



**The Lebanese Order of Pharmacists**  
26<sup>th</sup> Annual Congress

**Teaming Up for Excellence in Patient Care**  
**معاً للتميز في رعاية المريض**

## **Role of Pharmacist in the Quality Assurance**

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# Disclosure

I, Maya Farran, declare to meeting attendees that there are no financial relationships with any for-profit companies that are directly or indirectly related to the subject of this presentation

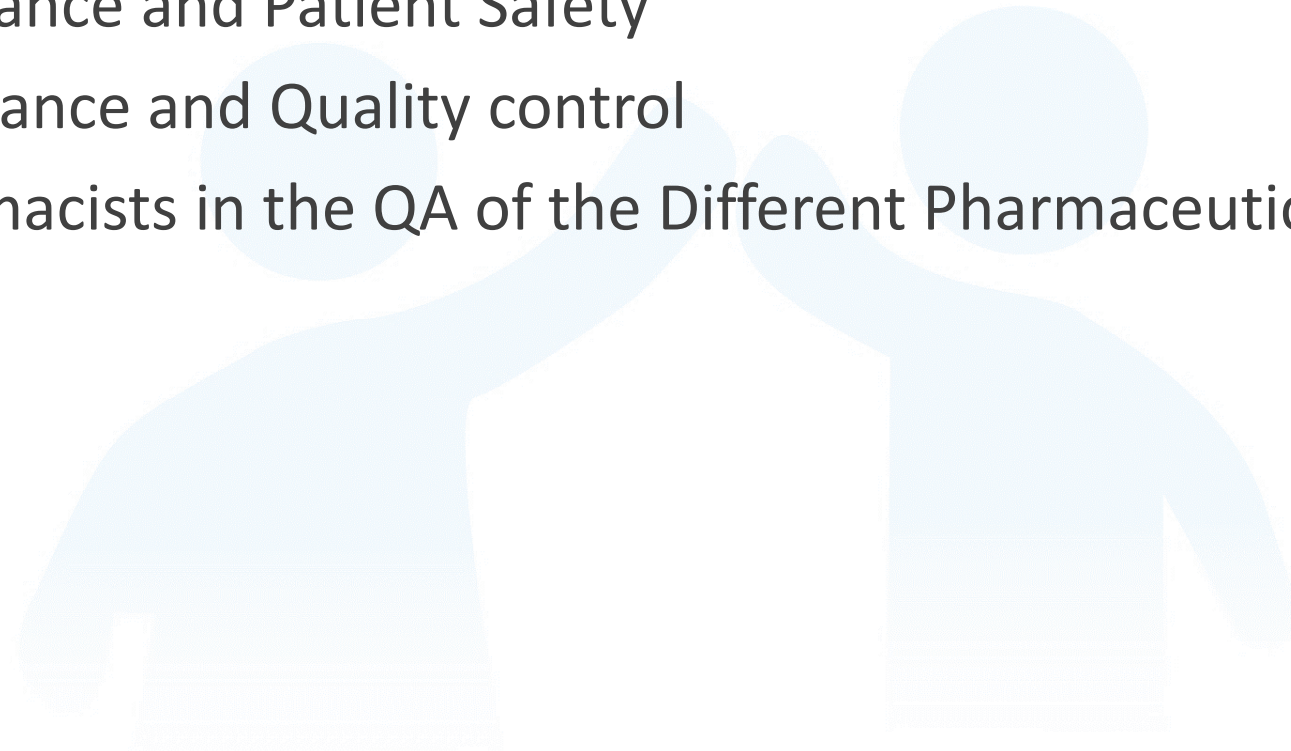




# Outline

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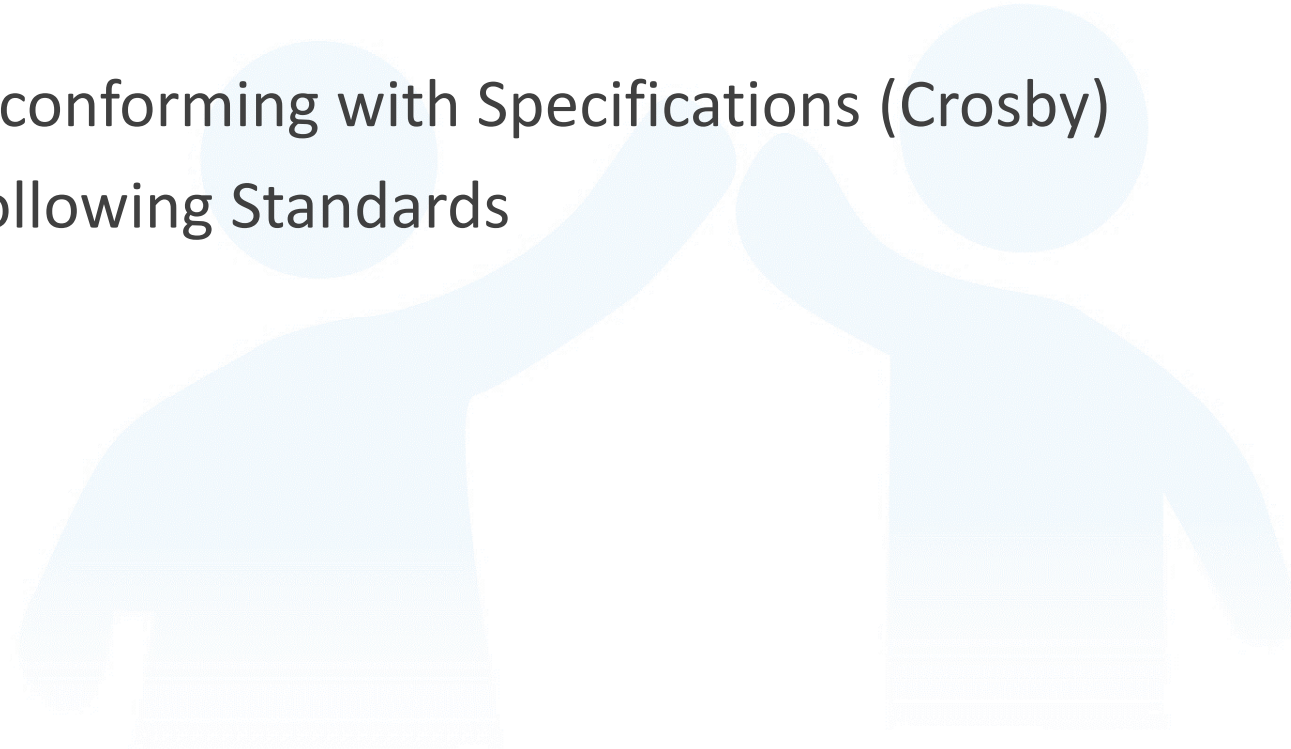
- 1) Quality a multifactorial approach
- 2) Quality and Challenges
- 3) Quality assurance and Patient Safety
- 4) Quality Assurance and Quality control
- 5) Role of Pharmacists in the QA of the Different Pharmaceutical Institutions





