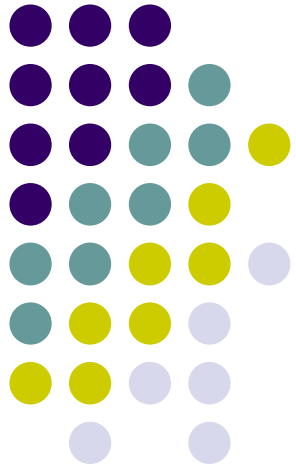
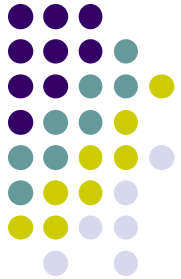
GMP & Accreditation in Blood Banks: Roadmap in Gujarat



Definition

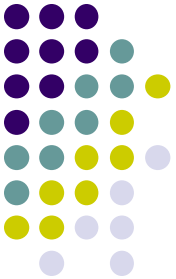
GMP is that part of quality assurance which ensures that products are consistently produced and controlled appropriate to their intended use, as per the defined standards

•History of GMP (1)



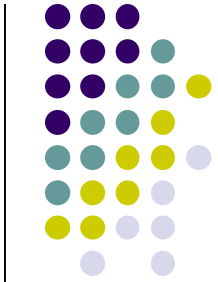
- 1963: USFDA developed GMP regulations
- 1971: UK regulators compiled guide to GMP
- 1992: EU enacted rules for Medicinal Prodt.

History of GMP (2)



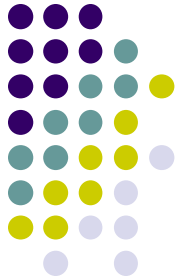
- USFDA enforced GMP (1991) in blood banks because of inadequate documentation
- GMP in BB is difficult due to batch variation
- All batches do not undergo QC test
- Aims is to reduce batch to batch variation

Basic requirement of GMP (1)



1. Quality management
2. Personnel & organization
3. Premises, equipment and materials
4. Documentation
5. Collection, testing & blood processing

Basic requirement of GMP (2)



6. QC & proficiency testing

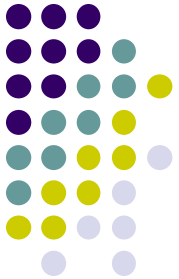
7. Complaints & component recall

8. Investigation of errors & accidents

9. Rejected units disposal & sample retention

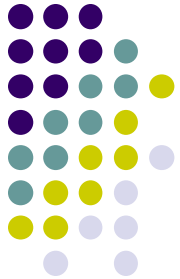
10. Self assessment, internal & external audit

1. Quality management



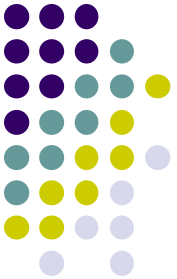
- Commitment from management
- Quality is the responsibility of all persons
- Independent unit for quality, reports to Medical Director or I/C Blood Bank.
- Identified QA, QC & QP person
- Production head cannot be QA/ QC head

2. Personnel & organization



- Organogram to identify reporting system
- Only Medical Doctor to head BB (D&C Act)
- KRA & job description for all personnel
- Induction training after joining organization
- Continuous in service training
- Principles of GMP should be known
- Knowledge about microbiology & hygiene

3. Premises, equipment, materials (A)



- **Premises**:

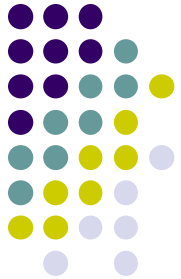
  # Planned & constructed as per D&C Act (minimum 7 areas with distinct function)

  # Layout & design must aim to minimize errors & operation in orderly manner

  # Lockable quarantine

  # Storage area must be temp. controlled, monitored & checked

3. Premises, equipment, materials (B)



- **Equipment:**

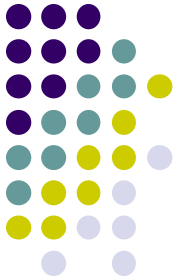
  # All equipment as per need & D&C Act

  # Equipment should be validated & installed as per design

  # All should be under warranty or AMC

  # Maintenance/ calibration be documented

3. Premises, equipment, materials (C)



- **Materials:**

  # Detailed pre-purchase specifications

  # All materials from qualified suppliers

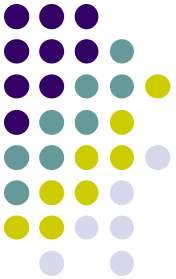
  # Certificate of compliance from manufact.

