# MODULE 1

Q.M.S

INTRODUCTION :

IN WORSHOP, THERE IS WORK AND SHOP….

WE WILL WORK TOGETHER.

WE WILL CREATE A GROUP OF FRIENDS AND EXPERTS WHICH WILL STAY IN TOUCH AND START A NETWORK OF PASSIONATE PEOPLE EXCHANGING INFORMATIONS AND GOOD PRACTICES FOR THE BEST OF THEIR MUTUAL INTERESTS

FOR DOING THAT, WE HAVE TO KNOW EACH OTHERS.

INTRODUCTION :

WE WILL WORK IN GROUPS TO EXCHANGE, INTERACT, AND CREATE THESE LINKS WHICH WILL STAY FOR YEARS AND HELP US IN OUR DAILY LIVES.

IT IS ALSO OUR AMBITION THAT ONCE YOU ARE BACK IN YOUR ORGANIZATION, YOU TEACH YOU COLLEAGUES AND EXTENT THE NETWORK.

EXCHANGING IN GROUPS WILL HELP YOU TO LEARN FROM THE OTHERS

WE ARE HERE BECAUSE WE ALL WORK IN ORGANIZATIONS WHICH SAVE LIVES !!!

INTRODUCTION :

I HAVE BUILT THIS PROGRAM ESPECIALLY FOR YOU TODAY AND TOMORROW.

THIS IS A PROGRAM BASED ON ALL THE AUDITS AND CONSULTING THAT I HAVE MADE IN DECADES.

THIS IS BASED ON THINGS THAT THE AUDITORS DO NOT WANT TO SEE ANYMORE.

THEY CAN BE BASICS, BUT 80 % OF THE POINTS NOTIFIED BY THE AUDITORS ARE BASICS.

WE WILL PROGRESS ALL TOGETHER.

YOU ARE DIVIDED IN GROUPS.

I SHALL ASK QUESTIONS

YOU WILL DISCUSS TOGETHER AND BRING ANSWERS

EACH GROUP WILL SPEAK « ONE VOICE »

# 11 QUESTIONS TO KNOW EACH OTHER BETTER

1. DO YOU HAVE A QUALITY SYSTEM ?
2. DO YOU HAVE A QUALITY ORGANIZATION MANAGED BY AN IDENTIFIED AND UNIQUE RESPONSIBLE PERSON ?
3. IS THIS PERSON A PHARMACIST ?
4. IS THIS PERSON INDEPENDANT FROM THE PLANT MANAGER ?
5. DOES THIS PERSON HAVE OTHER RESPONSIBILITIES ?
6. DO YOU HAVE IN YOUR ORGANIZATIONA DOCUMENTED AND EXTENSIVE TRAINING PROGRAM ?
7. ARE THE TRAININGS RECORDED AND TRACED ?
8. DO YOU HAVE A DATA INTEGRITY SYSTEM ENSURING THAT RECORDS CANNOT BE MODIFIED ?
9. DO YOU HAVE A CONTINUOUS IMPROVEMENT SYSTEM IN PLACE ?
10. IF YES, HOW IS IT ORGANIZED ?
11. ON WHAT IS THIS QUALITY SYSTEM FOCUSING ? Water sytems, HVAC, Process, Labs, Manufacturing, training, etc...

# Compliance plan vs. Quality Plan

A document setting quality objectives including action plans, resources and planning to re-establish cGMP compliance is a …….. Plan .

# Compliance plan vs. Quality Plan

By group, decide if it is a compliance plan or a quality plan ?

Write the good definition of the other document.

A spoke person will tell the other groups , the answer given by his group

# Compliance plan vs. Quality Plan

A document setting quality objectives including action plans, resources and planning to re-establish cGMP compliance is a compliance plan.

# Compliance plan vs. Quality Plan

## Organization of a compliance plan

1. Status of the situation :
    1. List findings.
2. Write a plan :
    1. Inputs/outputs
    2. Targets.
3. Write a strategy for execution.
4. Establish a governance.

# Compliance plan vs. Quality Plan

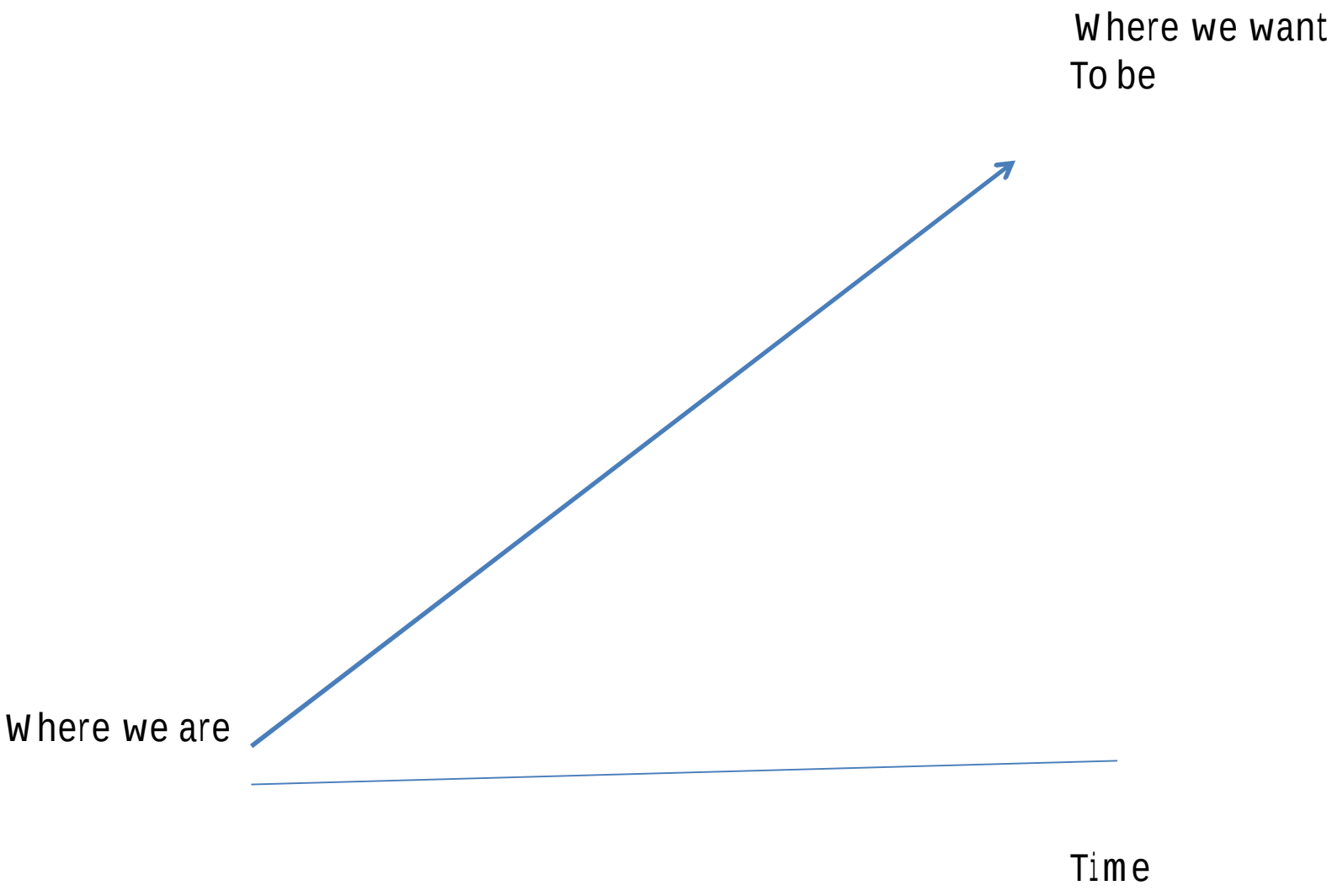
A document setting quality objectives and specifying necessary operational processes and related resources to maintain or progress cGMP compliance is a quality plan.

# Compliance plan vs. Quality Plan

A Quality plan must be :

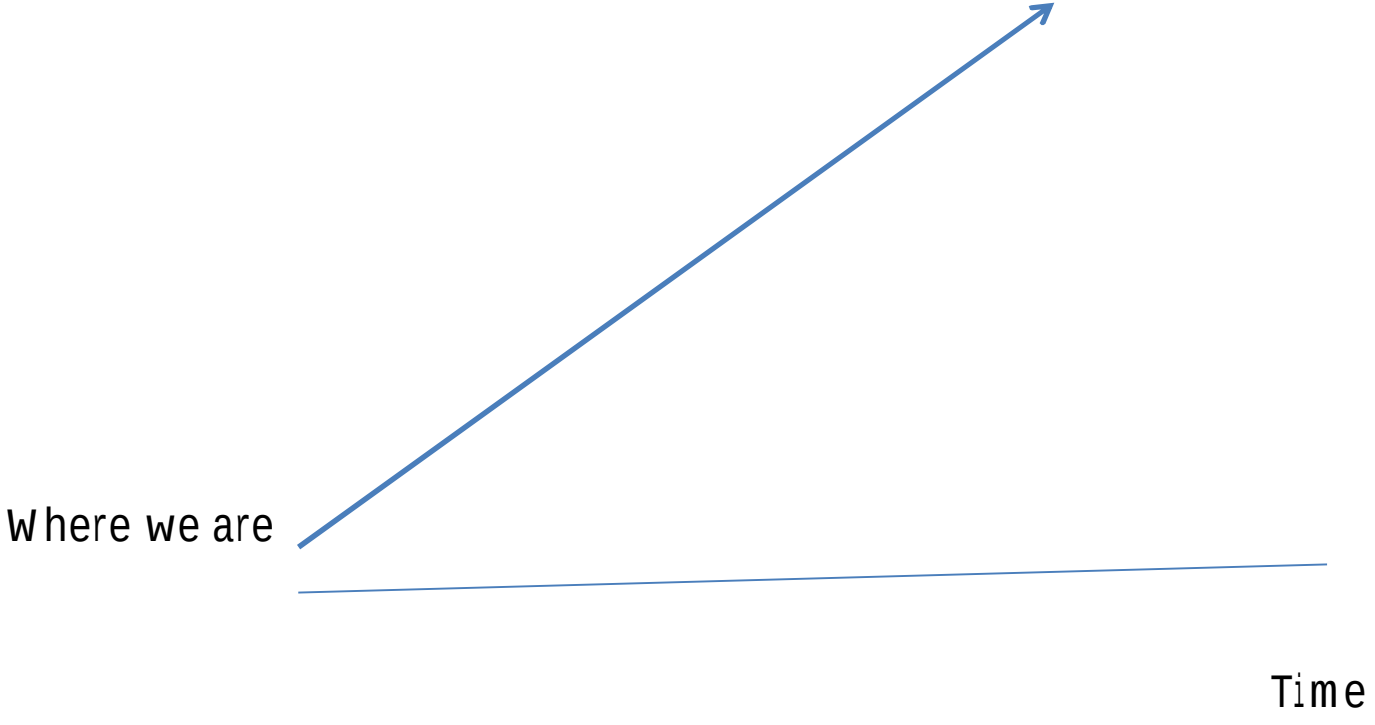
1. Targeted.
2. Data driven.
3. Ambitious : Where do we want to be in 12 months.
4. Realistic