# 1) Quality, a multifactorial approach

- Fit for use => Efficacy (Juran)
- Easy or Pleasant to use => Customer Satisfaction / Compliance (Ishikawa)
- Safe for use
- Final Quality is conforming with Specifications (Crosby)
- Production is following Standards







## 2) Quality and Challenges

Health Care Providers, particularly Pharmacists, face real challenges and are constantly looking for Quality Products and delivering Quality Services:

- **Patient Safety**
- Substandard Drugs
- Cost Effectiveness: Provide quality services/drugs within limited resources
- Trust and Confidence in Health Care Providers





# Quality and Challenges

Offering Quality Product or Service is no more optional nowadays

Not an added value, **Basic requirement for Sustainability** due to:

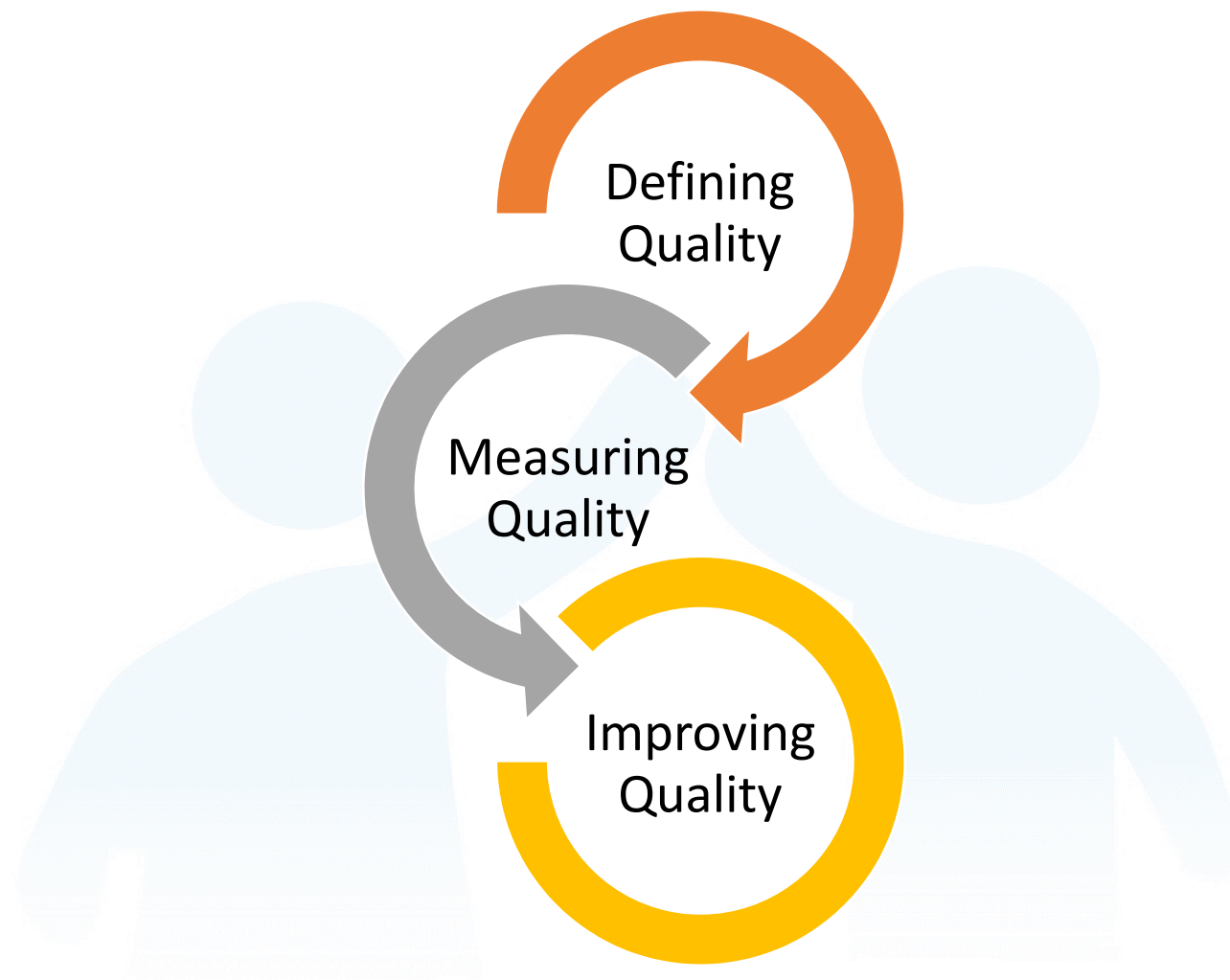
- Market Competition
- Patients exposed, knowledgeable and demanding
- Patients who are becoming reporters on Social Media

A satisfied customer, will tell to an average of 4 people

A dissatisfied customer, will tell to 12 people



### 3) Quality Assurance: 3 Pillars





## 3.1 Quality Assurance and Patient Safety

- Quality Assurance is the **Pharmaceutical Regulation** to establish Patient Safety Discipline.
- Those regulations were put in place as a response to tragic circumstances and as a prevention for future Tragedies.
- Till today, we are still far from perfection.

Alyssa Shinn, a baby born prematurely to a mother who had undergone IVF, received a fatal dose of Zinc in her hyperalimentation solution prepared by a part time pharmacist at a SL Hospital in Las Vegas.

- To counter this reality, Healthcare Professionals started adopting methods and regulations to reduce errors pioneered by Shewhart, Juran, Deming...





# Medication Errors: A sad reality

WHO publishes Statistics on Medication Errors

- 1 Death every day in the US due to Medication Errors in 2017
- in the US, around \$42 Billions cost of Medication errors in 2017
- Probability of patients suffering of Medication Errors in Australian hospitals is a distressing 16.6% whereas in Denmark the rate is around 10%.
- Medication Errors are underreported !



