds the cooperative environment essential for TQM.

2. Building Bricks-

Basically, on strong foundation of trust, ethics and integrity bricks are placed to reach roof of recognition. It contains

A) Training

B) Teamwork

C) Leadership

- Training- Training is important employees to be highly productive. Training the employees required interpersonal skill, ability to function within team.
- Teamwork- To become successful the teamwork is key element. With the use of team, the business will receive quicker and better solution of problem. It has 3 teams quality improvement team, problem solving team, natural working team.
- Leadership- It appears everywhere in organization. Leadership in TQM required the manager to provide an inspiration vision.

  3.Binding motor -It contains following types-
- Communication- it binds everything together. There are different ways of communication such as:

A. Downward communication – This is the dominant form of communication in an organization. Presentations and discussions basically do it. By this the supervisors can make the employees clear about TQM.

B. Upward communication – By this the lower level of employees can provide suggestions to upper management of the effects of TQM. As employees provide insight and constructive criticism, supervisors must listen effectively to correct the situation that comes about using TQM. This forms a level of trust between supervisors and employees. This is also like empowering communication, where supervisors keep open ears and listen to others.

C. Sideways communication – This type of communication is important because it breaks down barriers between departments. It also allows dealing with customers and suppliers in a more professional manner.

4. Roof-

A) Recognition-

It is a final element of TQM. It should be provided for both suggestions and achievement for team as well for individuals. It us an important factor act as catalyst and drives their level best. As every individual is hungry for Approbation and recognition. The last component of total quality management is recognition. The most crucial element that serves as a spark and encourages workers to work hard as a team and perform to the best of their abilities is recognition. Everyone yearns to be respected and acknowledged. Employees who suggest improvements and conduct exemplary work deserve to be recognized in front of everyone. To anticipate a fantastic performance from them even the following time, they should be duly rewarded.

3.ICH Guidelines Q series [18-44]

Regulatory agencies and the pharmaceutical industry get together to debate the scientific and technical facets of drug registration thanks to ICH, the international council for harmonization of technical criteria for medicines for human use. The goal of ICH is to increase global harmonization so that safe, effective, and high-quality medications are created and approved in the most resource-effective way possible. Harmonization accomplishments in the quality field include significant milestones like conducting stability studies, defining relevant impurity testing levels and improved risk management under good manufacturing practice (GMP).

The Guidelines of Q series are-

Q1A Stability testing of new drugs substances and products Q1B Stability testing.
Q1C Stability testing for new dosage form.
Q1D Bracketing and matrixing designs for stability testing of new drug substances and products.
Q1E Evaluation of stability data.
Q2 (R1) Validation of analytical procedures.
Q3A (R2) Impurities in new drug substances.
Q3B (R2) Impurities in new drug products.
Q3C (R5) Residual solvents.
Q3D Guidelines for elemental impurities.
Q4B Evaluation and recommendation of pharmacopeia texts for use in “ICH” regions.

Q5A (R1) Viral safety evaluation of biotechnology products derived from cell lines of human or Animal origin.
Q5B Quality of biotechnological products.
Q5C Quality of biotechnological products.
Stability testing of biotechnological/biological products.
Q5D Derivation and characterization of cell substrates.
Q5E Comparability of biotechnological/biological products subject to changes in their Manufacturing process.
Q6A Specifications: test procedures and acceptance criteria, for new drug substances and new drug Products.
Q6B Specifications: Test procedures and acceptance criteria for biotechnological/biological Products.
Q7 Good manufacturing practice guide for active pharmaceutical ingredients.
Q8 (R2) Pharmaceutical development.
Q9 Quality risk management.
Q10 Pharmaceutical quality system.
Q11 Development and manufacture of drug substances (chemical entities and Biotechnological/biological entities).
Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management.
Q13 Continuous manufacturing of drug substances and drug products. Q14 Analytical procedure development.

4 Quality by design-

Pharmaceutical manufacturers take several steps to make sure that good quality of product. Yet it has been found that several concerns plague the drug development and manufacturing processes.
The pioneer in quality Dr Joseph M Juran was first to develop the concept of QBD. He purposes that the quality must be design into the product if this is done there will not be any quality crises that one commonly encountered.
The ICH guidelines Q8(R2) define a systematic approach to development that design with the predefined objectives emphasize product, process understanding the process and control based on sound science and quality risk management. An endeavour to produce a dependable technique that can be proved with a high degree of certainty is the aim of a well-characterized method. Consistently generate data that satisfies predetermined requirements. When used within predetermined limits. QbD could Utilized in the creation and assessment of analytical method. When formulating the approach, all feasible influences (the
All important analytical replies (the outputs) and the inputs Are examined to ascertain the connections. Critical An method that identifies analytical factors Similar to how process development is defined in ICH Scientists who do analysis during the development and Operational labs as techniques are created and as
Variables that might cause technique failures include Categorized and managed.