# 1. Targeted : What is the objective ?



1. Targeted : What is the objective ?

THIS IS ALSO CALLED A QUALITY POLICY



1. DO YOU HAVE A QUALITY POLICY ?

2. IS IT PUBLIC ?

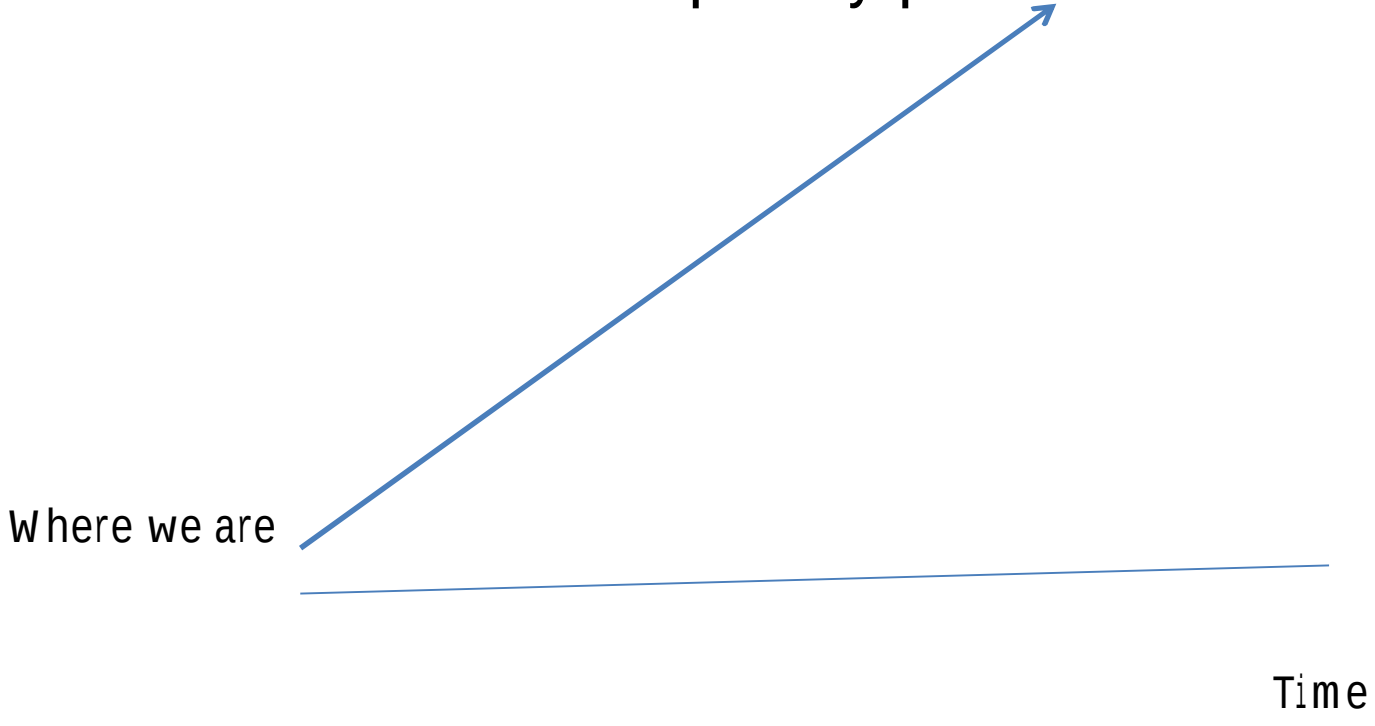
3. IS IT POSTED ?

4. IS EVERYBODY IN YOUR COMPANY AWARE OF IT ?

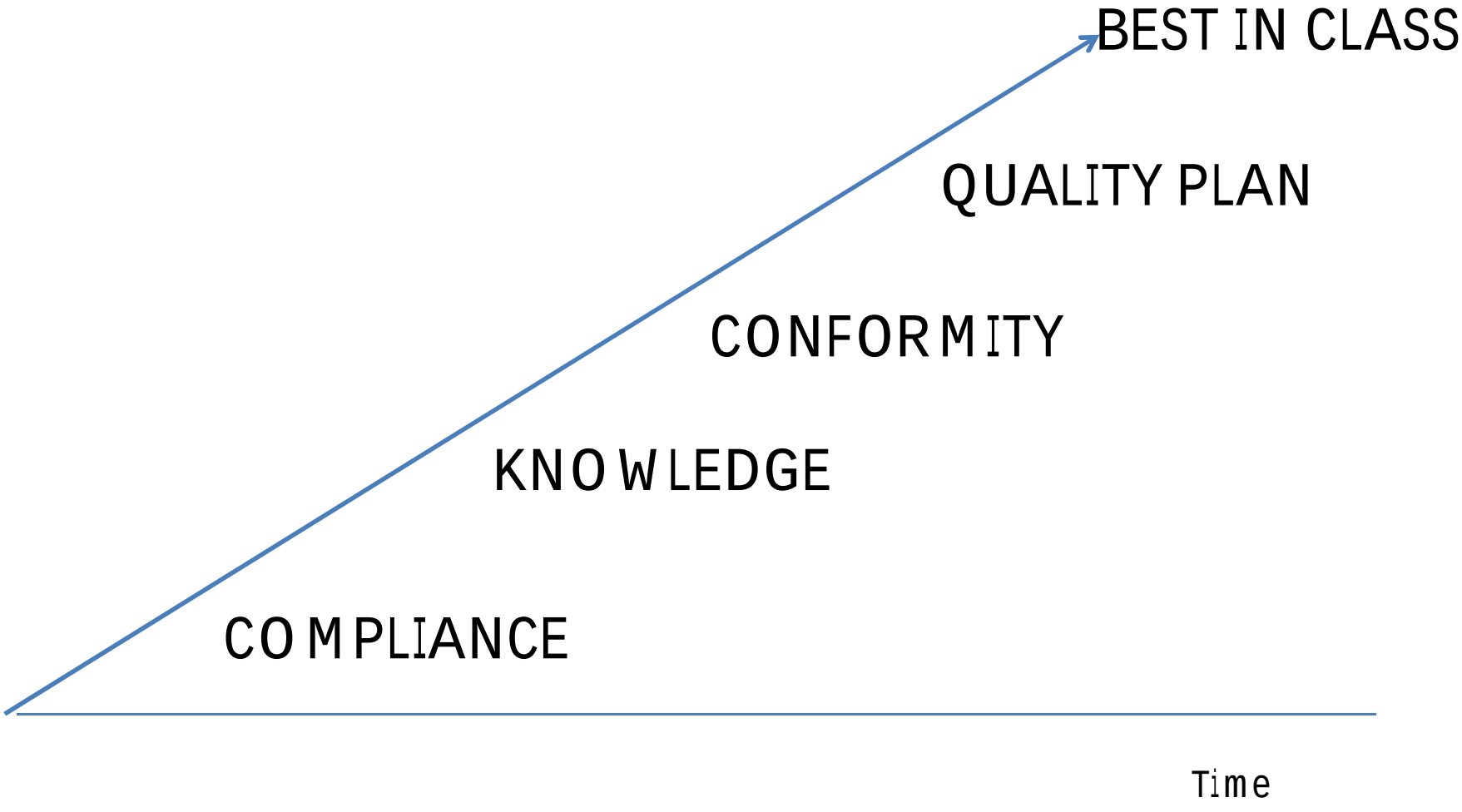
5. IS IT ON THE COMPANY WEBSITE ?

# 1. Targeted : What is the objective ?

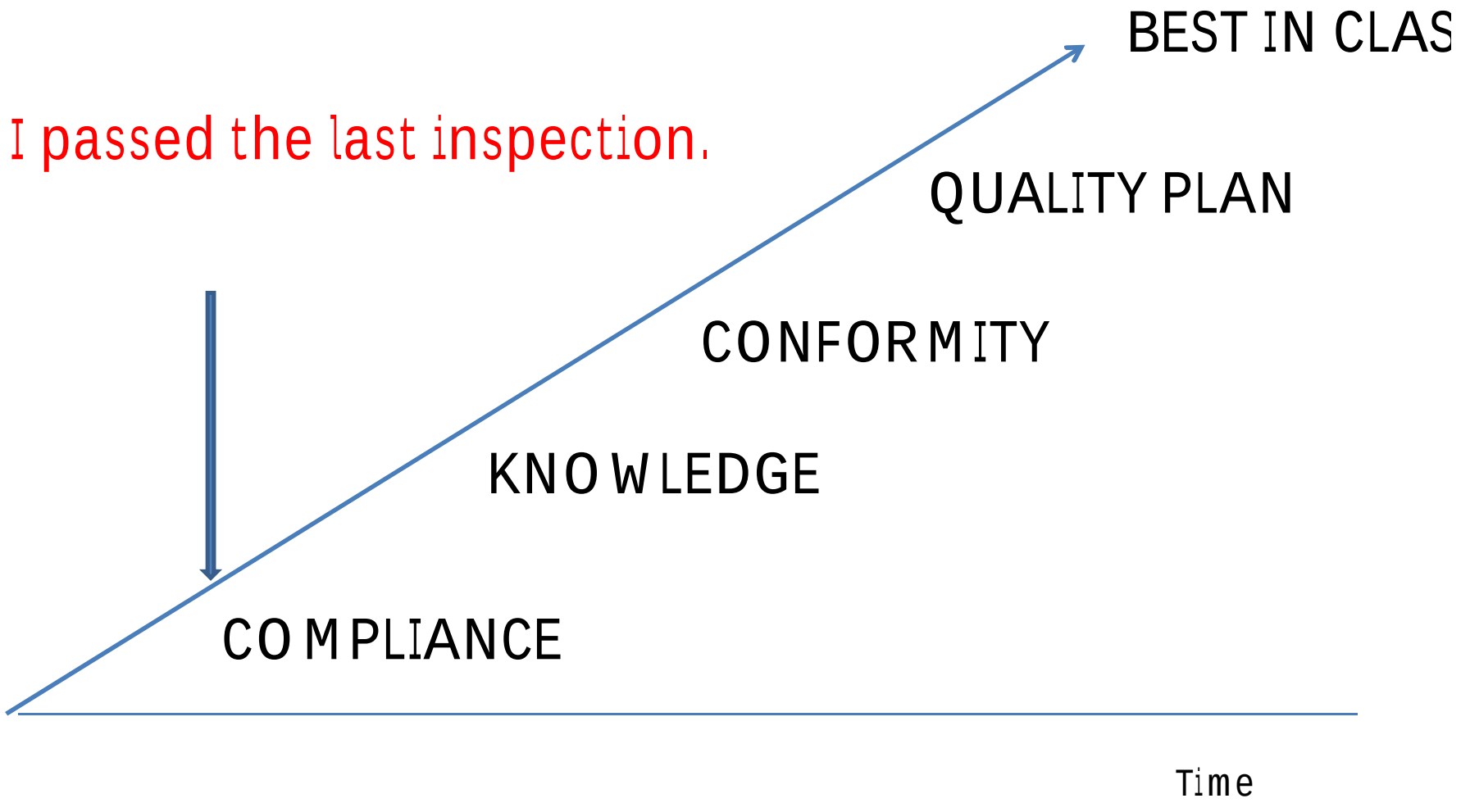
We will build a system giving us the insurance that all the aspects of our processes are under control and that quality problems will not happen