# Medication Errors causes

- Human Errors

Fatigue, overload, shortage of staff, lack or poor training, wrong information

- System failures

- Organization and Implementation of the Best Practices
- **Communication** and Coordination

- Lack of Internal Control/Quality Assurance

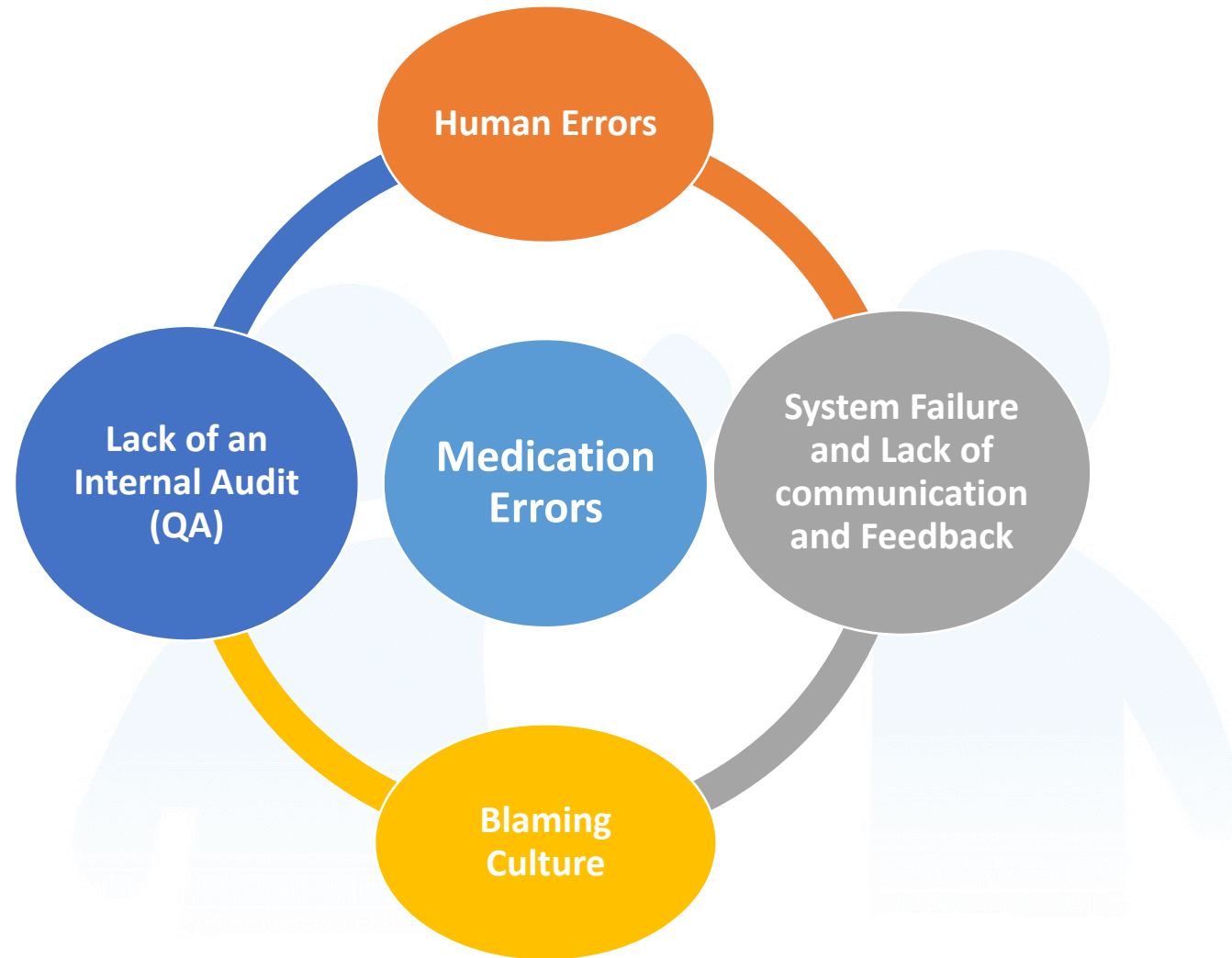
CAPA: Corrective Actions / Preventive Actions

- Culture

Avoid blaming when a mistake is made is the best environment for safe care



# Causes of Medication Errors





# Quality Assurance and Patient Safety

Quality Assurance is the Good Practice that will:

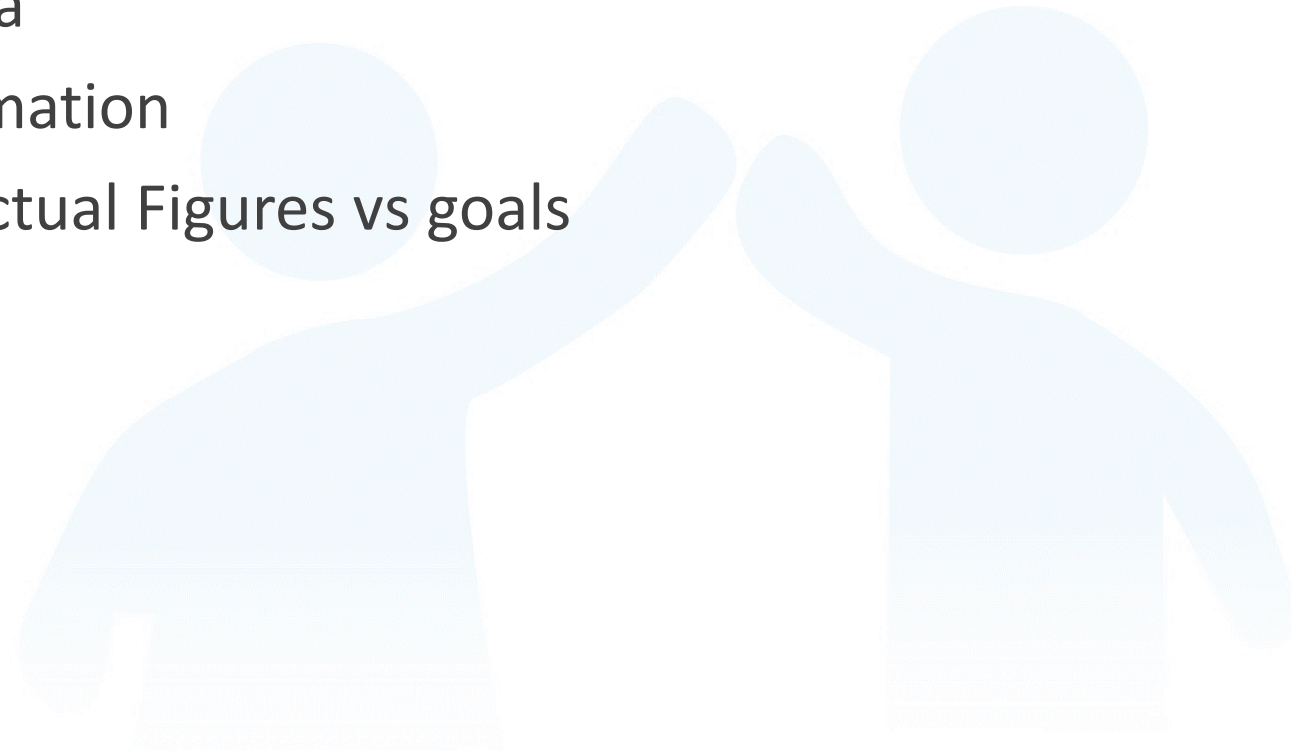
- Establish a Quality System providing **consistency** of results and a **systematic** approach independently of the human variability
- Audit compliance to the System
- Investigate Non Conformity
- Remain Independent
- Quality is a **culture and a mindset**:
  - Embedded in every step of the process
  - Responsibility of every person in the institution