Objectives-

- To ensure the quality product for that product and process characteristics important to desired performance.

- Desired attributes may be constructed.
- Experimental study of model ability through design space.
- Ensure combination of product and process knowledge gain during development.
- The product is made to satisfy both patient needs and performance standards.
- Process is created to consistently satisfy product requirements and Superior qualities of product.
- The effects of the initial raw materials and procedure .
- The criteria affecting product quality are known.
- Critical process variability sources are identified and Controlled.

Benefits of Quality by Design- [45-64]

1. For industry-

- Better understanding of process.
- Less batch failure
- Ensure better design of product with fewer problems in manufacturing.
- Allow for contentious improvement of product.

2. For FDA (Food and Drug Administration) -

- Enhances scientific based analysis.
- Provide better consistency.
- Provide more flexibility in decision making.

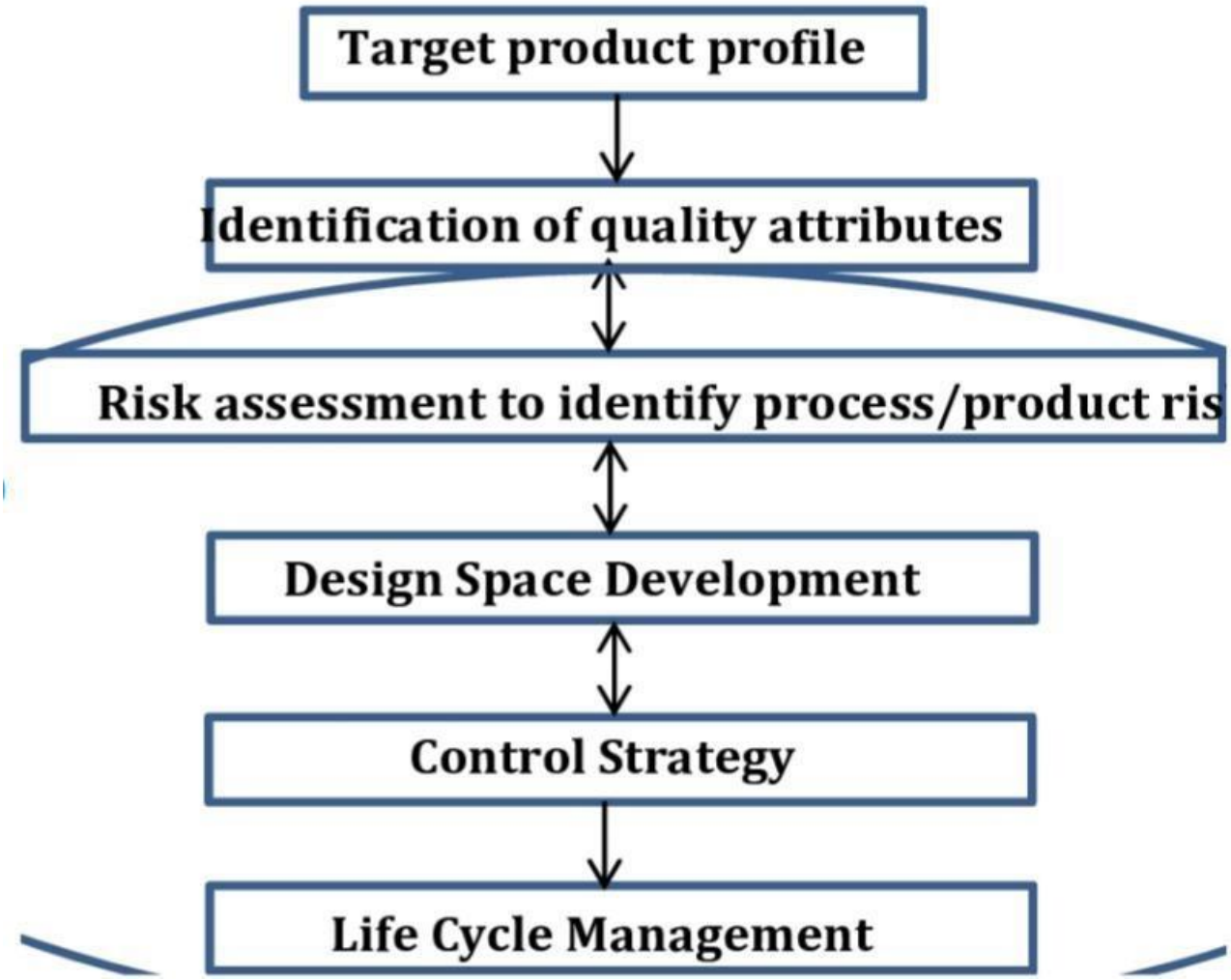
Elements of quality by design-

1. Quality target product profile (QTPP).
2. Critical quality attribute.
3. Risk Assessment (ICH Q-9).
4. Design of Experiments.
5. Control strategy (ICH Q8-R1).

Overview of Quality by design-

The objective of a well-characterized method development endeavor is to create a trustworthy technique that can be proven with a high degree of certainty to consistently provide data that meets stated criteria when used within defined bounds. The creation and assessment of analytical techniques may be done using QbD. All conceivable elements (the inputs) and all crucial analytical results (the outputs) are investigated to ascertain the correlations during method development. Critical analytical components are determined using a methodology similar to that which is specified for process development in ICH Q8 and Q9. Throughout the process, a corporate knowledge repository is necessary to make sure that crucial data is recorded, examined, and contributed to in the future so that lessons learnt may be applied to the particular procedure under consideration and to other comparable techniques being used on other items. Such a repository will make it possible for the method to be continuously improved and changed during its lifespan (in keeping with the ideas outlined in the draft ICH Q10). Corporate knowledge repositories are necessary at every stage of the procedure to make sure that important data is recorded,