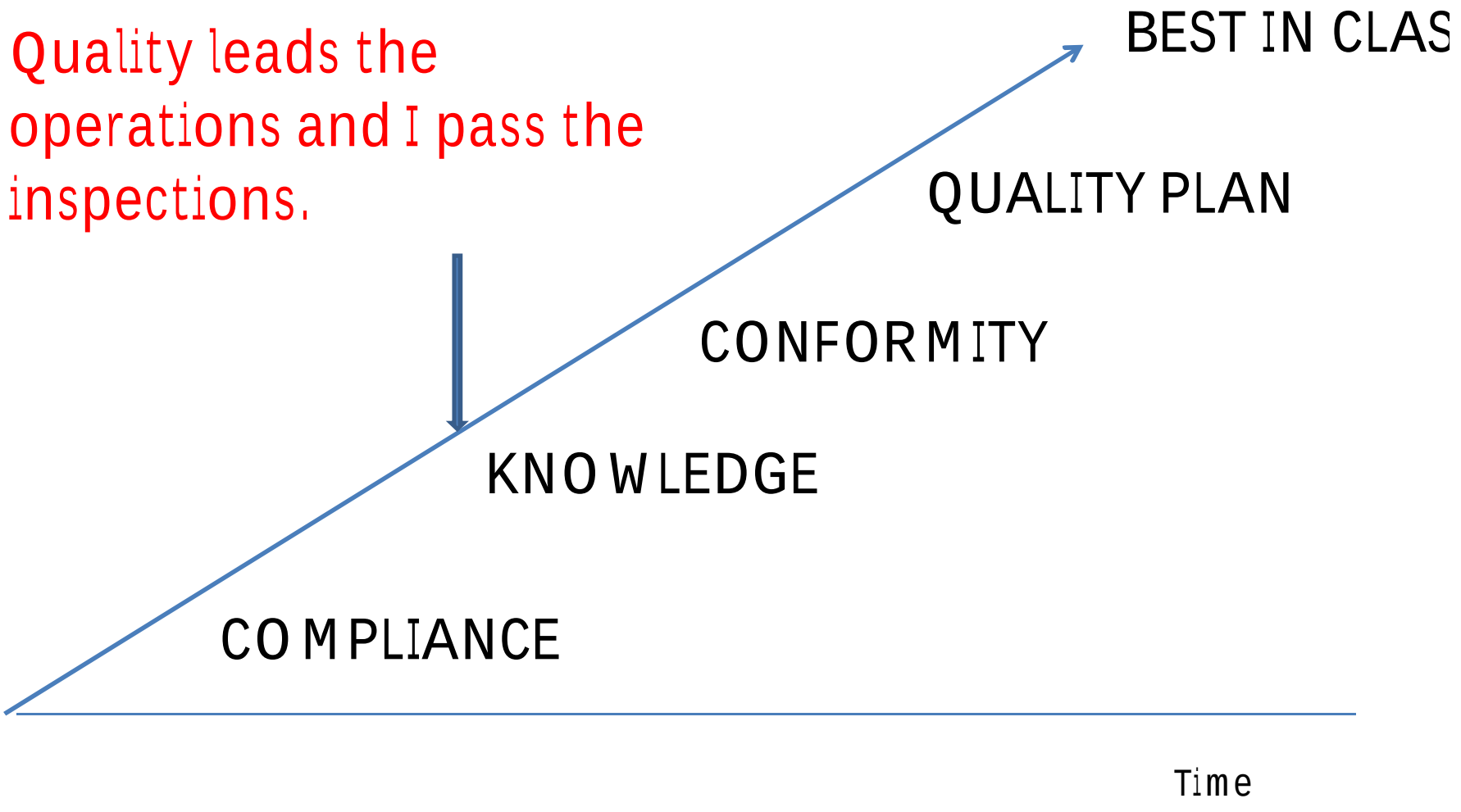
# 2 . DATA DRIVEN : PUT MILESTONES



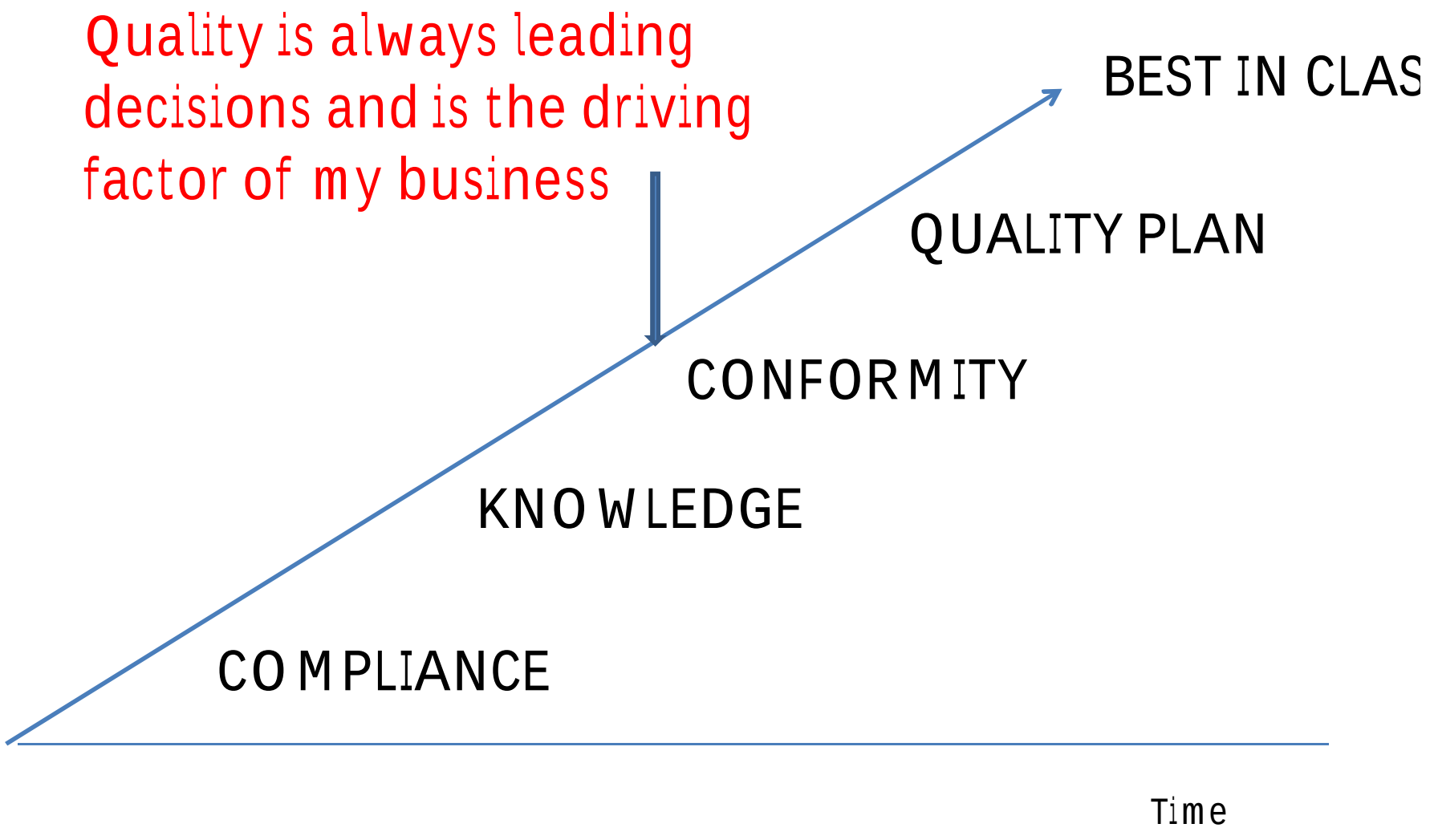
# 2 . DATA DRIVEN : PUT MILESTONES



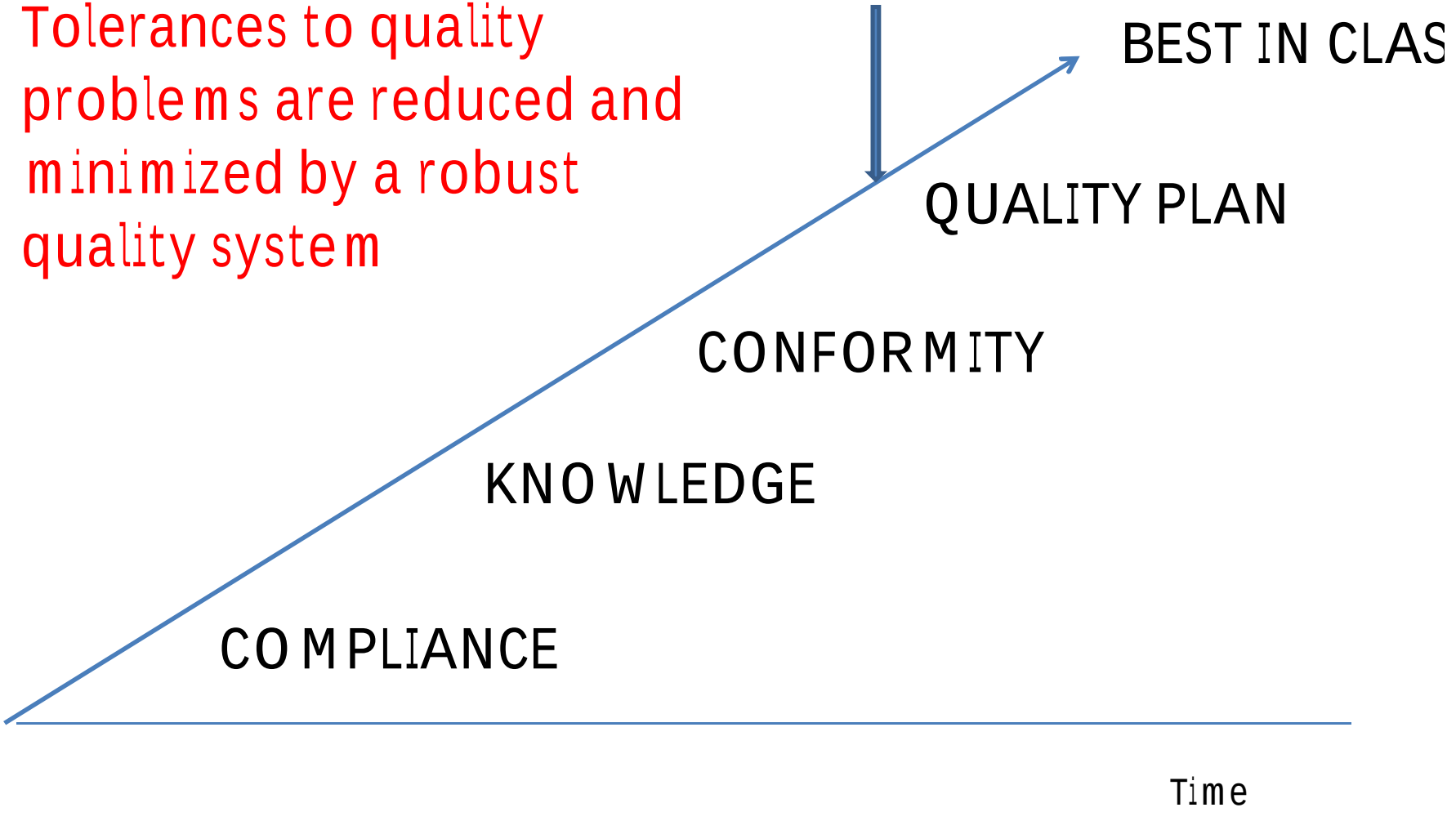
# 2 . DATA DRIVEN : PUT MILESTONES



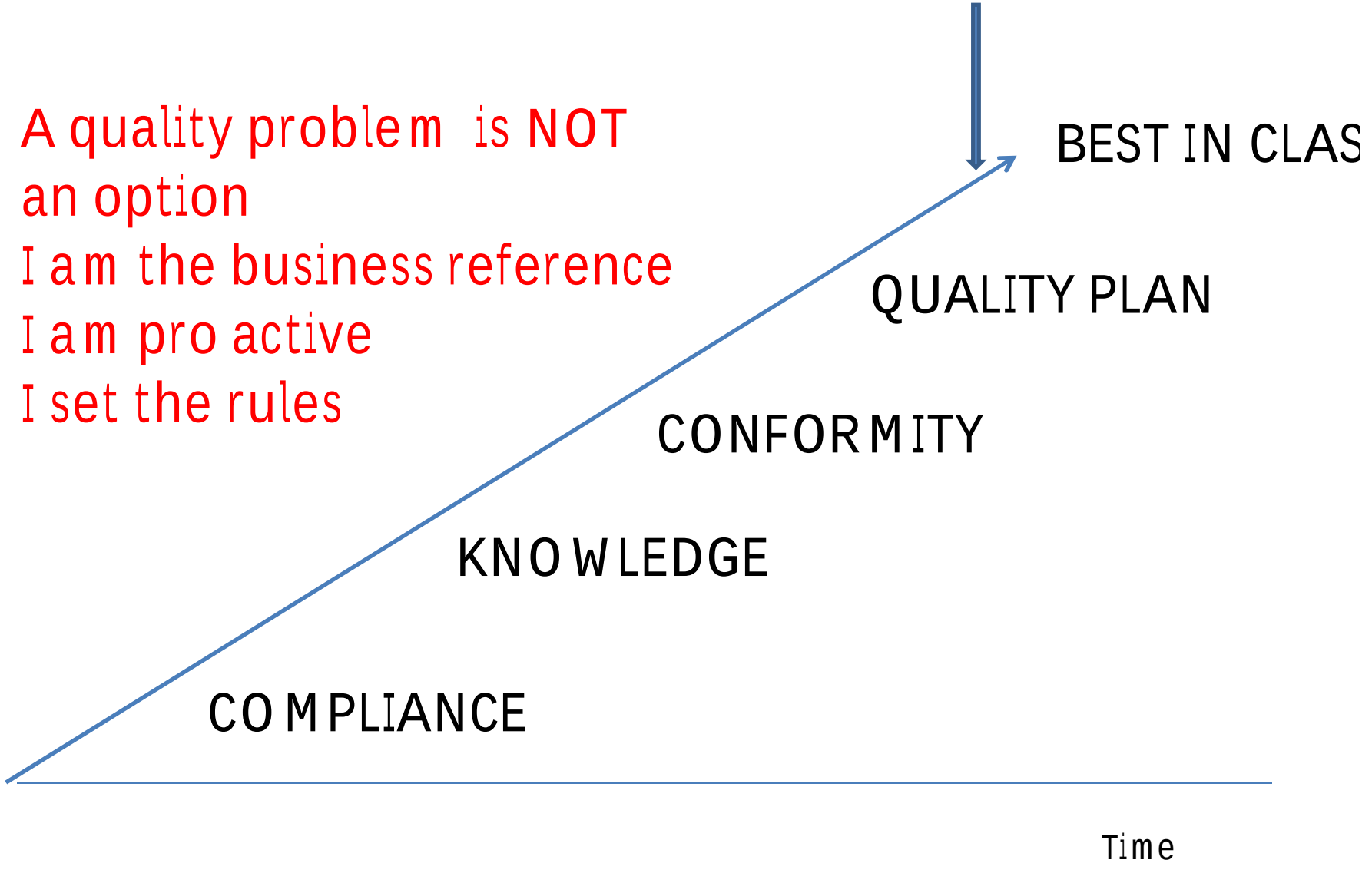
# 2 . DATA DRIVEN : PUT MILESTONES



# 2 . DATA DRIVEN : PUT MILESTONES



# 2 . DATA DRIVEN : PUT MILESTONES



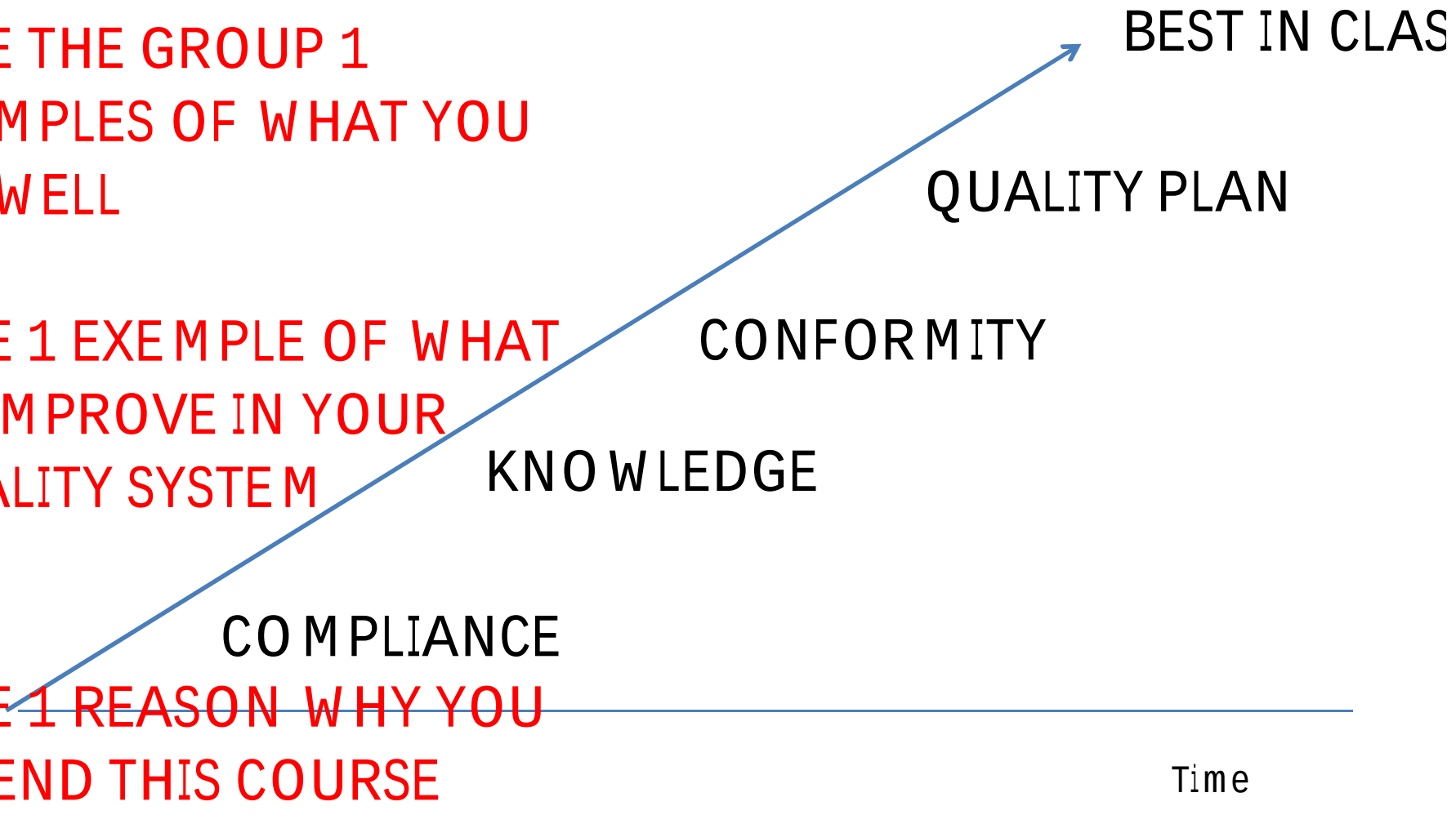
PLACE THE ARROW ON THE CURVE

WHERE ARE YOU ?

GIVE THE GROUP 1 EXEMPLES OF WHAT YOU DO WELL

GIVE 1 EXEMPLE OF WHAT TO IMPROVE IN YOUR QUALITY SYSTEM