## 3.2 Measuring Quality

- What cannot be measured cannot be improved
  - Identify indicators of performance
  - Collecting data
  - Analyze information
  - Benchmark Actual Figures vs goals





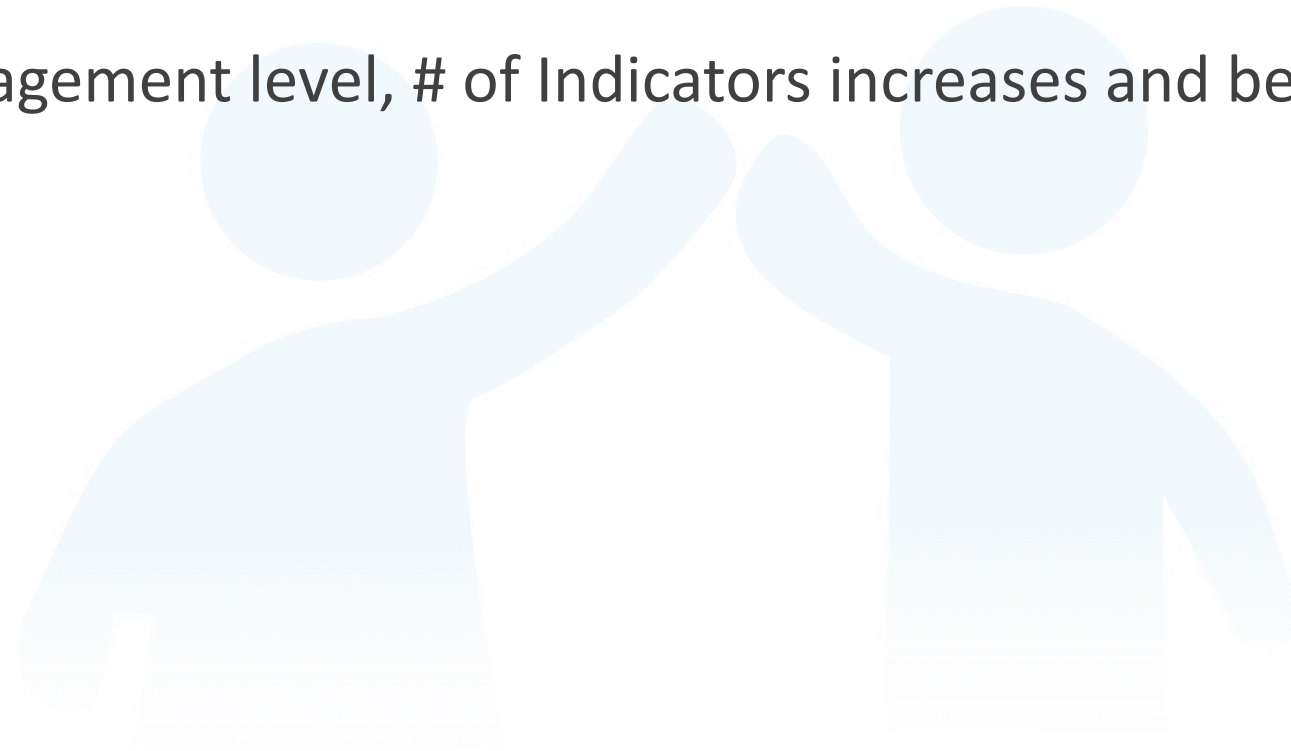
# Key Performance Indicators (KPI)

- KPI have different dimensions:
  - Financial Indicators: Occupancy Rate, Profit and Loss, Inventory Control, Expired Items...
  - Quality Indicators related to the internal processes and patients safety: Rate of readmission, Nosocomial Infections, Mortality rate, Medication errors, Length of stay....
  - Human Resources indicators: Patient Nurse Ration, Absenteeism, Turnover...



# Key Performance Indicators

- At the corporate Level, 5 to 6 Indicators are enough for the global analysis of the performance
- At middle management level, # of Indicators increases and becomes specific





# Key Performance Indicators

- Edwards Deming:

“ Quality depends by 85% on the Organization and 15% on the Personal Expertise”

