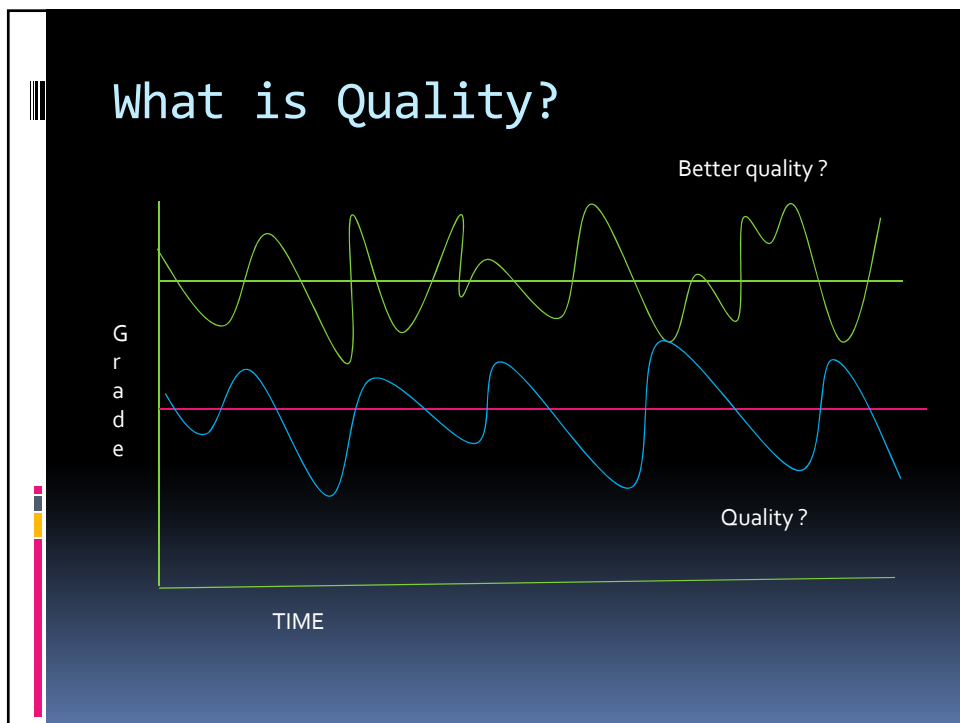
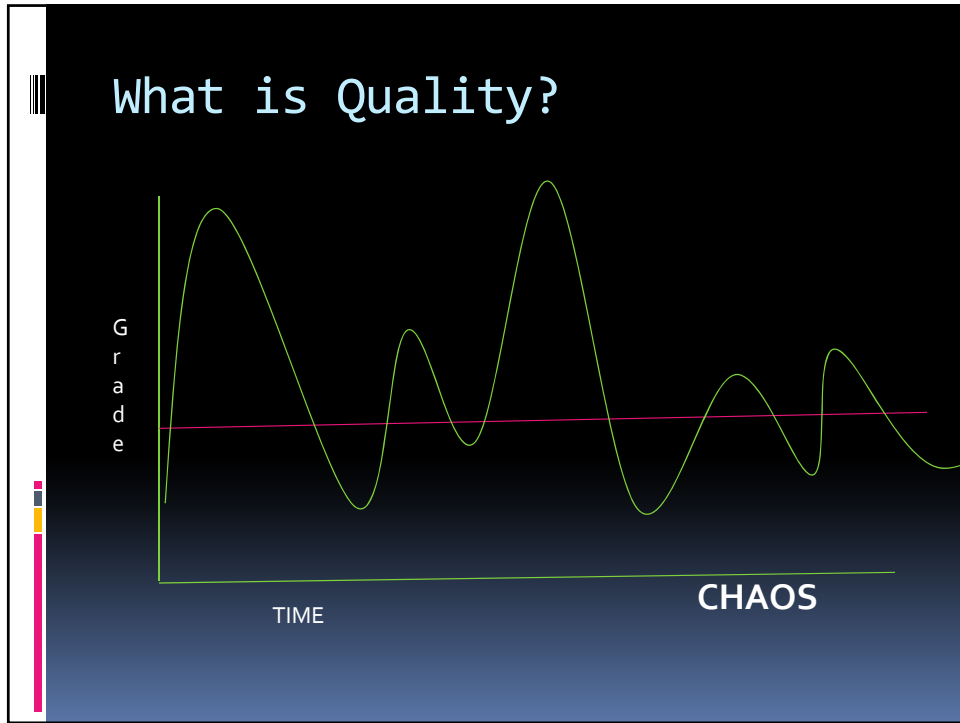


