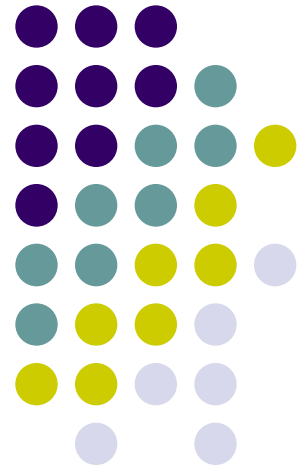


# GMP & Accreditation in Blood Banks: Roadmap in Gujarat

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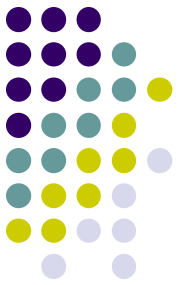
Dr. Nabajyoti Choudhury  
Addl. Director & Head  
Fortis memorial Research Center,  
Gurgaon, Delhi (NCR), India



# 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)

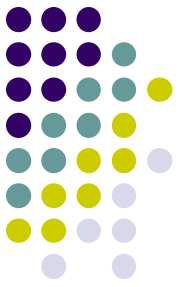
- USFDA enforced GMP (1991) in blood banks because of inadequate documentation
- GMP in BB is difficult due to batch variation
- All batches do not undergo QC test
- Aims is to reduce batch to batch variation

# Basic requirement of GMP (1)

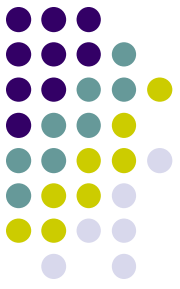


1. Quality management
2. Personnel & organization
3. Premises, equipment and materials
4. Documentation
5. Collection, testing & blood processing

# Basic requirement of GMP (2)



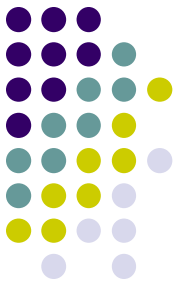
6. QC & proficiency testing
7. Complaints & component recall
8. Investigation of errors & accidents
9. Rejected units disposal & sample retention
10. Self assessment, internal & external audit



# 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

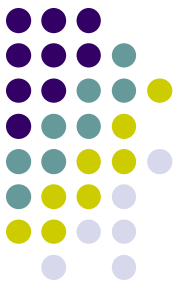
## 2. Personnel & organization



- 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:**

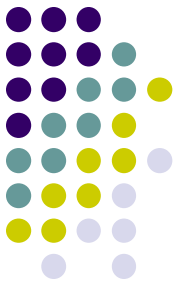
- # Planned & constructed as per D&C Act (minimum 7 areas with distinct function)

- # 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:**

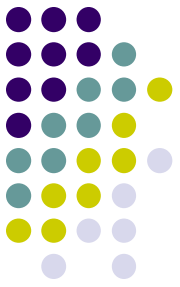
- # All equipment as per need & D&C Act

- # Equipment should be validated & installed as per design

- # All should be under warranty or AMC

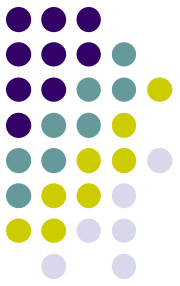
- # Maintenance/ calibration be documented

# 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

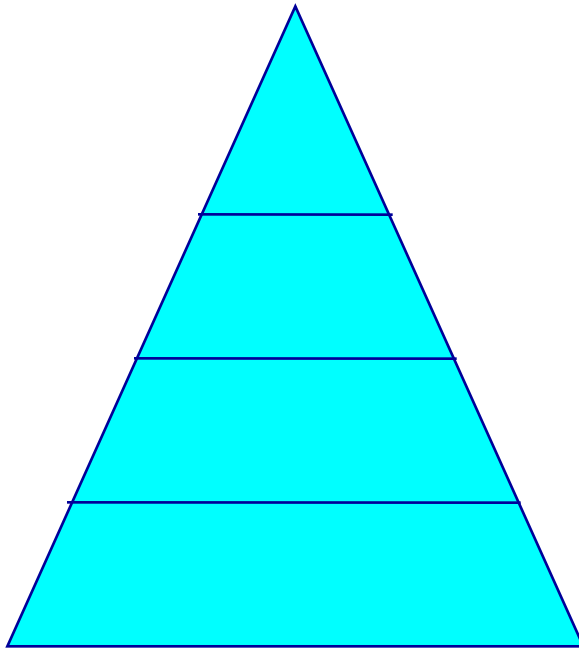
# 4. Documentation (A)