reviewed, and added to in the future so that lessons learned can be applied to the particular method being considered as well as to other similar methods being applied to other products. Such a repository will make it possible for the method to be continuously improved and changed during its lifespan (in keeping with the ideas outlined in the draft ICH Q10). Analytical technology transfer exercises and ICH validation should be replaced by a QbD strategy based on a risk-assessed change control mechanism. A method evaluation and, if necessary, an equivalency exercise should be carried out if the change is suspected of having the ability to move the method outside of its known design space in order to make sure method performance criteria are still satisfied.



5. NABL Accreditation- [65-70]

National Accreditation board for testing and calibration Laboratories (NABL) is a constitution board of Quality council of India.

Laboratory studies from an important part of assessing the quality of product for result to be accepted at national and international levels they must be proven to be reliable.

As accreditation of laboratories is a process through which an authorized independent agency examines and certifies the competent and quality.

The National Accreditation Board for Testing and Calibration Laboratories (NABL) oversees laboratory accreditation activities, with the accreditation committee and assessment team acting as recommending authority. NABL is an Asia signatory.
International Laboratory Accreditation (ILA) and Pacific Accreditation Cooperation (APAC)
Mutual Recognition Arrangements (MRA) for cooperation (ILAC). They are founded on
Mutual assessment and approval of the other MRA partners. The likes of international agreements
Allow MRA partner nations to accept test and calibration findings.

Steps in NABL Accreditation- 1. filling of application.
2. Pre-assessment Audit.
3. Final Assessment.
4. Corrective Reassignment.
5. Granting of Accreditation.

Benefits of NABL-
- International and national recognition.
- Enchanted customer confidence and Smartification.
- Quality management system increases.
- Potential increase in business due to enchanted customer confidence l.

Some testing medical laboratories-
1. Clinical laboratories.
2. Genetic laboratories.
3. Nuclear laboratories.
4. Histopathology laboratories
5. Radiological laboratories

6. Conclusion

The quality management system is an important system that involves continues improvement of product with the assurance of product passed through all testing data and have been analgised. It focusses on tool which help to provide good quality products. It provides various approach like Quality control, Quality Assurance, Good Manufacturing practices, Total Quality Management, International Conference on Harmonization, Quality by Design, NABL Accreditation which help to synthesized standard product which is free from any detect.

References -
1. M. Dubey Ne, Gupta H, Sharma RK, Dubey Ni, Dubey N (2011) Pharmaceutical Quality Management System: Current Concept. Journal of Advanced Pharmacy Education & Research 2: 120-124.
2. Quality assurance of pharmaceuticals: A compendium of guidelines and related materials 2, 2nd updated edition, good manufacturing practices and inspection.

