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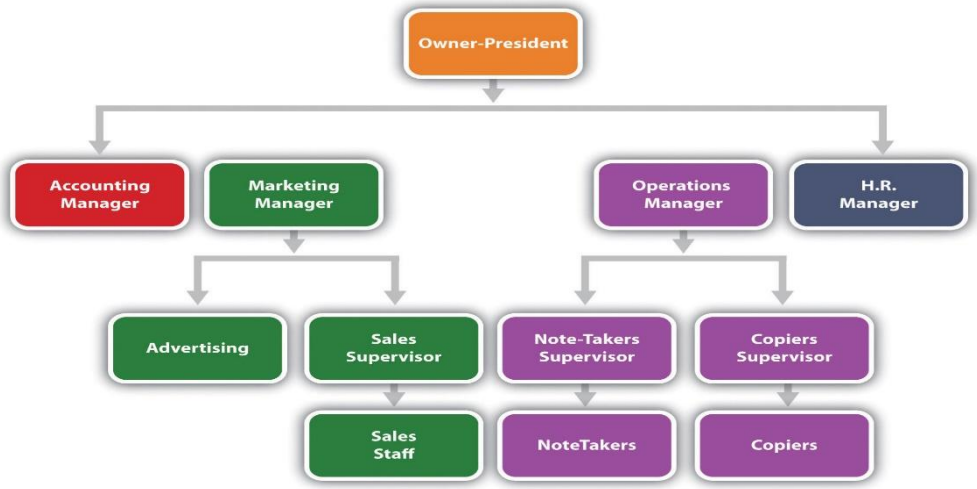
Quality Management System

[1.]Himmat Prajapat [2.]Dr Gaurav Kr Sharma [3.]Dr Kaushal K Chandraul

[1].Student of mewar university [2].HOD of pharmacy [3.]Principal , Department of Pharmacy Mewar University Chittorgarh (Raj),

QUALITY ???

- How properly does product layout meet client perception?
- Does dosage shape supply the favored safety, efficacy and stability?
- Does it fulfill Provider- Controller- Consumer?



QMS model – Customer-to-customer for customer

TOTAL QUALITY MANAGEMENT

QMS principles

1. Customer focus
2. Leadership
3. Process method
4. Involvement of people
5. System method to management
6. Continual improvement
7. Factual method to decision-making
8. Mutually useful provider relationship

12 Steps

1. Assure guide of key energy group
2. Use chief behaviour to generate electricity for extrade
3. Use symbol & language to sell effort
4. Build in stability
5. Surface dissatisfaction with gift state
6. Ensure complete participation in extrade process
7. Give praise for accomplishment
8. Allow time to disengage from gift state

9. Project & conversation a clean photo of future
10.Use a couple of motivation
11.Develop organizational crew for transition to TQM
12.Builds-in systematic remarks for preserving TQM

Six Pillar

1. Commitment of pinnacle management
2. Organizational structure & Roles
3. Education & Training
4. Transparent & powerful communication
5. Recognition & Rewards
6. Customer focus & satisfaction

PDCA Cycle

Level of QMS

1. Customer focus
2. Organizational management
3. Process control
4. Inspection & Audit
5. Market sound

Organizational Management

Personnel

1. Training & ability development
2. Change control
3. Health & hygiene
4. Performance competency

Management

1. Policy making
2. Decision making
3. Pilot plan scale up & maintenance
4. Implementation of regulations

Process Control

Control

1. Entry level
2. Production level
3. QC Lab
4. Sampling & documentation
5. Release management & marketplace survey

Inspection:

1. Internal inspection
2. External inspection

a. Routine
b. Concise
c. Follow up
d. Special
e. QS review
f. Problem dealing

Regulation

For pleasant control on Global level:

1. ISO
2. WHO
3. ICH
4. Regional Legislation

ISO (International Organization for Standardization)