GIVE 1 REASON WHY YOU ATTEND THIS COURSE



BE AMBITIOUS

GIVE THE TEAMS AN OBJECTIVE WHICH IS JUST ABOVE WHAT THEY CAN REACH

ANTOINE DE SAINT EXUPERY

Time

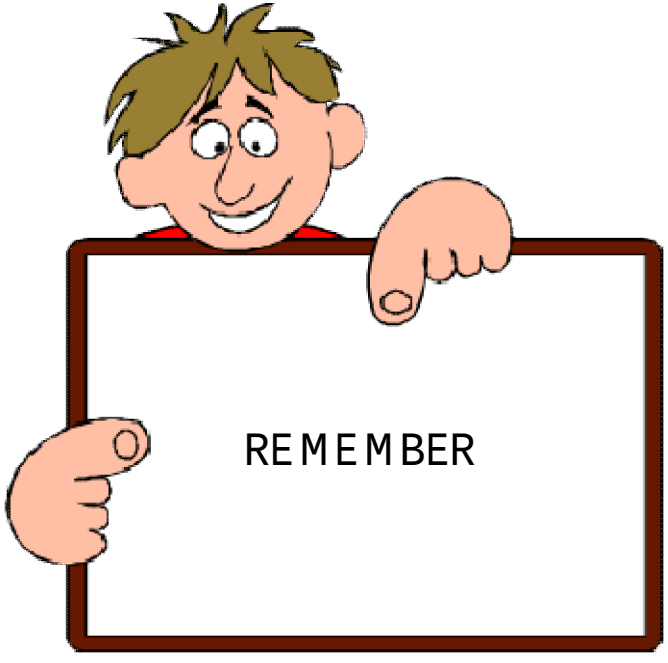
# MONITOR THE OBJECTIVES

1. RIGHT COMMITTEE.
2. RIGHT PEOPLE
3. RIGHT SYSTEM
4. RIGHT FOLLOW UP

# MONITOR THE OBJECTIVES – QUALITY AUDITS

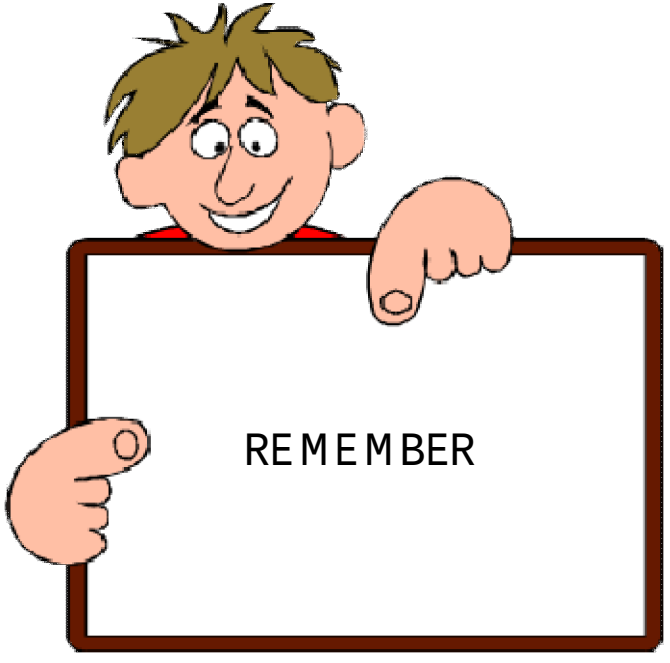
Internal quality audits are recommended by authorities as it give assurance that the management is involved in the quality system, the employees are trained and that the SOPs are followed.