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

- # 1<sup>st</sup> level doc. (Q. Policy & Q. manual)
- # 2<sup>nd</sup> level doc. (Q. procedures, process control)
- # 3<sup>rd</sup> level doc. (SOPs)
- # 4<sup>th</sup> level doc. (Records, forms, labels, registers, data sheet etc)

# 4.Layers of Documentation (B)



## ISO 9000 - 1994 (E)

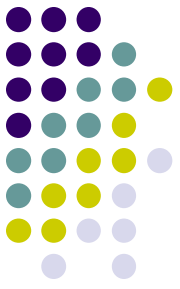
Level 1 Quality manual (policies)

Level 2 Quality procedures

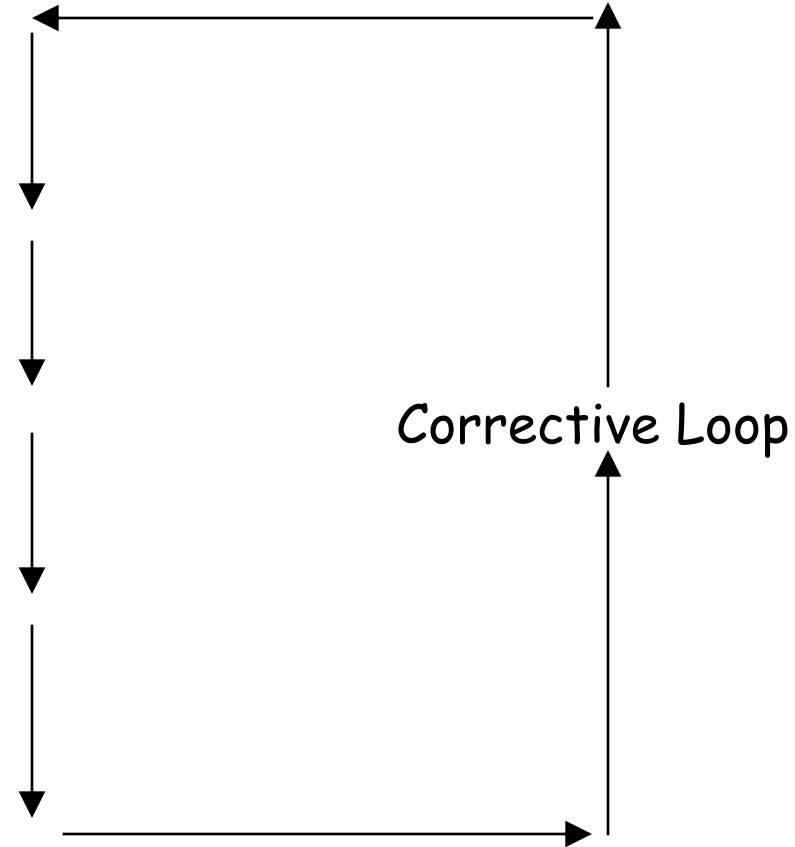
Level 3 SOPs

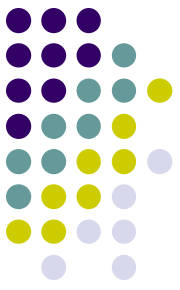
Level 4 Records

# 4. Documentation – Corrective Loop



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

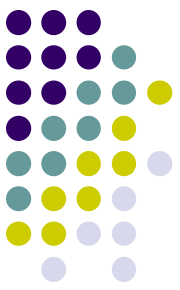




## 4. Documentation (D)

- 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.

