QUALITY ASSURANCE IN INDIA

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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?

Better quality?

Quality?
What is Quality

Quality is a continuous process:

- PLAN
- DO
- CHECK

DEMMING 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

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
LET'S MAKE QUALITY – A WAY OF LIFE