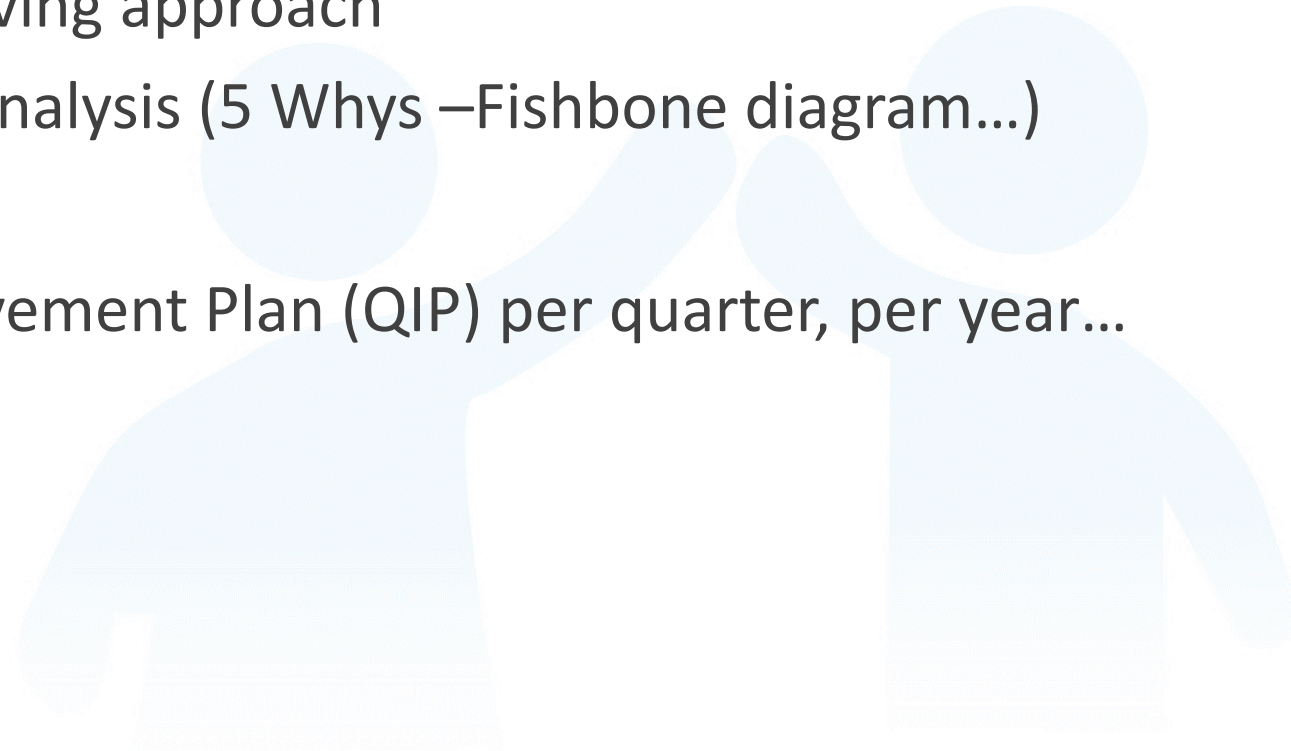






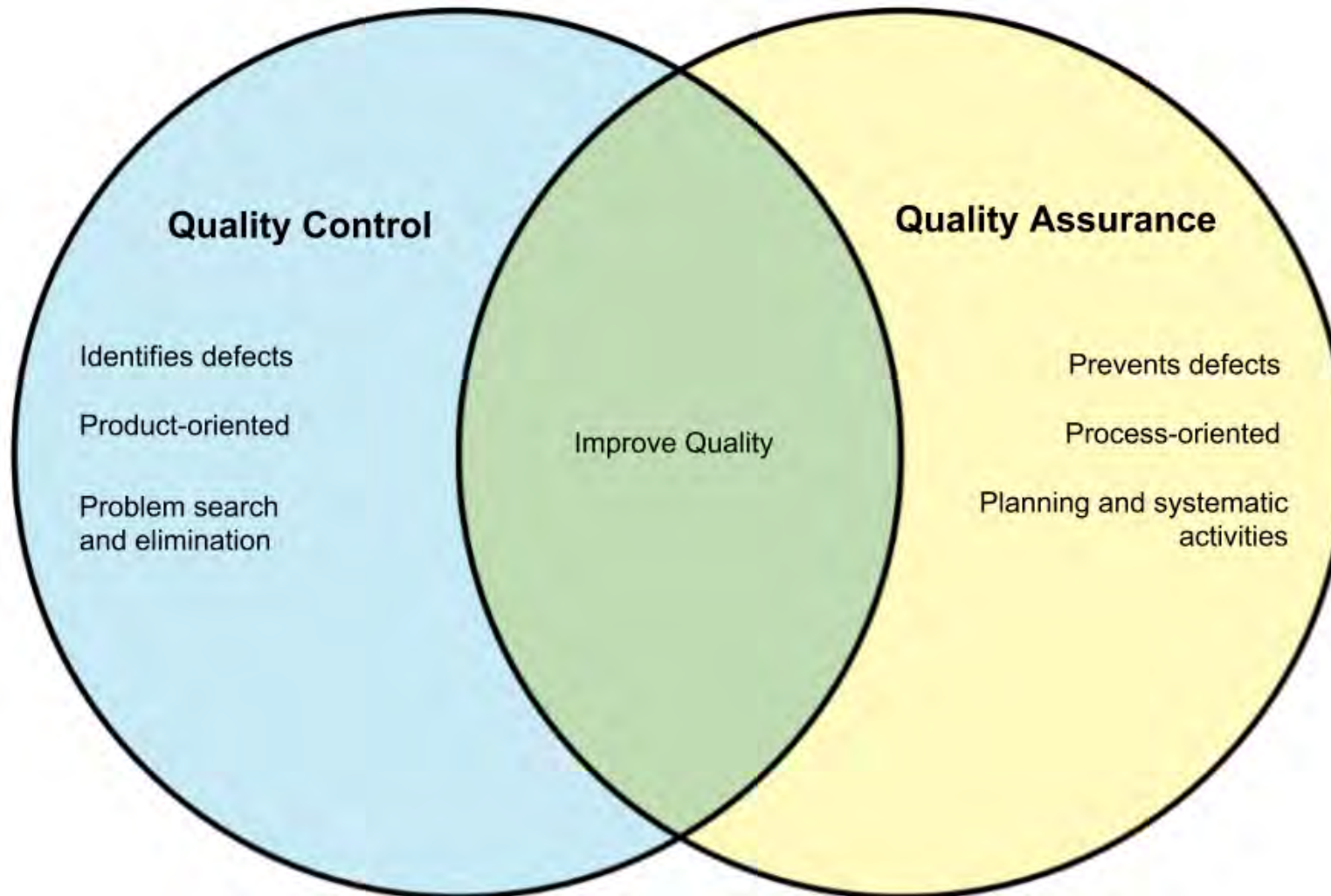
## 3.3 Improving Quality

- Assessment of KPI evolution over time
- Investigation to take a **C**orrective **A**ction/ **P**reventive **A**ction (**CAPA**)
  - Problem/ Solving approach
  - Root Cause Analysis (5 Whys –Fishbone diagram...)
  - Gap Analysis
- Quality Improvement Plan (QIP) per quarter, per year...





## 4) Quality Assurance and Quality Control





## 5) Role of Pharmacists in QA of the Different Pharmaceutical Institutions

- Pharmaceutical Industries
- Hospitals
- School of Pharmacies
- Regulatory Sector (MOPH)
- Clinical Research
- Community Pharmacies





## 5.1 Role of Pharmacists in QA of Pharmaceutical Industries

- The QA Pharmacist ensures that Production is in compliance to quality requirements as dictated by current **Good Manufacturing Practices (cGMP)**
- Documentation of the quality system
- Writing and approving of Standard Operating Procedures (SOP) to establish a system to be followed
- Investigation of Non Conformity
- Release or Rejection of Manufactured Lots
- Participating in self inspections and regulatory inspections.





## 5.2 Role of Pharmacists in QA of Hospitals

- In the hospitals settings, the Quality System is regulated by the **MOPH Accreditation, JCI ... that will establish patient safety.**
- Pharmacists are responsible for the whole Medication Management and Safety Chapter all through the hospital:
  - Procurement and selection
  - Storage
  - Ordering, and transcribing
  - Preparing and dispensing
  - Administering medication
  - Monitoring medication effects
  - Evaluation of the medication management process