3. Lakhal L, Pasin F, Liman, M (2006) Quality management practices and their impact on performance. Int J Qua. Rel. Mgmt. 23(6): 625-646.
4. (2009) Q10 Pharmaceutical Quality System, U.S. Department of Health and Human Services Food and Drug Administration Centre for Drug Evaluation and Research (CDER) Centre for Biologics Evaluation and Research p. 2-19.
5. CFR - Code of Federal Regulations, Title 21 "Food and drugs" Chapter I"
6. Food and drug administration" sub chapter C "Drugs-General" Part 211 "Current Good Manufacturing Practice for Finished Pharmaceuticals".
7. Mario Chen (2007) Brief Introduction to the ICH Guidelines. Family
8. Health International Biostatistics Workshop, New Delhi, India.
9. Quality Assurance Guide by organization of Pharmaceutical Products of India.
10. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related Materials Vol I WHO Publications.
11. Good Laboratory Practice Regulat4. A guide to Total Quality Management- Kushik Maitra and Sedan K Ghosh
12. Good laboratory Practices – Marcel Decker Series Ions, 2nd Edition, Sandy Weinberg Vol. 69.
13. Howw to Practice GMP's – P P Sharma.
14. ISO 9000 and Total Quality Management – Sadhank G Ghosh
15. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis And Quality specification for Pharmaceutical Substances, Excipients and Dosage Forms.https://www.isixsigma.com/total-quality-management-tqm/eight-elementstqm/
16. Amar, Kifayah and Zain, ZuraidahMohd (2002), Barriers to implementing TQM in Indonesian manufacturing organizatons, The TQM Magazine Vol.14 no.6.
17. Anjard, R.P. (1998), "Total quality management: key concepts", Work Study, Vol. 47 No. 7.
18. Aroef, M. (1999), " Beberapa observasiTentangUpaya Masyarakat
19. Meningkatkan Produktivitas Dan Mutu", KertasKerja Seminar Sehari Strategi PeningkatanProduktivitas dan ManajemenMutu yang Tergolong " World Best Practice ", Bandung.
20. ICH guidelines, ISO 9000 and 14000 guidelines
21. ICH Q1A (R2) – stability testing of new drug substances and products.
22. ICHQ1B-stability testing: photo stability testing of new drug substances and products.
23. ICH Q1C- stability testing for new dosage forms.
24. ICH Q1D- bracketing and matrixing design for stability testing of new drug substances and products.
25. ICH Q1E- evaluation of stability data.
26. ICH Q2 (R1)-validation of analytical procedures: text and methodology.
27. ICHQ3A (R2)-impurities in new drug substances.
28. ICHQ3B (R2)-impurities in new drug products.
29. ICHQ3C (R5)-impurities: guidelines for residual solvents.
30. ICHQ3D-guidelines for elemental impurities.
31. ICHQ4B-pharmacopeias .
32. ICHQ5A (R1)-viral safety evaluation of biotechnology products derived from cell lines of human or animal origin.

33. ICHQ5b- analysis of the expression construct in cells used for production of RDNA derived protein products.
34. ICHQ5C-stability testing of biotechnological/biological products.
35. ICHQ5D- derivation and characterization of cell subtracts used for production of biotechnological/biological products.
36. ICHQ5E-comparability of biotechnological/biological products subject to changes in their manufacturing process.
37. ICHQ6A-specifications: test procedure and acceptance criteria for new drug substances and new drug products: chemical substances.
38. ICHQ6B-specification: test procedures and acceptance criteria for biotechnological/biological products.
39. ICHQ7-good manufacturing practice guide for active pharmaceutical ingredients. .
40. ICHQ8 (R2)-pharmaceutical development
41. ICHQ9-quality risk management
42. ICHQ10-pharmaceutical quality system.
43. ICHQ11-development and manufacture of drug substances (chemical entities and bio technological/biological entities.).
44. ICHQ12-technical and regulatory considerations for pharmaceutical product life cycle management.
45. ICHQ13-continous manufacturing of drug substances and drug products.
46. ICHQ14- analytical procedure development
47. Woodcock J, The concept of pharmaceutical quality.
48. American Pharmaceutical Review, 7(6), 2004, 10–15.
49. Q9: Quality Risk Management. ICH Harmonized Tripartite
50. Guidelines. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals For Human Use, 2006.
51. Q10: Pharmaceutical Quality System, ICH Tripartite
52. Guidelines. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals For Human Use, 2007.
53. Lionberger RA, Lee LS, Lee L, Raw A ,Yu LX, Quality by Design: Concepts for ANDAs, The AAPS Journal, 10, 2008, 268–276.
54. FDA Guidance for Industry and Review Staff: Target Product
55. Profile – A Strategic Development Process Tool (Draft Guidance).
56. Q8 (R1): Pharmaceutical Development, Revision 1, ICH
57. Harmonized Tripartite Guidelines, International Conference
58. On Harmonization of Technical Requirements for
59. Registration of Pharmaceuticals for Human Use, 2007.
60. Callis JB, Illman DL, Kowalski BR, Process analytical
61. Chemistry. Analytical Chemistry, 59, 1987, 624A–637A.
62. Yu LX, Pharmaceutical quality by design: Product and process
63. Development, understanding, and control. Pharmaceutical Research, 25, 2008, 781–791.
64. 53.Munson J, Gujral B, Stanfield CF, A review of process
65. Analytical technology (PAT) in the U.S. pharmaceutical