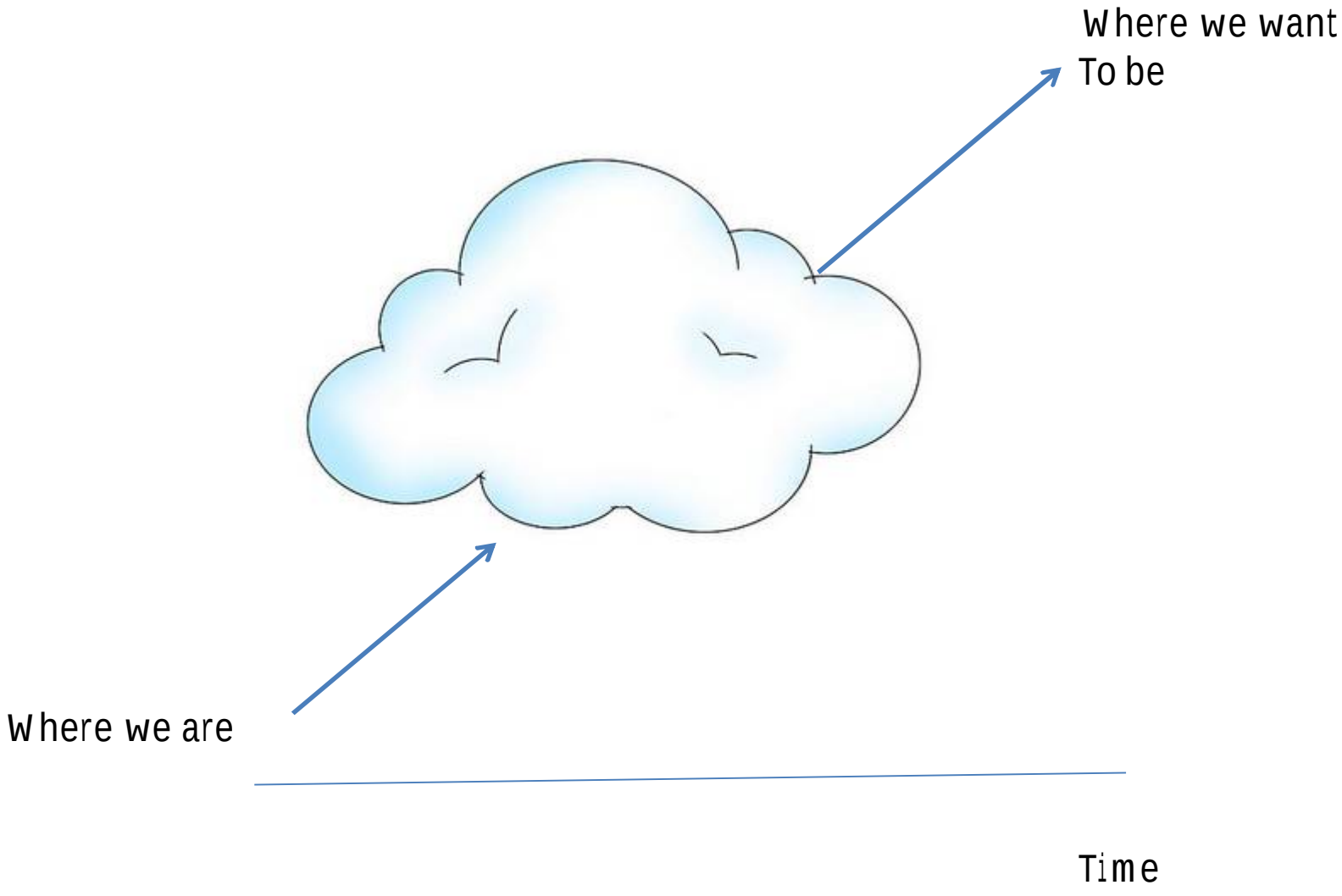
Internal quality audits must b uous improvements.



# MONITOR THE OBJECTIVES – QUALITY AUDITS

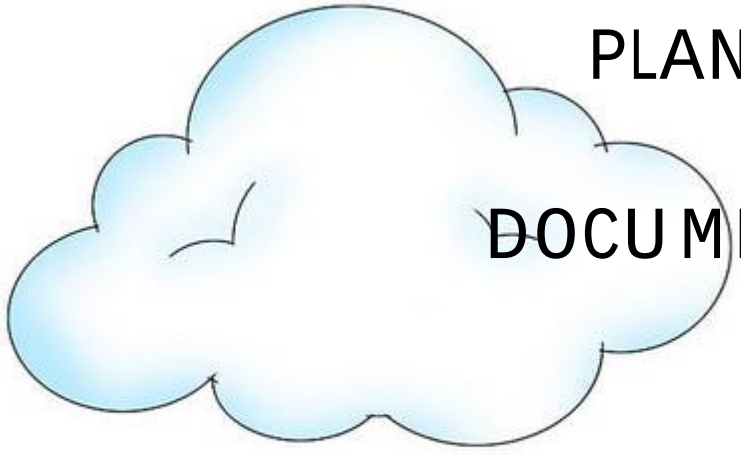
Internal quality audits must be a base for A continuous improvements program.




Where we want
To be
Where we are
Time

THIS IS WHERE WE NEED GUIDANCE

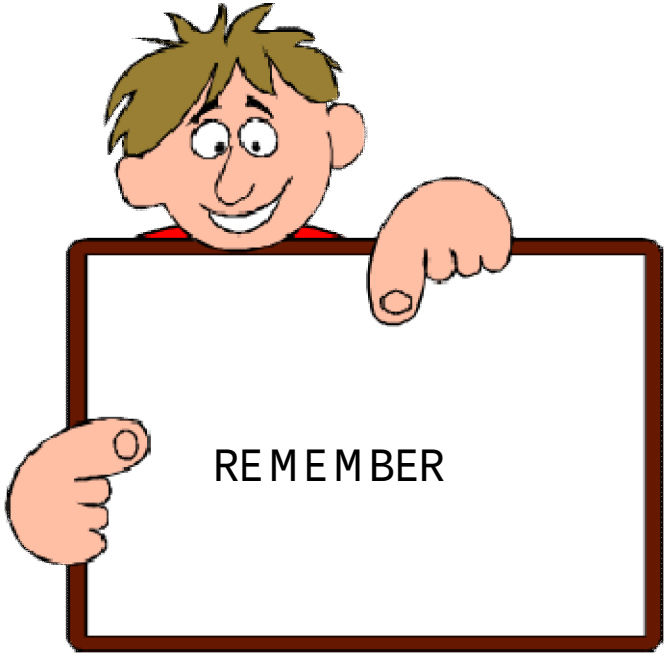
PROCEDURES



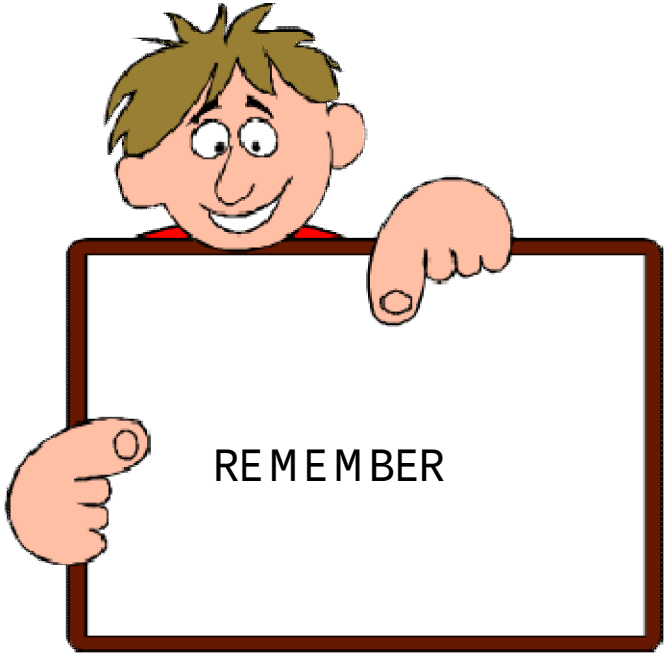

A DOCUMENT IS A WRITTEN TRANSLATION OF A FLOW CHART

FLOW CHARTS ARE LANGUAGE INDEPENDENT AND THEREFORE INTERNATIONAL

•Standard Operating Procedures are written instructions that enable the operator to performs a task.