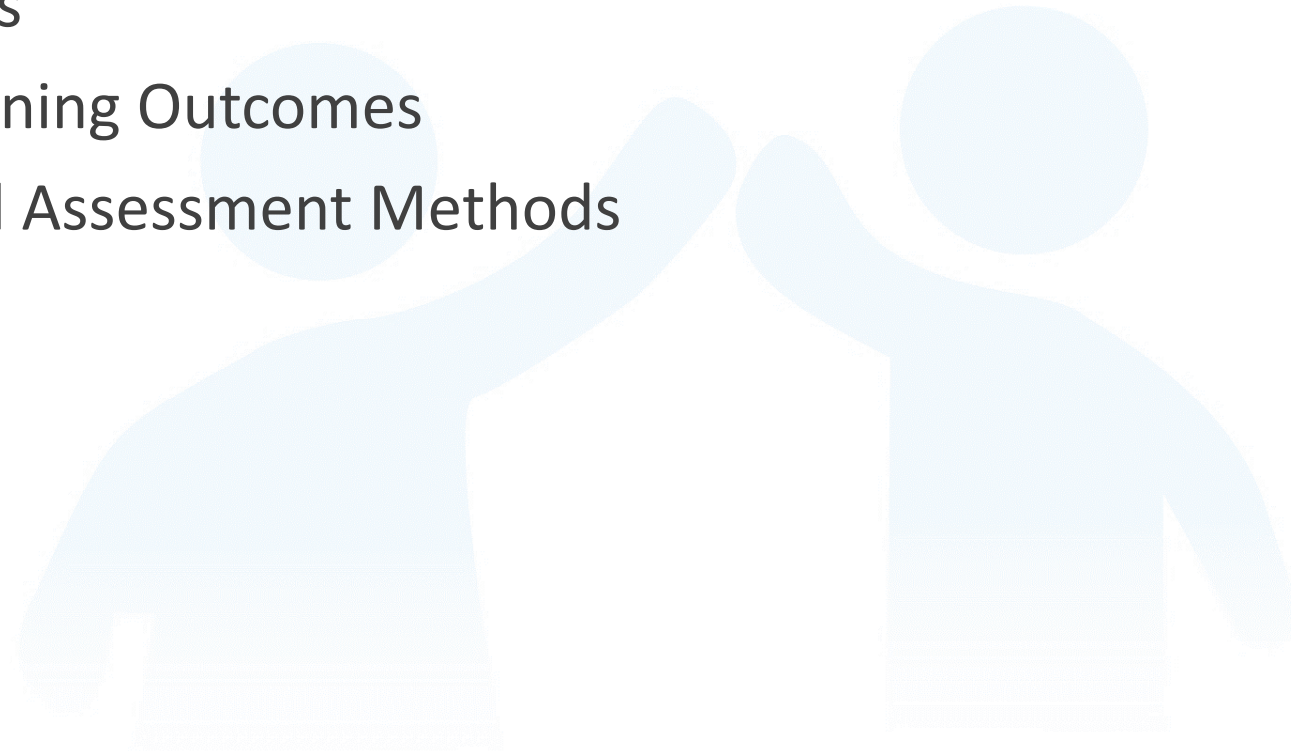
## 5.3 Role of Pharmacist in School Of Pharmacies Accreditation

- The Accreditation Council for Pharmacy Education (ACPE) is an autonomous and independent agency whose Board of Directors is derived through:
  - American Association of Colleges of Pharmacy (AACCP)
  - American Pharmacists Association (APhA)
  - National Association of Boards of Pharmacy (NABP)
  - American Council on Education (ACE)for the accreditation of professional degree programs in pharmacy.



# Role of Pharmacist in School Of Pharmacies Accreditation

- The ACPE sets a system for
  - Domains of Foundational Knowledge, Pharmaceutical Cares....
  - Competencies
  - Program Learning Outcomes
  - Teaching and Assessment Methods





## 5.4 Role of Pharmacists in Quality Regulatory

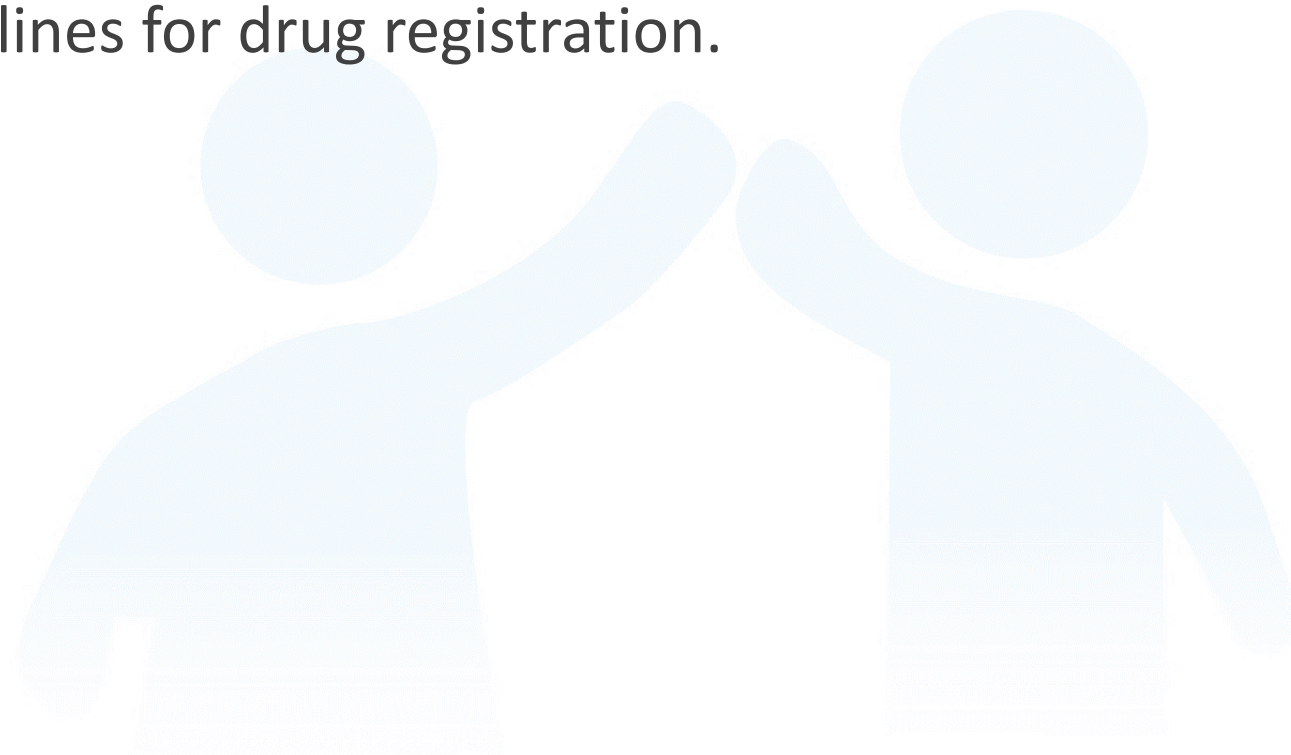
- Pharmacists in the MOPH technical committees studies and assesses product files submitted for registration.
- Filter for the market that will reject Substandard Products
- Quality, Safety and Efficacy information are in one unified common format, the **CTD File** (Common Technical Document ) that enabled implementation of **Good Review Practices**.