  # Pre receipt quality check & acceptance

  # Any deviation, inform manufacturer

  # Internal indent, FIFO, release

4. Documentation (A)



"Documentation ensures that work is standardized and there is traceability in all steps in manufacturing process".

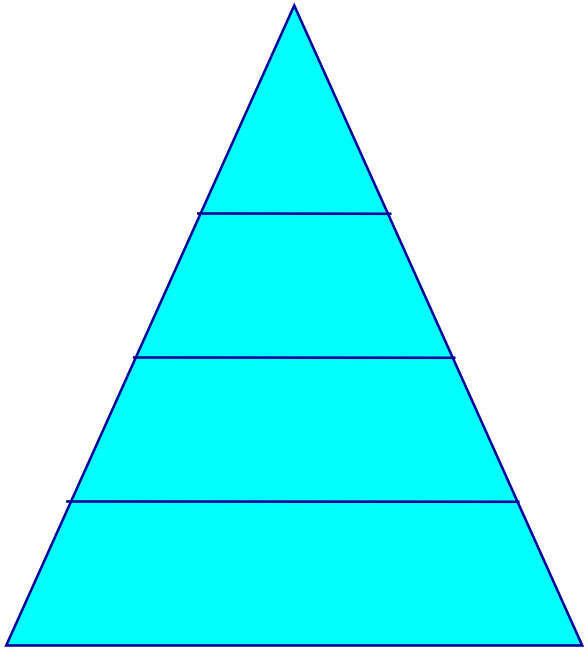
1st level doc. (Q. Policy & Q. manual)

2nd level doc. (Q. procedures, process control)

3rd level doc. (SOPs)

4th level doc. (Records, forms, labels, registers, data sheet etc)

4.Layers of Documentation (B)



ISO 9000 - 1994 (E)

Level 1 Quality manual (policies)

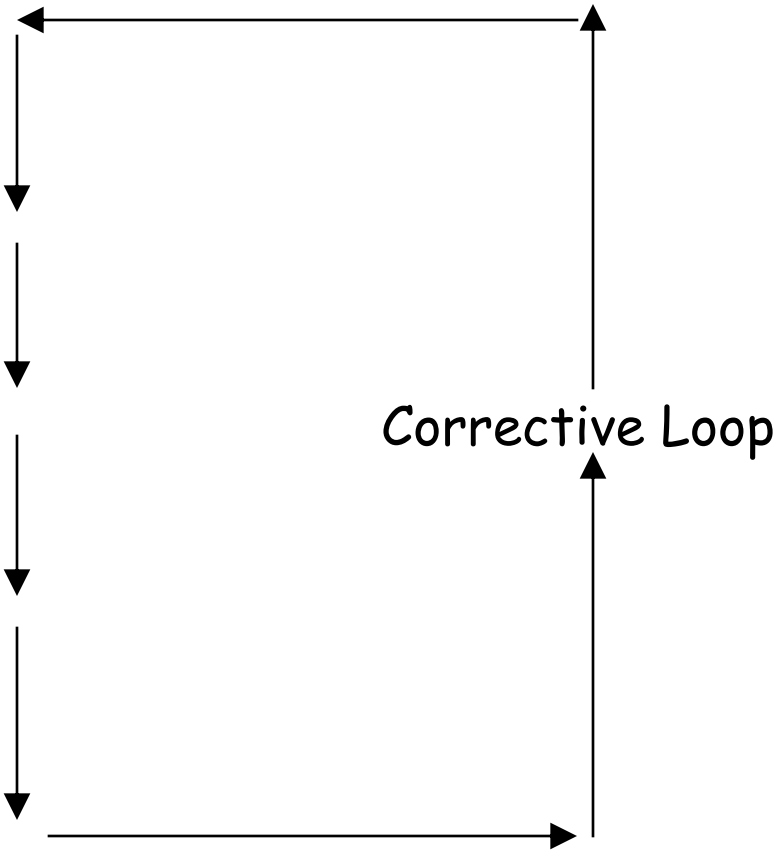
Level 2 Quality procedures

Level 3 SOPs

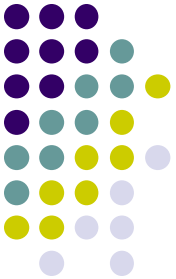
Level 4 Records

4. Documentation – Corrective Loop

- Write what you do
- Do what is written
- Record what you did
- Revise what you will do