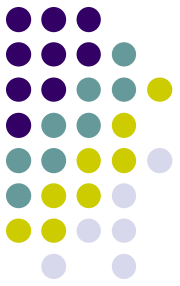
# 5. Collection, testing, blood processing



- 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 3<sup>rd</sup> 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

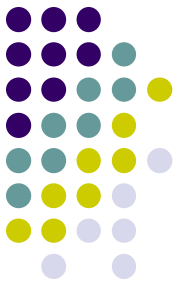


- As per national Standards/ regulation:
  - # Patient sample (x 7 days)
  - # Donor sample (x 30 days)
  - # Donor sample (x 5 years= western world)
- Disposal of rejected units as per SOP & national regulation with traceability

# 10. Internal & external audit

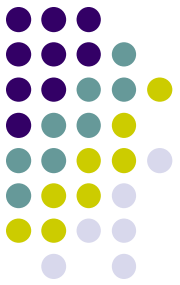


- Internal audit: required to monitor & document compliance of GMP/ISO and to propose necessary corrective action
- External audit by independent designated approved/ competent authorities.
- All audits must be documented & recorded



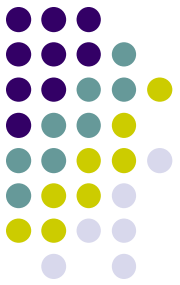
# Phases of GMP

- 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

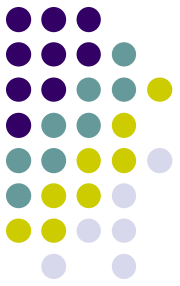
- Concept of GMP is to minimize error & making mistake to minimum
- Written procedures & documented records
- Trace mistakes if committed & take action
- Trained personnel for appropriate job.



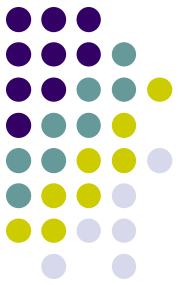
# ACCREDITATION



# What is Accreditation?



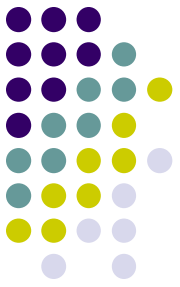
- Accreditation is a public recognition of the achievement of accreditation standards by an organization, demonstrated through an independent external peer assessment organization.



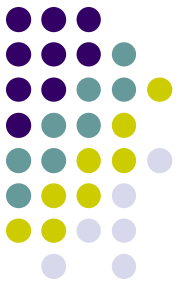
# Types of Certification

- **First Party Certification** : Laboratory belongs to user, who is satisfied and uses for his own jobs
- **Second Party Certification** : Laboratory does not belong to user but user using his own means certifies the laboratory, and uses for his own 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

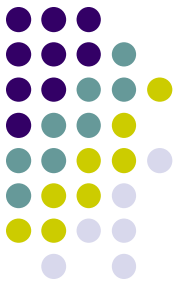


- First of its kind in India
- Guidance from the Project Director, GSCBT
- Our chance to improve in quality patient care through safe blood supply
- Strength: existing good infrastructure
- Trained manpower
- Concurrent NABH & NABL program
- Who will be benefited by this?.....

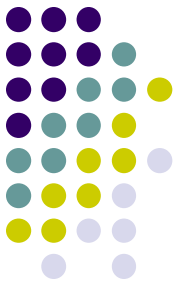


# *Benefits of Blood Banks Accreditation*

# 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...

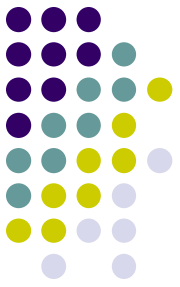
- Accreditation benefits all stake holders,
- Patients are the biggest beneficiary:
  - # High quality of care and patient safety
  - # Services by credential medical staff
  - # Rights of patients are respected & protected
  - # Patient satisfaction is regularly evaluated.