66. Industry. Current Pharmaceutical Analysis, 2, 2006, 405–414.
67. Leuenberger H, Puchkov M, Krausbauer E, Betz G, Manufacturing pharmaceutical granules, Is the granulation
68. End-point a myth, Powder Technology, 189, 2009, 141–148.
69. Miller CE, Chemometrics and NIR: A match made in heaven,
70. Am. Pharm. Rev. Food and Drug Administration CDER, Guidance for industry, Q8 pharmaceutical development; 2:41–48, 2006.
71. Nasr M. Risk-based CMC review paradigm, Advisory Committee for pharmaceutical science meeting, 2004.
72. Food and Drug Administration CDER. Guidance for industry:
73. Immediate release solid oral dosage forms scale-up and post
74. Approval changes: Chemistry, manufacturing, and controls,
75. In vitro dissolution testing, and in vivo bioequivalence Documentation, 1995.
76. Food and Drug Administration CDER. Guidance for industry:
77. Modified release solid oral dosage forms scale-up and post
78. Approval changes: Chemistry, manufacturing, and controls,
79. In vitro dissolution testing, and in vivo bioequivalence Documentation, 1997.
80. Food and Drug Administration CDER. Guidance for industry:
81. Non sterile semisolid dosage forms scale-up and post
82. Approval changes: chemistry, manufacturing, and controls, in
83. Vitro dissolution testing, and in vivo bioequivalence Documentation, 1997.
84. Food and Drug Administration CDER. Guidance for industry:
85. Changes to an approved NDA or ANDA, 2004.
86. Woodcock J, The concept of pharmaceutical quality.
87. American Pharmaceutical Review, 2004, 1–3.
88. Food and Drug Administration, Office of Generic Drugs White Paper on Question-based Review: OGD/QbR.htm.
89. Food and Drug Administration, Guidance for industry, Q6A Specifications for new drug substances and products:
90. Chemical substances, 1999.
91. Nasr M, FDA's quality initiatives: An update,
92. . Com/daten/download/FDAs_Quality_Initiative.pdf, 2007.
93. 65.9. ICH guidelines, ISO 9000 and 14000 guidelines.
94. Chital NK, Bhat VG, Chavan PD, et al. The road to laboratory accreditation: experience of a tertiary care oncology center. Indian J Cancer 2016;53(1):204–205. DOI: 10.4103/0019-509X.180858.
95. Kanagasabapathy AS, Rao P. Laboratory accreditation—Procedural guidelines. Indian J Clin Biochem 2005;20(2):186–188. DOI: 10.1007/BF028 67425.
96. Maurya MR, Maurya B. Current scenario and distribution of NABL
97. Accreditated laboratories in INDIA. J Pharmacol Clin Res 2017;3(5):555625. DOI:
98. 10.19080/JPCR.2017.03.555625.
99. Wadhwa V, Rai S, Thukral T, et al. Laboratory quality management system: road to accreditation and Beyond. Indian J Med Microbiol 2012;30(2):131–140. DOI:

100. 10.4103/0255-0857.96647.
101. Sinha M, Saini S, Gupta P, et al. Current status and way forward for national accreditation board for Testing and Calibration Laboratories Accreditation of L aboratories in Govern ment Organizations. In dian J Pathol Microbiol 2018;61(3):461–463. DOI: 10.4103/IJPM.IJPM_630_17.