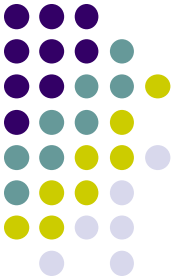
4. Documentation (D)



- Should be approved by authorized person
- Signed & validation with date & time
- Retained for specific period (as per law)
- Can be stored in non-written form (eg. soft copy, microfilm, xerox etc.)
- Use of information technology

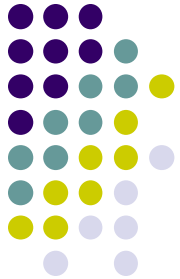
  # Software validation, security levels, web-enable, hardware-interface etc.

5. Collection, testing, blood processing



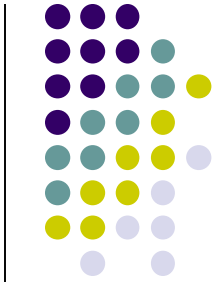
- Final product depends upon raw materials
- All process should be carefully controlled
- System of traceability is must
- Component processed in closed system
- All products/ containers should be labeled
- Lockable quarantine & product release
- Storage & distribution in required temp.

6. QC & proficiency testing



- QC: activities including steps of verification & testing which are used to assure that materials & process meet their specification
- Internal QC: following of Lab procedure by using QC samples & all procedures to correct & prohibit deviations
- External QC: analysis of unknown samples & evaluation by a 3rd party
- Proficiency testing: ability of personnel to perform tasks they are supposed to do.

7. Complaints & component recall



- System of Grievance Redresal & feedback
- System of component recall & info to Hosp
- Look-back/ hemovigilance/ biovigilance
- Traceability: donor to product to recipient
- Post collection info to donors

8.Investigation of errors & accidents

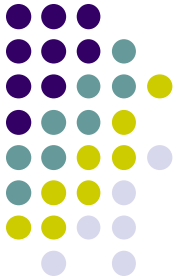
- BB to register errors & accidents to identify system problem for correction
- Priority to investigation of incidents with potential risks for serious adverse events
- Preventive & corrective actions should be documented & effectiveness assessed

9. Sample retention & unit disposal

- As per national Standards/ regulation:
  # Patient sample (x 7 days)
  # Donor sample (x 30 days)
  # Donor sample (x 5 years= western world)

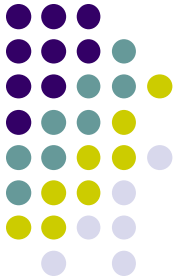
- Disposal of rejected units as per SOP & national regulation with traceability

10. Internal & external audit



- Internal audit: required to monitor & document compliance of GMP/ISO and to propose necessary corrective action
- External audit by independent designated approved/ competent authorities.
- All audits must be documented & recorded

Phases of GMP



- Phase I: Training of staff:

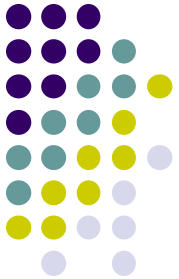
  # at all levels
- Phase II: Application:

  # manufactg process, documtn, flow chart process validation, calibration & validation of equipment & reagents
- Phase III: Audit:

  # Monitor process, locate errors, correction

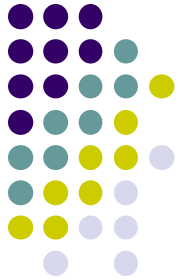
Summary of GMP

- Concept of GMP is to minimize error & making mistake to minimum
- Written procedures & documented records
- Trace mistakes if committed & take action
- Trained personnel for appropriate job.



ACCREDITATION

What is Accreditation?



- Accreditation is a public recognition of the achievement of accreditation standards by an organization, demonstrated through an independent external peer assessment organization.