# 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

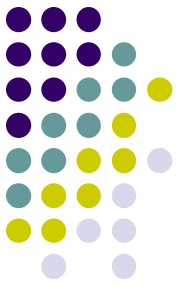


# Steps for BB accreditation (2)



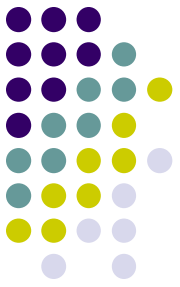
- Filling of human resource gaps
- Filling of structural resource gaps
- Filling equipment resource gaps
- Training of core team on Stand. & Objective
- Patients & employees satisfaction
- Quality Manual
- Annual/ Comprehensive Mainten. Contract

# Steps for BB accreditation (3)

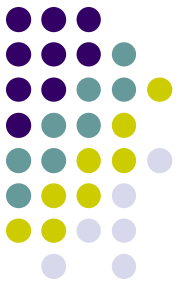


- Calibration
- International Quality Control
- External Quality Control (EQAS)
- Internal audit
- Review meeting of the Committee
- Internal audit report GSCBT
- Final review at GSCBT level

# 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

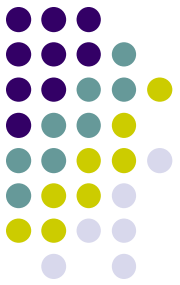


- Legal identity
- Responsibility
- Ethics in BB
- Management system
- Policies processes & procedures

## 2. Accommodation & Environment

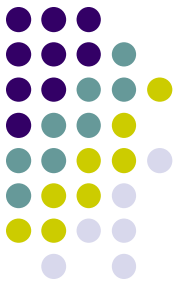


- Space allocation (9 areas; AC; component; apheresis; blood donation camps)
- Environmental control
- Biological Chemical & radiation safety
- Internal communication system



## 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

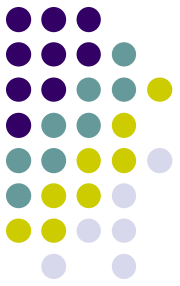


## 4. Equipment

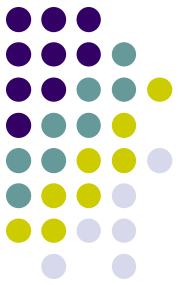
- Required equipment
- Selection & validation of equipment
- Use of equipment
- Equip detail record & unique identification
- Program for calibration & maintenance
- Equip for storage of blood & component
- Computer system
- Breakdown of equip



# 5. External services & supplies



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



## 6. Process control

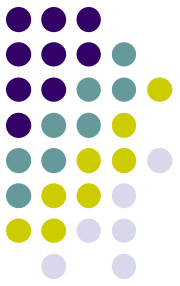
- Policies & validation of process/procedure
- Donor selection
- Component Laboratory
- Quarantine & storage
- Labeling
- Testing of donated blood
- Compatibility testing
- Transfusion reaction & evaluation
- Documentation in transfusion services
- Histocompatibility testing
- Quality Control
- Proficiency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

# 7. Deviations & adverse events

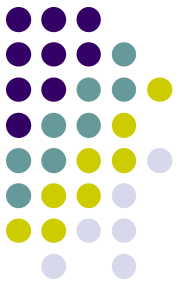


- NC in policies & procedures
- Procedure to release NC blood/component
- Preventing recurrence of NC

# 8. Performance improvement



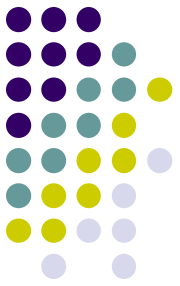
- Addressing complaints
- Corrective action
- Preventive action



# 9. Document control

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

# 10. Records



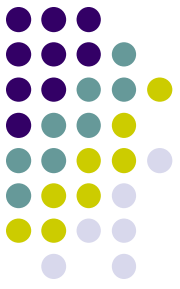
- Record identification
- Quality & technical records
- Records retaining period

# 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

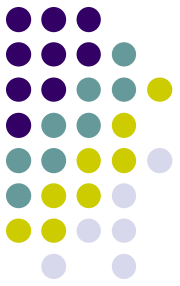
# Jobs for Blood Banks (1)



- 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

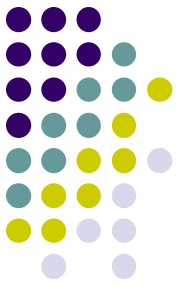


# Jobs for Blood Banks (2)



- 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