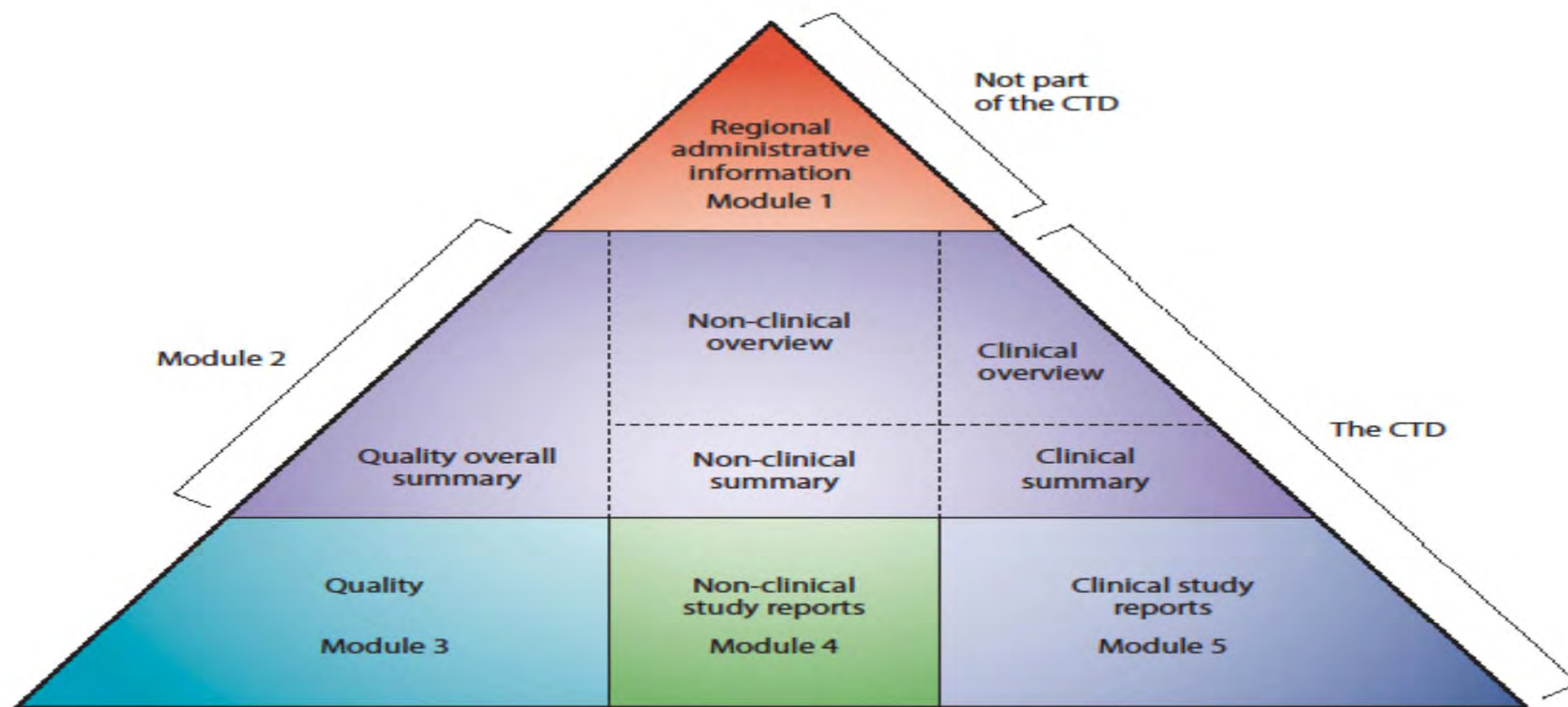


# Role of Pharmacists in Quality Regulatory

- The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (**ICH**) is unique in bringing together the regulatory authorities and pharmaceutical industry to established scientific and technical guidelines for drug registration.



# CTD Triangle



**The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.**



## 5.5 Role of Pharmacists in Clinical Researches

- Clinical Researches are regulated by Good Clinical Practices





## 5.6 Role of Pharmacists in QA of Community Pharmacies

- Community Pharmacy practice is appropriately managed to allow safe and effective delivery of services.
- Current status:
  - Community Pharmacies create the **greatest exposure** with patients so far not controlled, relying on the individual effort of Community Pharmacists.
  - Community Pharmacies are monitored so far by the Law and internal regulations of the MOPH and OPL.
  - Quality improvement is related to update in information through the CE Program imposed by the OPL





# Role of Pharmacists in QA of Community Pharmacies

- Shall an accreditation for the community pharmacy be installed?
- Deep thinking of Key Quality Indicators to be set, implemented and followed is required