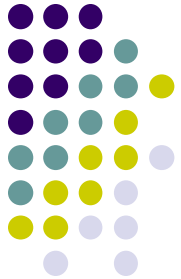
Types of Certification

- **First Party Certification** : Laboratory belongs to user, who is satisfied and uses for his own jobs

- **Second Party Certification** : Laboratory does not belongs to user but user using his own means certifies the laboratory, and uses for his won requirements

- **Third Party Certification** : Certifying/Accreditation body or laboratories, is neither the owner of the laboratory nor is the user

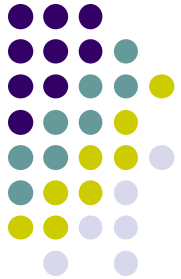
Accreditation of Govt. Medical Colleges: Gujarat



- First of its kind in India
- Guidance from the Project Director, GSCBT
- Our chance to improve in quality patient care through safe blood supply
- Strength: existing good infrastructure
- Trained manpower
- Concurrent NABH & NABL program
- Who will be benefited by this?.....

Benefits of Blood Banks Accreditation

Blood Banks…



- Accreditation to a blood bank stimulates continuous improvement
- It enables blood bank in demonstrating commitment to quality care
- It raises community confidence in the services provided by the blood bank.
- It also provides opportunity to healthcare unit to benchmark with the best.
- **IT IS ALWAYS VOLUNTARY**

Patients…

- Accreditation benefits all stake holders,
- Patients are the biggest beneficiary:

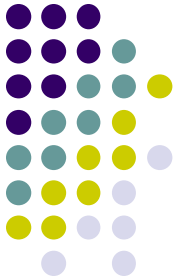
  # High quality of care and patient safety

  # Services by credential medical staff

  # Rights of patients are respected & protected

  # Patient satisfaction is regularly evaluated.

Staff…



- Staff in accredited BB are satisfied lot

  # Provides continuous learning,

  # Good working environment,

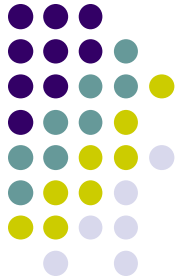
  # Leadership & ownership on clinical process

- Improves:

  # Professional development of Clinicians & Paramedical staff

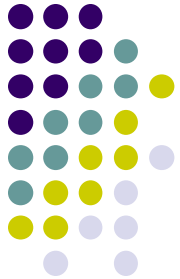
  # Provides leadership for quality improvement within medicine and nursing.

Steps for BB accreditation (1)



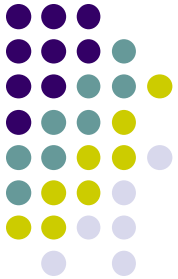
- Sensitization of top management /personnel
- Sensitization of other staff
- Orientation to NABH Standard to key staff
- Orientation to NABH Stand. to other staff
- Baseline assessment
- Gap analysis & submission of report
- Development of action program
- Formation of Quality Assurance Committee

Steps for BB accreditation (2)



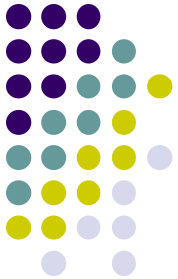
- Filling of human resource gaps
- Filling of structural resource gaps
- Filling equipment resource gaps
- Training of core team on Stand. & Objective
- Patients & employees satisfaction
- Quality Manual
- Annual/ Comprehensive Mainten. Contract

Steps for BB accreditation (3)



- Calibration
- International Quality Control
- External Quality Control (EQAS)
- Internal audit
- Review meeting of the Committee
- Internal audit report GSCBT
- Final review at GSCBT level

Steps for BB accreditation (4)

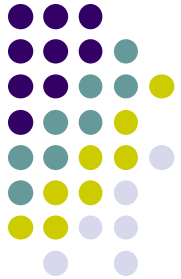


- Application for NABH Pre-Assessment
- Pre- Assessment by Lead Assessor
- Full filled the Gaps: local QA Committee
- Final assessment by NABH team
- Full filling Gaps (NC): Local QA Committee
- Winning Accreditation
- Renewal

How to go ahead? Clauses…

1. Organization and management
2. Accommodation and environment
3. Personnel
4. Equipment
5. External Services: Supplies & Reagents
6. Process Control
7. Identification of deviations and Adverse Effects
8. Performance Improvement
9. Document Control
10. Records
11. Internal Audit and Management review