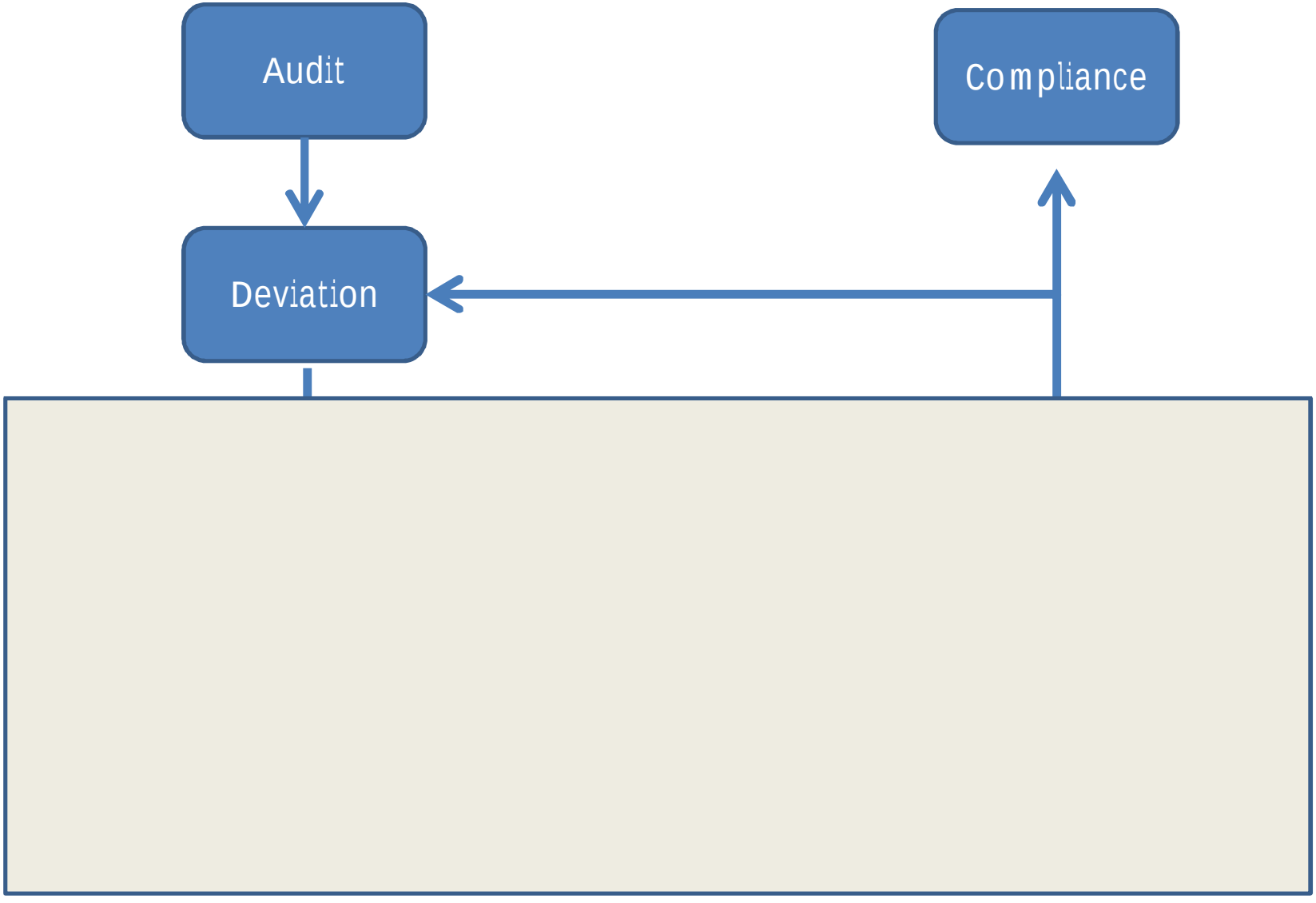


- All employees engaged in GxP activities must be appropriately trained, including successful testing, prior to conducting work activities.



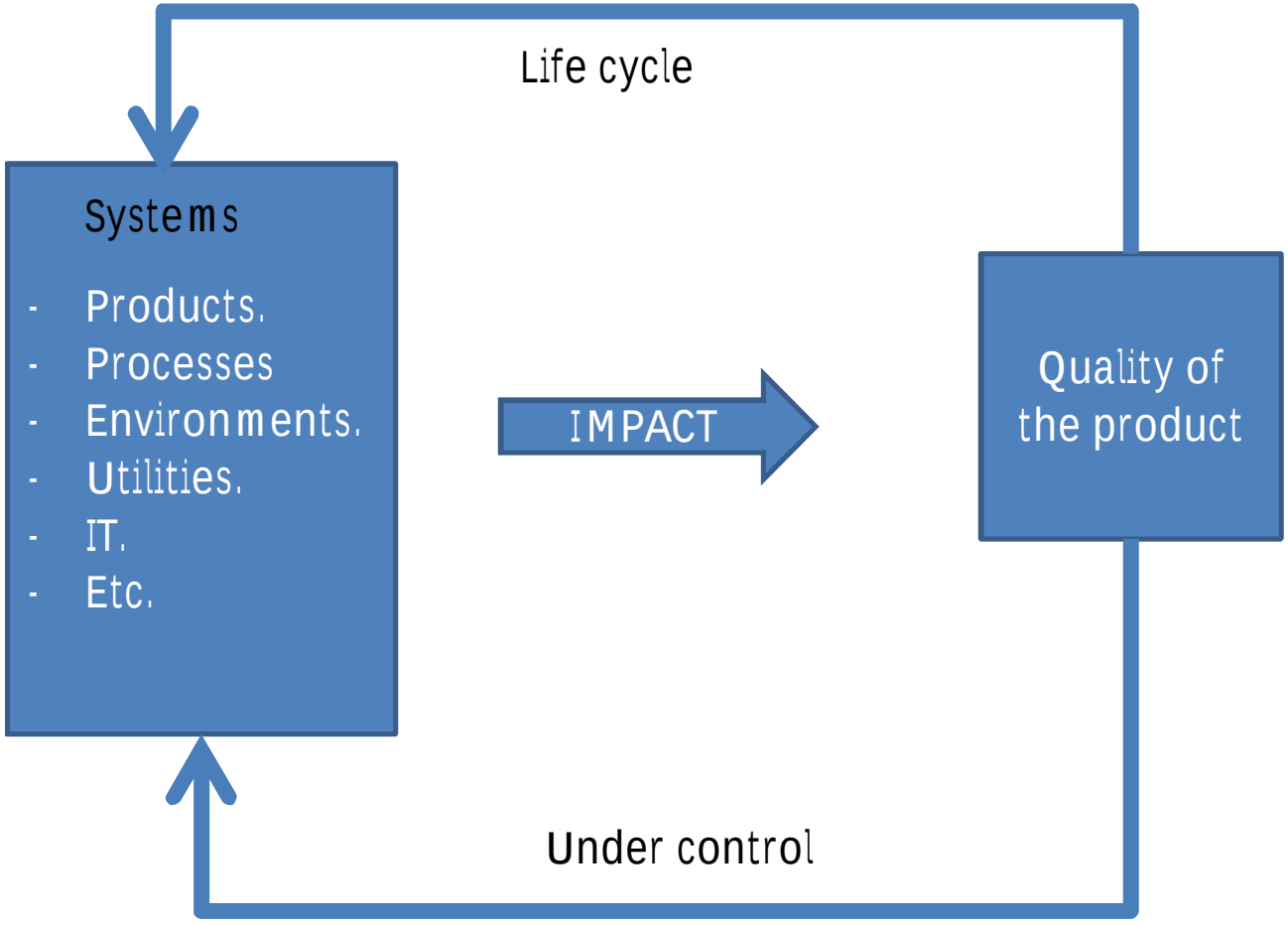
# LET US MAKE A FLOW CHART OF A COMPLIANCE PLAN