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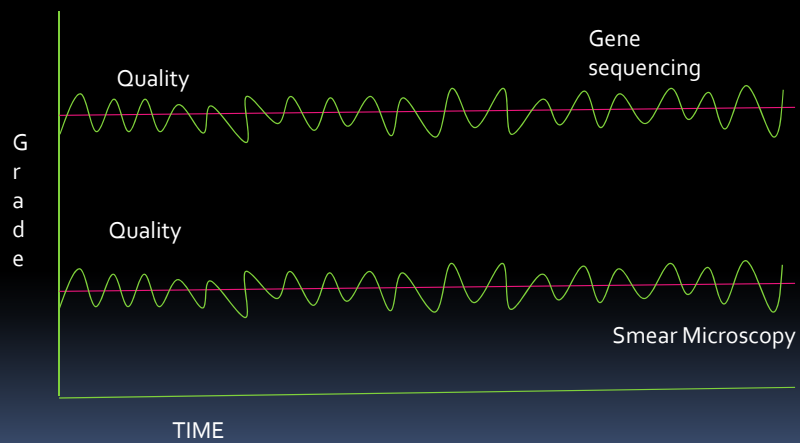
QUALITY ASSURANCE IN INDIA

Why am I doing this

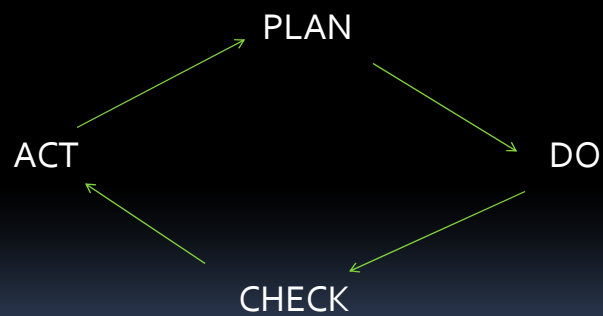
- ISO 9001: 2000
- ISO 17025:1999
- ISO 15189:2007
- cGMP
- GLP
- ICH GCP
- NABH
- Lead Assessor NABL
- Madhu said so



What is Quality



Quality is a continuous process:



DEMINGS CYCLE of QUALITY

Basic in all standards

Say what you do
Do what you say
Prove it
Improve it

ALL QUALITY STANDARDS REVOLVE AROUND THESE

Quality standards

- Any organization – a process driven standard
ISO 9001:2000
- Any Laboratory – ISO 17025
- Medical Laboratory - ISO 15189 / CAP / NATA
- Research Laboratory – GLP
- Manufacturing unit – cGMP
- Clinical Studies – ICH GCP
- Hospitals - NABH

Standards

- Established by Standards agencies
 - LAW (US CFR 21, CLIA 88, DCGI)
 - Non Governmental (NATA / CAP/ JCAHO)
 - Governmental Agency (NABL / NABH)
- Mature standards
- Immature standards (Prescriptive, require modifications for specific spectra)

Basic principles

- Top down approach
- 4 tier approach
 - Policy
 - Procedure
 - Work Instructions
 - Documents and Records

Broad Divisions in lab standards

- Management requirements
- Laboratory requirements

Management requirements (Salient)

- Organization
- Quality Management system
- Document control
- Services and Supplies
- Complaints
- Corrective and preventive action
- Continual improvement
- Internal audit
- Management review

Laboratory requirements

Salient

- Staff
- Environmental conditions
- Equipment
- Pre testing procedures
- Testing procedure
- Post test procedure
- Assuring Quality
 - IQC
 - EQA
- Reporting

In India

- Diagnostic Laboratories
 - NABL
 - CAP
- Research laboratories
 - GLP
 - GCP
 - DCGI – Clinical Trials
- Hospitals
 - NABH
 - JCAHO (JCI)
 - ISO 9001 (ubiquitous)

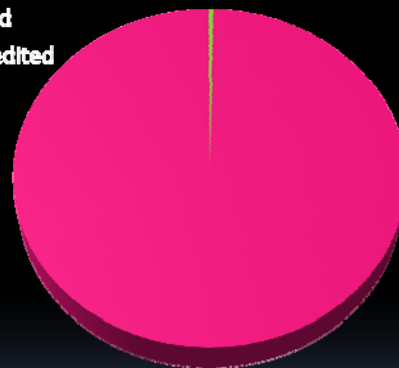
In India

- Quality Council of India
 - Governmental agency
 - Apex body for Quality
- NABL
 - Division of DST
 - Unclear status as of now w.r.t QCI

Accredited / certified labs in India

NABL
ISO
NABH
CAP
JCI
< 200 labs certified

■ Accredited
■ Non accredited



Total no. of labs –
estimated 50,000

Ancillary agencies

- Calibration
- Device manufacturers
- Lab designers
- QC providers
- PT providers
- Preventive maintenance
- Quality consultants

Why Quality

- Marketing tool
- Management tool
- External review
- Not a law in India
- International business requirement
- Especially for clinical trial work and BA / BE evaluations for patent expiry drugs
- And for true believers that QMS works