1.Organization & Management

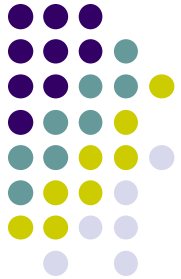


- Legal identity
- Responsibility
- Ethics in BB
- Management system
- Policies processes & procedures

2.Accommodation & Environment

- Space allocation (9 areas; AC; component; apheresis; blood donation camps)
- Environmental control
- Biological Chemical & radiation safety
- Internal communication system

3.Blood Bank Personnel

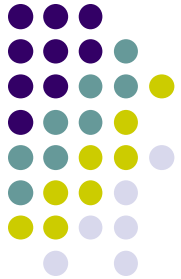


- Personnel requirement
- Qualification
- Job description/ responsibility
- Responsibilities of I/C, Medical Officer, Quality Manager & Technical Manager
- Training
- Proficiency testing
- Personnel records

4.Equipment

- Required equipment
- Selection & validation of equipment
- Use of equipment
- Equip detail record & unique identification
- Program for calibration & maintenance
- Equip for storage of blood & component
- Computer system
- Breakdown of equip

5. External services & supplies

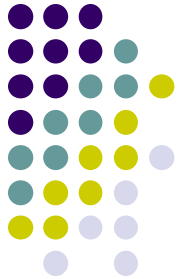


- Policies/ procedure for supplier’s selection
- Inventory control
- Evaluation of suppliers

6. Process control

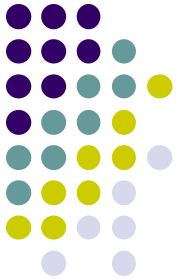
- Policies & validation of process/procedure
- Donor selection
- Component Laboratory
- Quarantine & storage
- Labeling
- Testing of donated blood
- Compatibility testing
- Transfusion reaction & evaluation
- Documentation in transfusion services
- Histocompatibility testing
- Quality Control
- Proficiency testing
- Biomedical waste disposal

7. Deviations & adverse events



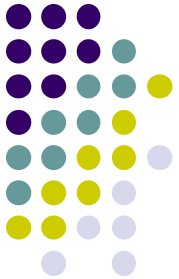
- NC in policies & procedures
- Procedure to release NC blood/component
- Preventing recurrence of NC

8. Performance improvement



- Addressing complaints
- Corrective action
- Preventive action

9. Document control

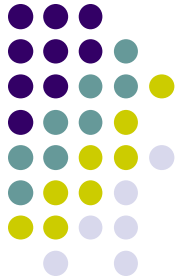


- Procedure for review & control of doc.
- Document required
- Maintenance of doc for computer software

10. Records

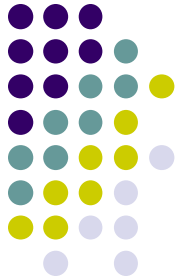
- Record identification
- Quality & technical records
- Records retaining period

11. Internal Audit & Management Review



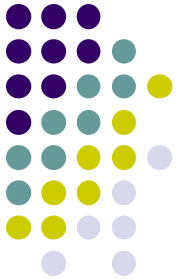
- Policy for internal audit & management review
- Procedure of internal audit
- Procedure for management review
- Documentation of internal audit & management review

Jobs for Blood Banks (1)



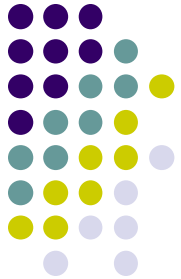
- Appointing/ designating Quality Manager and Technical manager.
- Study the NABH Quality Manual
- Study NACO Technical Manual
- Distribute work among responsible staff
- Rewrite/ modify all SOPs as per ‘generic SOP’ provided
- Constitute ‘QA Committee’ for blood bank

Jobs for Blood Banks (2)



- Try to find out Non Technical gaps as per Standard (space, personnel, equipment: AMC/ CMC Error reporting, proficiency testing, document control, internal audit & management review).
- Find out Technical Gaps (study NACO Technical Manual, all points in clause 6 to be covered)

Responsibility of Central Quality Committee



- Sensitization of other staff
- Orientation to Quality & NABH Standard to key staff
- Baseline assessment
- Help in Gap analysis and Coordinating full filing Gaps with State Quality Manager
- Assistance in preparing Quality Manual
- Submission to NABH application with fees