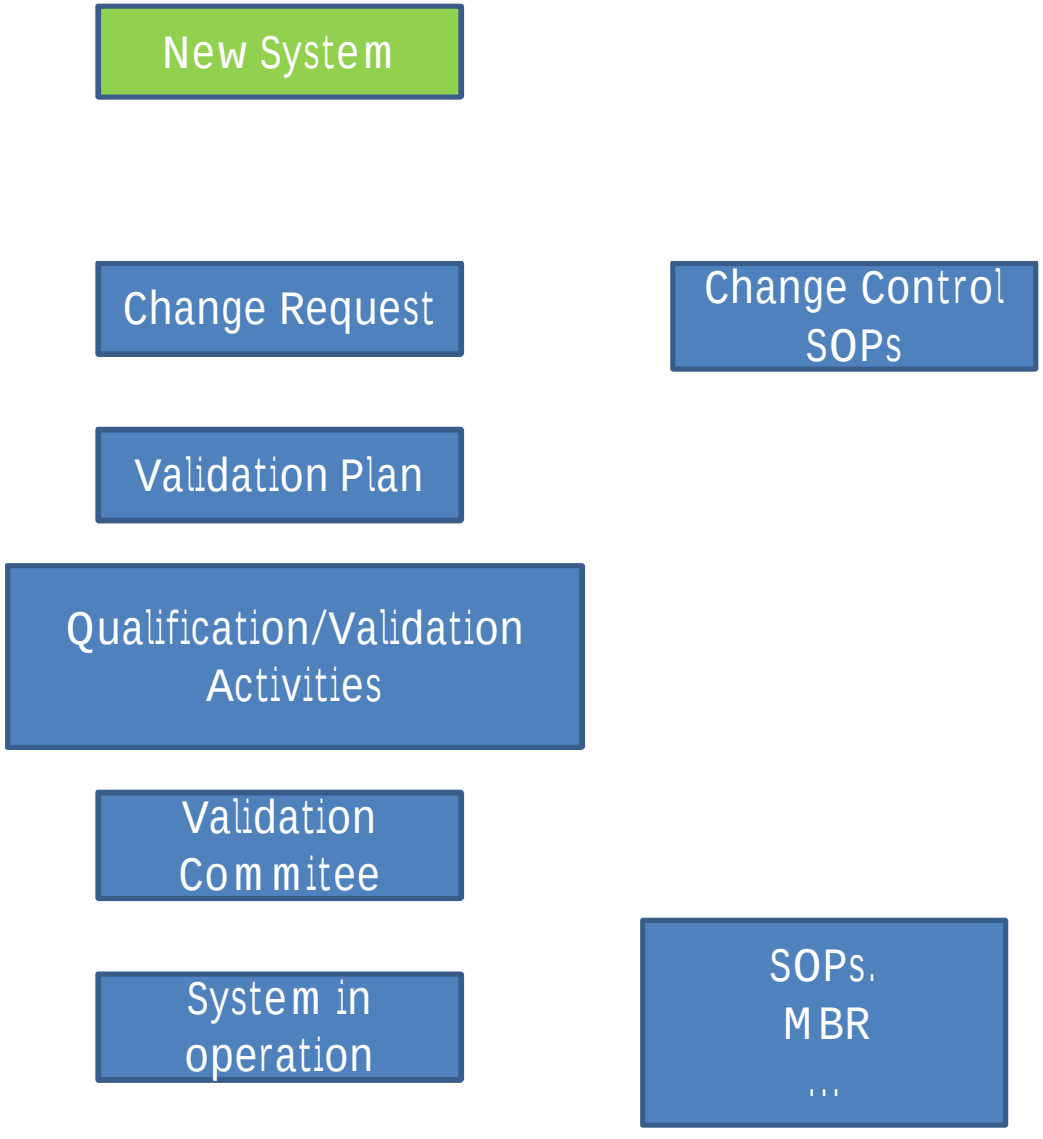
# Compliance Plans

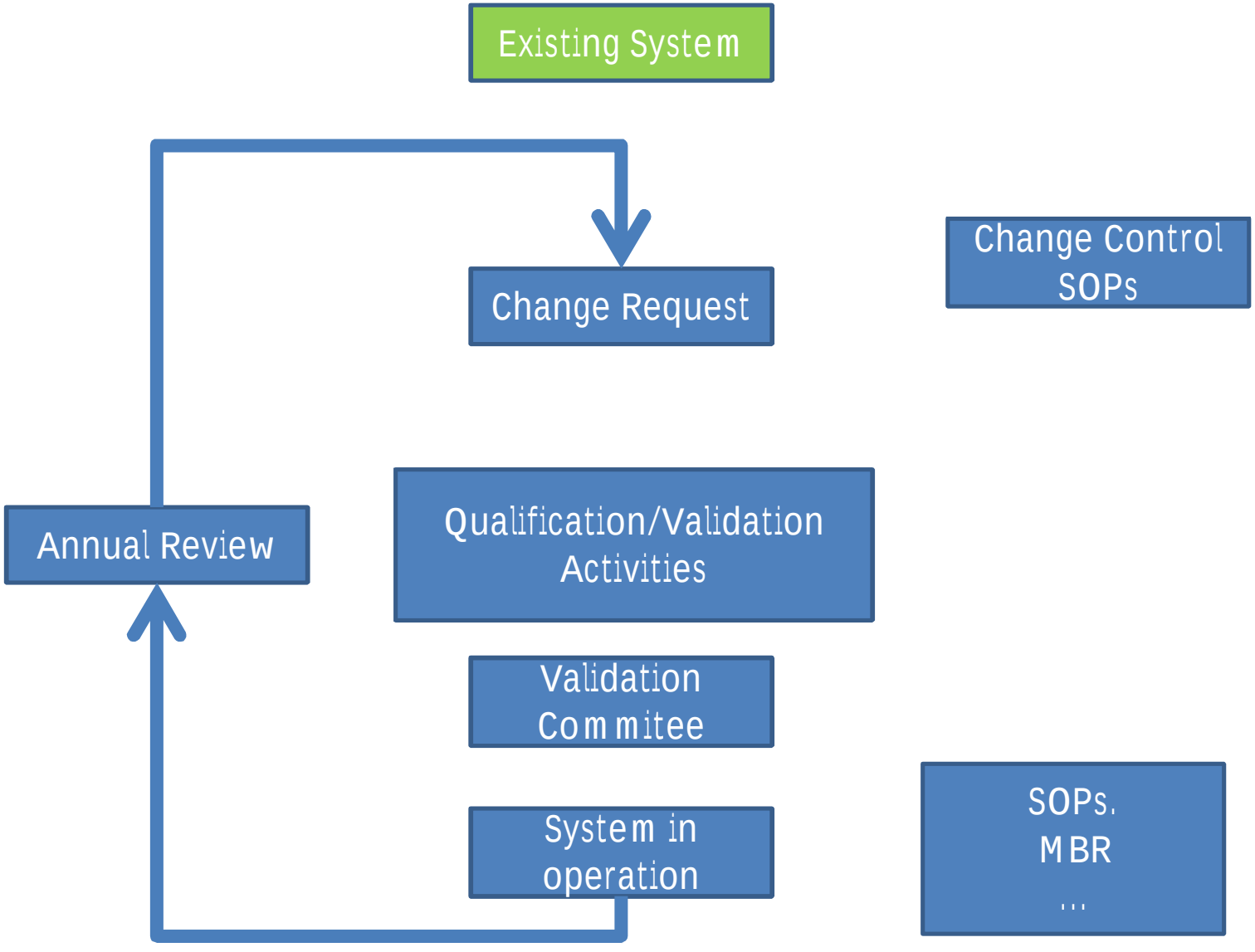


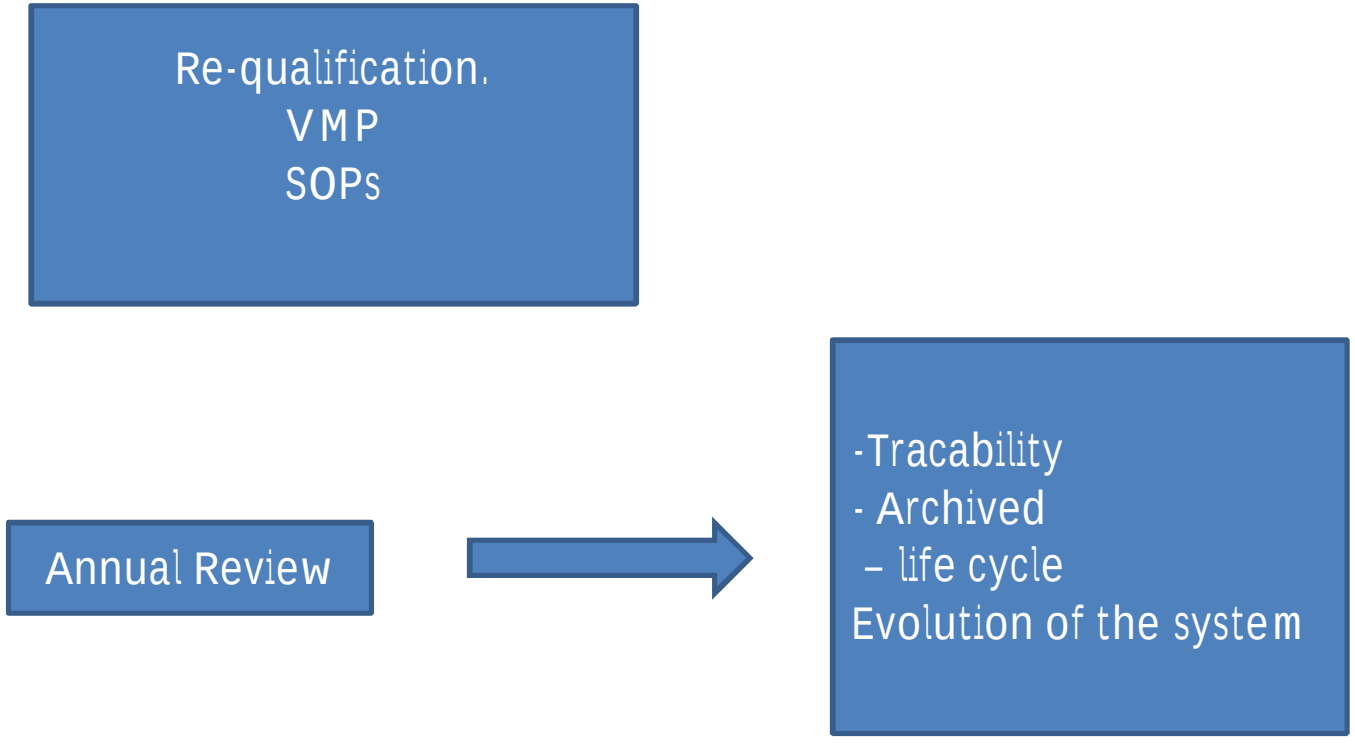
AND A FLOW CHART OF A QUALITY SYSTEM

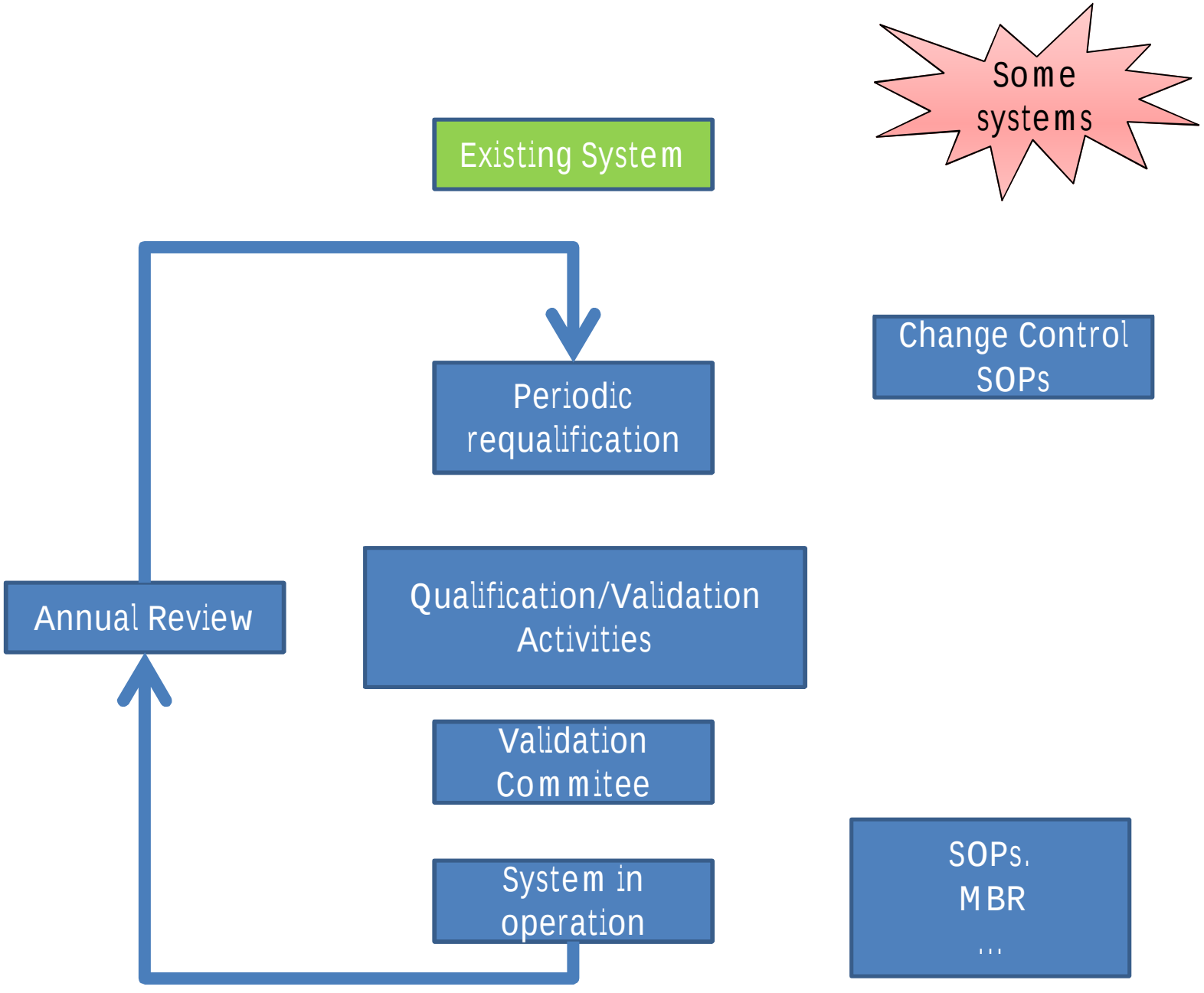
The Quality System in place provides insurance that all the systems with an impact on the quality of the product is maintained under control during the life cycle of the system


Life cycle
Systems
- Products.
- Processes
- Environments.
- Utilities.
- IT.
- Etc.
IMPACT
Quality of the product
Under control


New System
Change Request
Change Control SOPs
Validation Plan
Qualification/Validation Activities
Validation Commitee
System in operation
SOPs.
MBR
...


Existing System
Change Request
Change Control SOPs
Annual Review
Qualification/Validation Activities
Validation Commitee
System in operation
SOPs, MBR ...