Federation of 156 countries.
ISO/TS 16949 – Tech. specification at improvement of QMS aimed disorder prevention, discount in variants, persistent improvement.
First drafted as ISO 16949:2002 (March 2002)
ISO 9000 series – QMS (Published in 1987)
ISO 9000:2005 – Cover primary concept & Vocabulary used
ISO 9001:2008 – Set requirement of QMS
ISO 9004:2009 – How to make QMS extra efficient & effective
ISO 9011:2011 – Set guiding principle on Int. & Ext. audit of QMS
ISO 10005 – Prepare excellent plan for projects
ISO 10011 - 1/2/3 - Guideline for auditing a excellent system
ISO 10012 – Caliberation system & size control
ISO 10013- Quality guide for precise excellent need

Popular standard
ISO 9000 Quality management
ISO 14000 Environment management
ISO 3166 Country codes
ISO 26000 Social responsibility
ISO 50001 Energy management
ISO 31000 Risk management
ISO 22000 Food safety management
ISO 27001 Information security management
ISO 20121 Sustainable events

ICH (International convention on Harmonization)
ICH Q-Documents
Q1 Stability
Q2 Analytical Validation
Q3 Impurities
Q4 Pharmacopoeias
Q5 Quality of Biotechnological Products
Q6 Specifications
Q7 Good Manufacturing Practice
Q8 Pharmaceutical Development
Q9 Quality Risk Management
Q10 Pharmaceutical Quality Systems

Q10 = ICH Q7 + ISO GMP guideline
Objective of Q10 –
1. To acquire product realization
2. Establish & keep nation of control
3. Facilitate improvement

ICH Q10 Pharmaceutical Quality System
ICH Q10 demonstrates enterprise and regulatory authorities` assist of an effectivepharmaceutical exceptional gadget to decorate the exceptional and availability of drugs round theglobal withinside the hobby of public health. Implementation of ICH Q10 at some point of the productlifecycle need tofacilitate innovation and persistent development and fortify the hyperlink betweenpharmaceutical improvement and production activities.
FDA`s steering documents, which include this steering, do now no longer set up legally enforceableresponsibilities. Instead, guidances describe the Agency`s cutting-edge wondering on a subject and need tobe regarded most effective as recommendations, until particular regulatory or statutorynecessities arecited. The use of the phrase need to in Agency guidances manner that some thing is usually recommended orrecommended, however now no longer required.

Quality regulation in Ayurveda
1. Government of India
2. AYUSH Ministry
3. India Quality Council (QCI)
4. State legislature and committee
5.5. CCRAS (Gives a protocol for research)

6. ICMR
7. Faculty of Science and Technology
8. Ministry of Chemicals and Fertilizer
9.PLIM

AYUSH Mark for Quality

• AYUSH Meet with QCI for pleasant trouble in Dec 2008, and signal an aggrement to to help in accredation to ayurvedic product in July 2009 and released AYUSH mark in Aug 2009.
• QCI Gives accredation
1. NABL offers accredation to the labotatories (Should meet std. of ISO17025)
2. NABCB offers Ayush mark on requirements of ISO manual 65.
• Logo of NABCB emerge as obligatory considering the fact that June 2011.

AYUSH Mark

1. Premiun- In compliance to International regulatory requirements.
2. Standard- In compliance to home regulatory requirements.

Summary in terms of Ayurveda

• 1920 & 1940 in adhiveshana, government says that when freedom Ayurveda could be countrywide scientific pathy.
• The D&C act 1920 framed while quinine great become compromised.
• In 1940, D&C act become framed apart from law for TM.
• In 1964 law for ASU medication become introduced to D&C act, with attempt of Pt. Shiv Sharma & Pt. Anant Sharma and CCIM become constituted.
• APC become constitutes to assess and submit great standards.
• ASUDTAB become set up below sec.33C.
• Dept. of ISM&H become set up in 1995 which become renamed as Dept. of AYUSH and once more it have become Ministry of AYUSH in Nov. 2014.
• CCRAS watch great in studies in Ayurveda.
• PLIM to broaden and compare laboratory protocol for testing.
• Ayurveda now ruled below D&C act 1940 via way of means of DCG of India via country government.
• 2008 Pharmacovigilence application become released.
• AYUSH mark released in 2009.
• ASIIA become released in 2007 (GoI & DST) - to restore early omission)
• WHO realize TM in 2000.
• WHO has released method for TM 2002-2007 and 2014-2023.

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