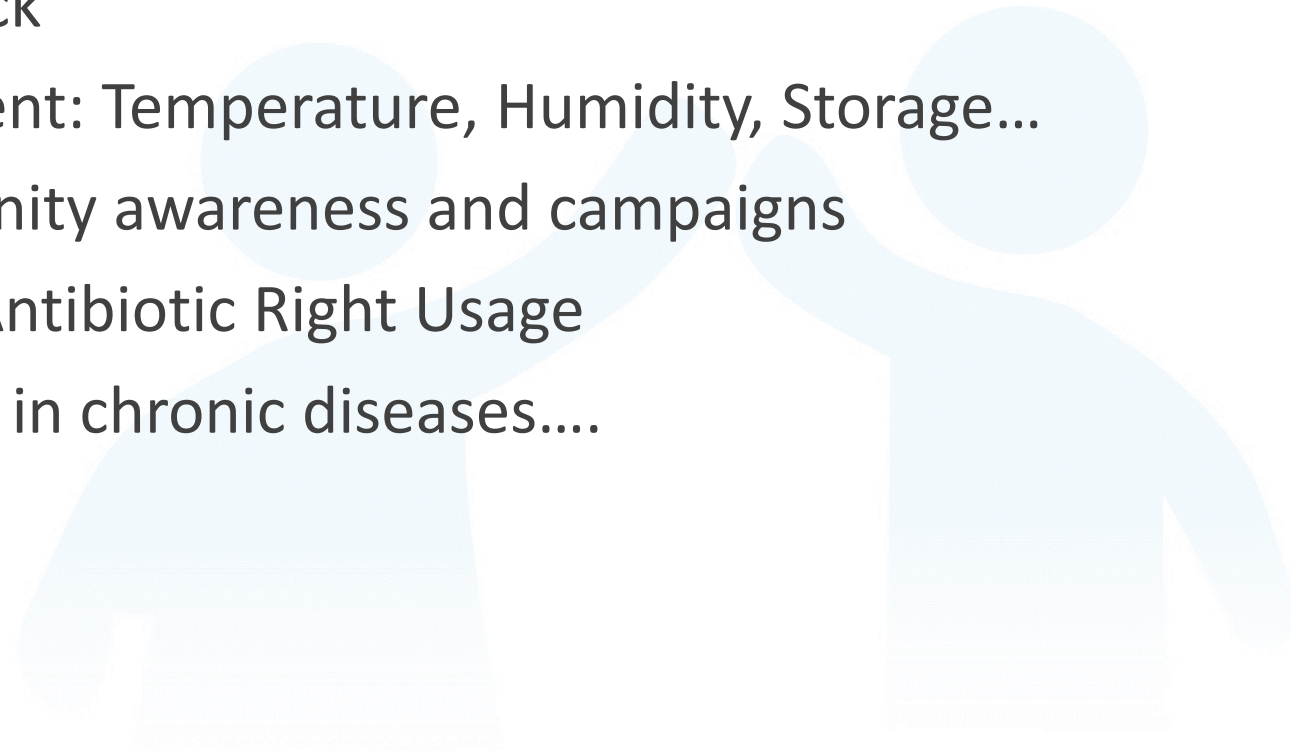






# Quality Care Indicators for Community Pharmacies

- Proactive Patient Counseling
- Staff Training
- Patient feedback
- Safe Environment: Temperature, Humidity, Storage...
- Role in community awareness and campaigns
- Major Role in Antibiotic Right Usage
- Preventive role in chronic diseases....





# Community Pharmacy Accreditation

- By establishing an accreditation for the Pharmacies, The **Patient Safety Journey** will be fully controlled.
- The role of **Pharmacist as Health Care Provider** will be strongly empowered
- This system requires a well trained educators and auditors pharmacists
- It will open hundreds of new posts for the pharmacists
- Should it be Voluntary or Obligatory?
- Should it organized by OPL or MOH?



## 6) Conclusion

- Accreditation will not make life easier, but it is a **positive force** to improve performance
- Patient Safety has an economic and financial burden
- Accreditation should be **rewarded** by MOPH by giving some privileges to the Pharmacies or Hospitals achieving high scores or those maintaining their high rank
- **“Pay For Performance”** is a concept that Healthcare Industry has to fight for, so that:
- **Quality becomes a Habit**, not only an act (Aristotle).



# Take Home Messages

- Quality is a basic requirement to satisfy demanding patients needs
- Quality assurance creates a systematic approach independently of Human intervention to secure Patient Safety
- A culture has to be established in every institution to promote quality
- Quality has to be measured to be improved
- Establish Key Performing Indicators
- Pharmacists primary challenge is prevention of Medications Errors and Patient Safety
- Pharmacists are responsible for implementing Good Practices either in Hospitals, Industries, Schools, MOPH....
- Accreditation for Community Pharmacies: A required future improvement plan





# References

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- *ICH Q10, Pharmaceutical Quality System*
- *The Business Case for Quality, Jones & Barlett Publishers*
- *EU GMP, Chapter 1, Pharmaceutical Quality System*
- [www.pharmacypracticeaccredit.com/files](http://www.pharmacypracticeaccredit.com/files)
- *WHO guidelines*
- *Developing and using quality indicators in French health care organisation, E. Minville*





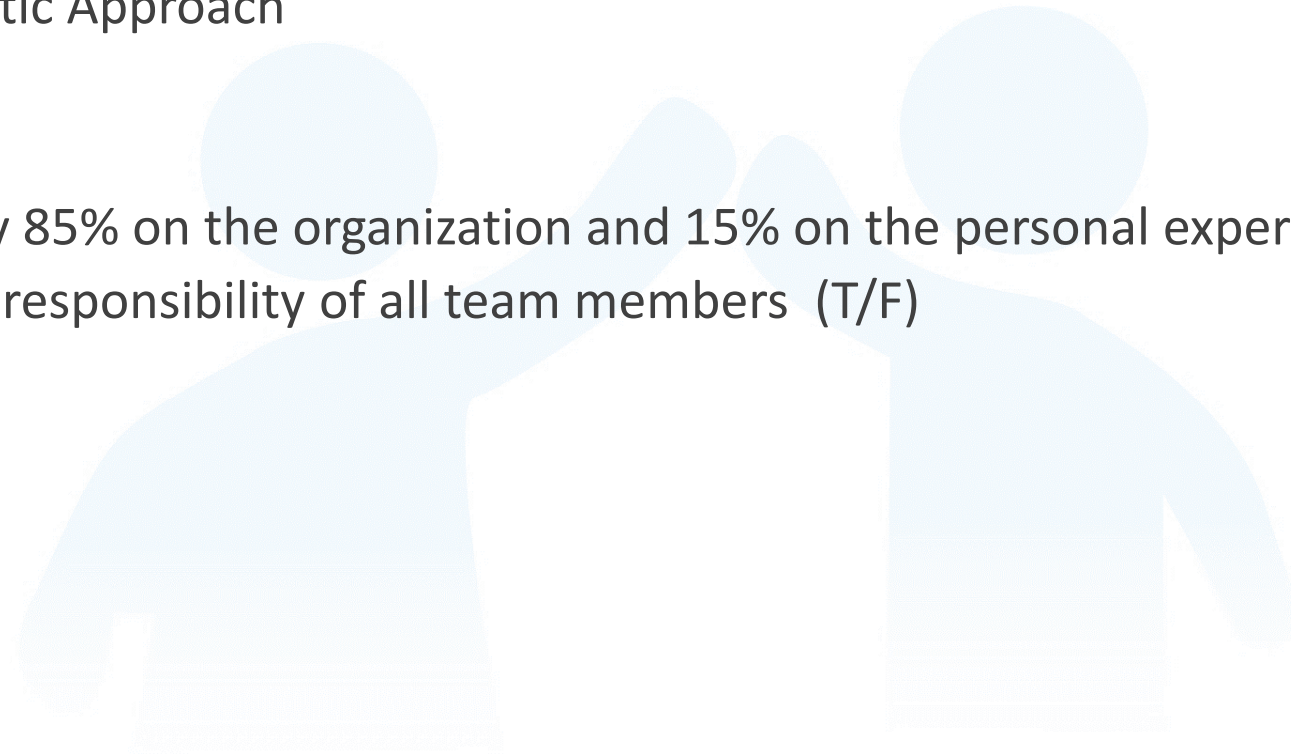


- **What is the first stage in any quality improvement initiative?**
  - A) Planning
  - B) Check the Talk
  - C) Analyze the data
  - D) Management Commitment
  
- **What are the Quality Measurement tools?**
  - A) Quality Control
  - B) Key Performance Indicators
  - C) Regular Inspection
  - D) CAPA: Corrective Measure/Preventive Measure



# MCQ

- Medication Errors are due to:
  - A) Lack of Training
  - B) Blaming Culture
  - C) Lack Of Systematic Approach
  - D) All of the Above
  
- Quality depends by 85% on the organization and 15% on the personal expertise **(T/F)**
- Quality is a shared responsibility of all team members **(T/F)**



# Trust me, I am a Pharmacist