Re-qualification.
VMP
SOPs
Annual Review
-Tracability
- Archived
– life cycle
Evolution of the system


Some systems
Existing System
Periodic requalification
Change Control SOPs
Annual Review
Qualification/Validation Activities
Validation Commitee
System in operation
SOPs, MBR ...

# Qualification / Validation

Design
- URS
- SPECS
- Strandards.
- Compliance with regulatory

Qualification
- Conformity with URS

Validation
- Documented evidence that (rechercher la définition…)

Qualification / Validation


Retrospective :

- From the results obtained historically :
- Ex( sterility period from historical data coming from media holds).

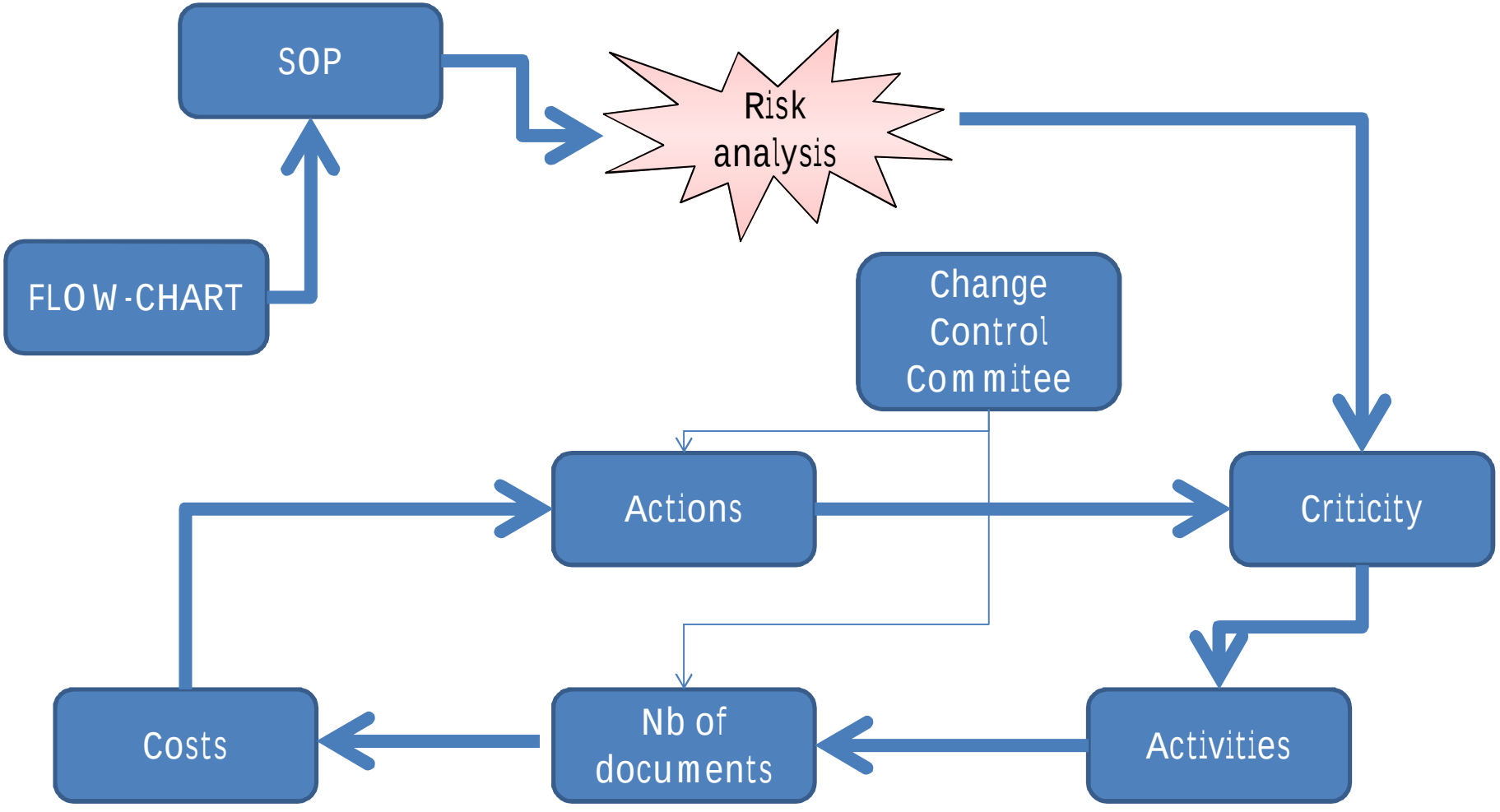
Prospective

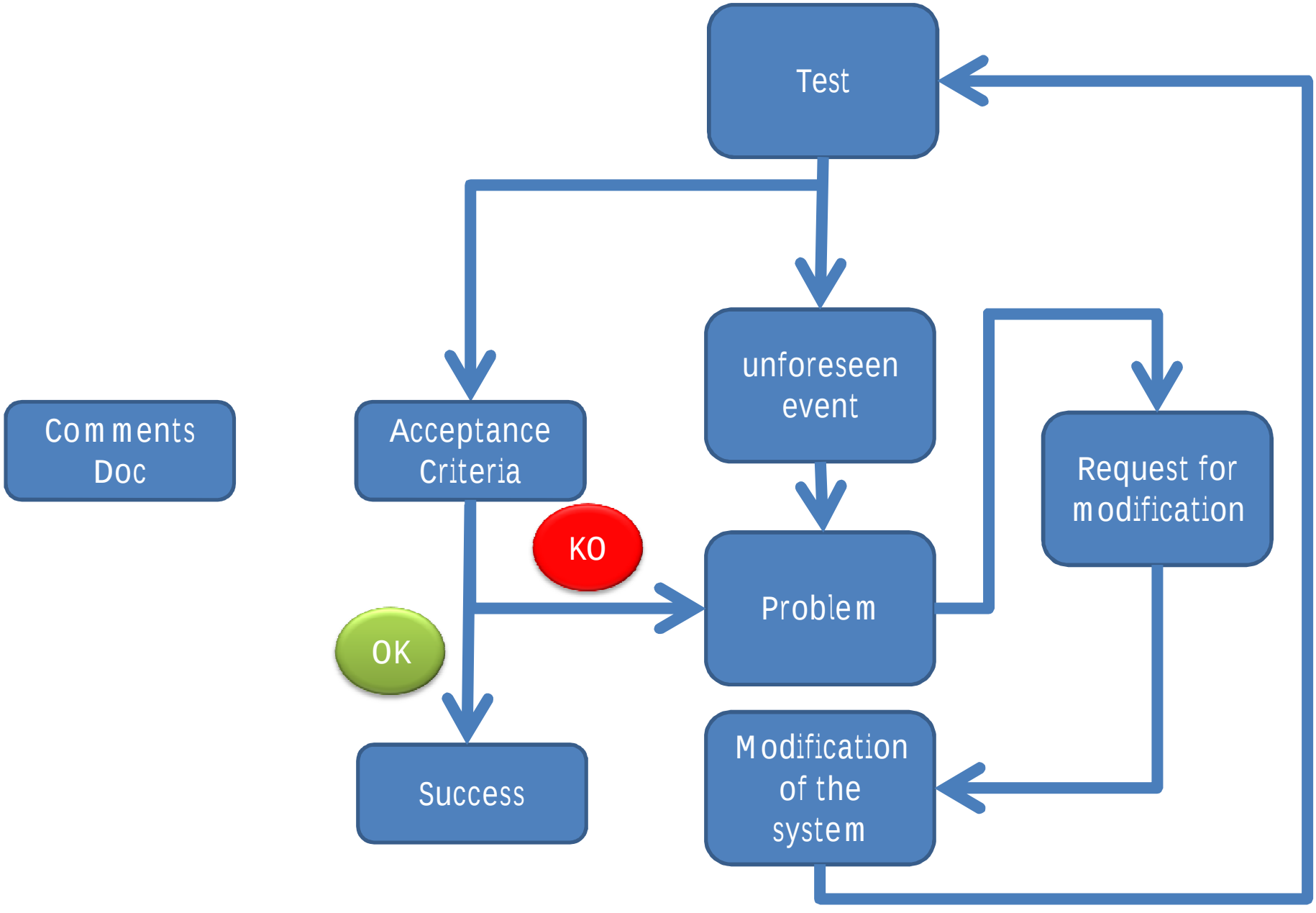
- Sterilization of a tank.

Concurrent

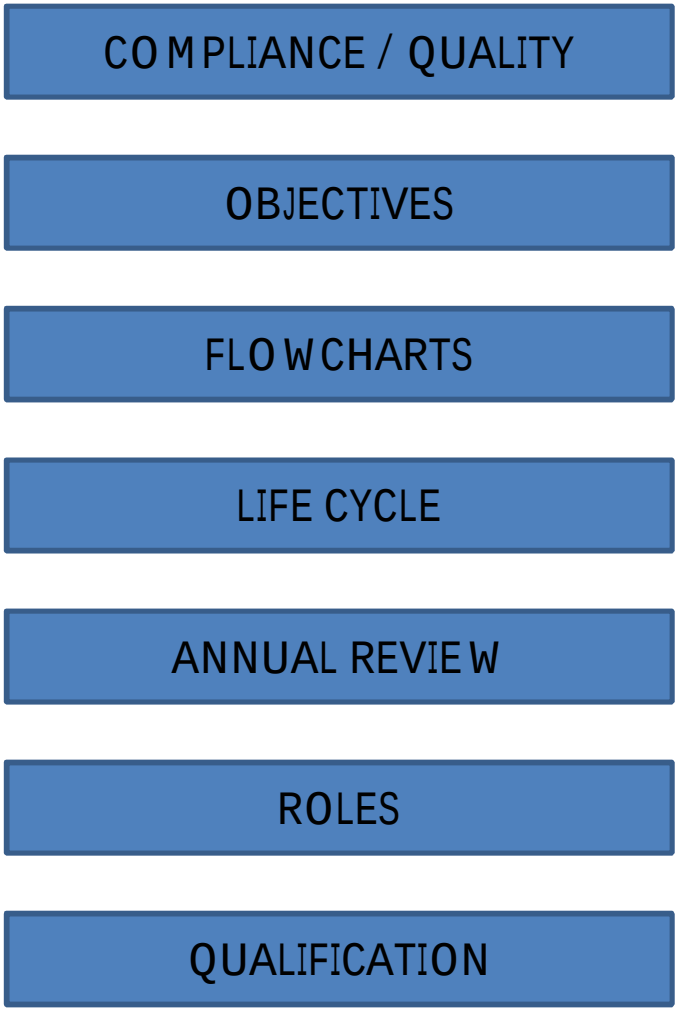
- Cleaning validation.

Qualification / Validation




Test
unforeseen event
Request for modification
Comments Doc
Acceptance Criteria
KO
Problem
OK
Success
Modification of the system


Take away


COMPLIANCE / QUALITY
OBJECTIVES
FLOWCHARTS
LIFE CYCLE
ANNUAL REVIEW
ROLES
QUALIFICATION


NEXT


VALIDATION
RETROSPECTIVE
PROSPECTIVE
CONCURRENT
ACCEPTANCE CRITERIA
CPP – CAPABILITY – CQA - CRITICITY
DOCUMENTS
COSTS