وائل عطيه

مدير قدرات تأكيد الجودة
شركة بروكتر أند قامبل
(مصنعي الدمام – دبي)

البرنامج:

- تعريف الجودة , أهميتها
- تاريخ وبرامج الجودة المختلفة
- GMP
- برنامج الجودة في شركة بروكتر وقامبل

WHAT IS QUALITY?

الـجــودة

- منتج يطابق المواصفات الموضوعة
- منتج يرضي العميل
- منتج آمن على المستهلك
- منتج يحقق الربحية للشركة

مـنـتــج مـنـاسـب للاستخدام

Quality Is Vital To Business Results

- Win With Consumers
  - Choose – 1st Moment Of Truth
  - Use – 2nd Moment Of Truth
- Thin Margin Of Repurchase Rate Between Success & Failure
- Win With Customers

Quality Related Losses according to the QA QRL template.

$900 million per annum

تاريخ الجودة

- الجودة في العصور القديمة
- 1784 أول قانون ضد تلف الأغذية
- ظهور FDA عام 1906
- GMP :1963

برامج الجودة

- GMP
- ISO

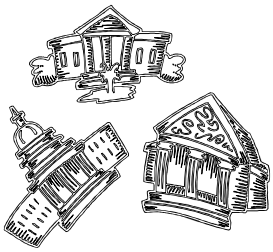
(,,,,,22716 ,27001 ,22000 ,14001, 9001)

- FDA
- 6 Sigma

Good Manufacturing Practices

GMP Training Program

GMP
Good Manufacturing Practice

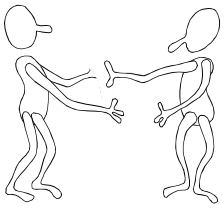


Regulations developed and enforced by the Food and Drug Administration, an agency of Federal Government.

100 % Right

Our customers trust each of us to make sure that we know our jobs, and that we do our jobs right 100% of the time.

Our customers don't want us guessing!



The FDA

The FDA represents our customers.

They inspect our company to ensure that our customers can trust us.

What is the cost of failure in our business?

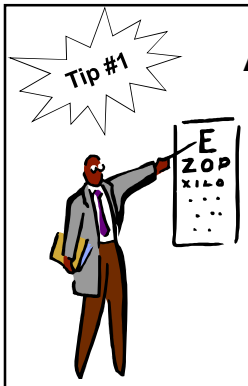
Our Paperwork helps us produce high quality Products

Standard Operating Procedures

SOPs

It's important that we <u>always</u> follow our SOPs.

Following our SOP's ensures that we produce consistently good products, that meet all our specifications, all the time.



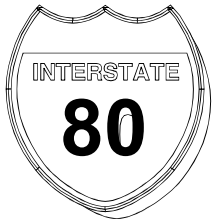
A good SOP is easy to read.

It's written for the reader.

A good SOP is mutually understood.

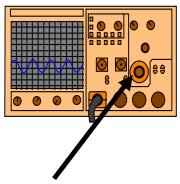
A good SOP follows a step by step approach.

Tip #3



A good SOP uses pictures and graphics.

Tip #4



Adjust this knob to 80.

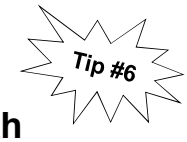
A good SOP contains the right level of detail.

Tip #5

Not too little that we can't find what we need.

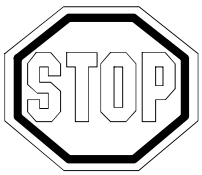
Not too much that we're overwhelmed.

A good SOP is approved by the proper people, with their signatures attached, and is the current revision.



A good SOP is a controlled document, and any changes must be evaluated and approved.

What do you do when you cannot follow a written procedure?

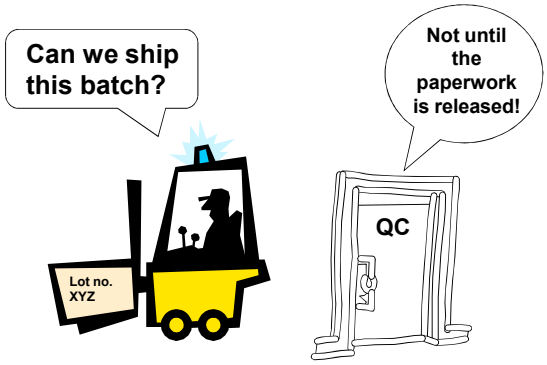


Get Help!

Our Paperwork is a Product

The paperwork we produce is of equal importance to the products we produce.

Product = Paperwork



Why is so much paperwork required?

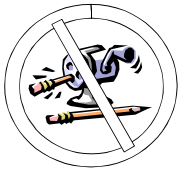
- To make sure we know exactly what we did, and when we did it.
- To be able to correct mistakes if they happen.
- To be able to PREVENT mistakes from happening in the future.

Good Record Keeping Tips

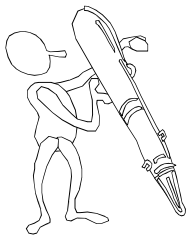
Here are four record keeping tips for us to remember.

Record Keeping Tip #1

Use a non-water soluble pen for writing on any official document.

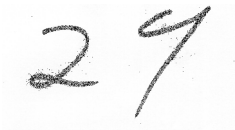


No pencils.



Record Keeping Tip #2

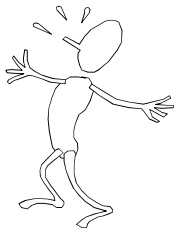
Clearly record the data.



Record Keeping Tip #2

Take your time and write clearly.

- **Slow down a little.**
- **Take a deep breath!**
- **Relax your body before writing on a document.**



Record Keeping Tip #2

Sloppy writing is 100% preventable.

A few seconds of composure helps reduce stress too, leading to a healthier you!

Record Keeping Tip #3

There is a proper method for making corrections.

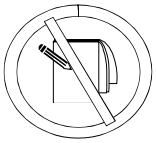
asa **13 March 2012**

~~27~~ 29

Record Keeping Tip #3

No erasures.

No correction fluid.



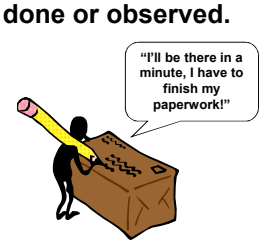
No "Post-it" notes.

Record Keeping Tip #4

Enter enough details so the document can be understood in the future.

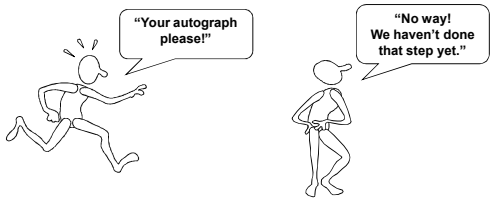
Record Keeping Tip #5

Document your work when the work is done or observed.



Record Keeping Tip #6

Only document work that has been performed. Do not sign for work until it is complete.



Record Keeping Tip #7

Make sure you record the date and time correctly.

Dates are written:	Times are written:
13 Mar 12	10:00 AM or 1000 h
or	3:00 PM or 1500 h
13 MAR 12	

Record Keeping Tip #8

Never falsify a work document or record.

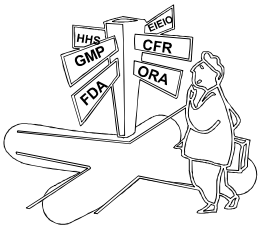
Record Keeping Tip #9

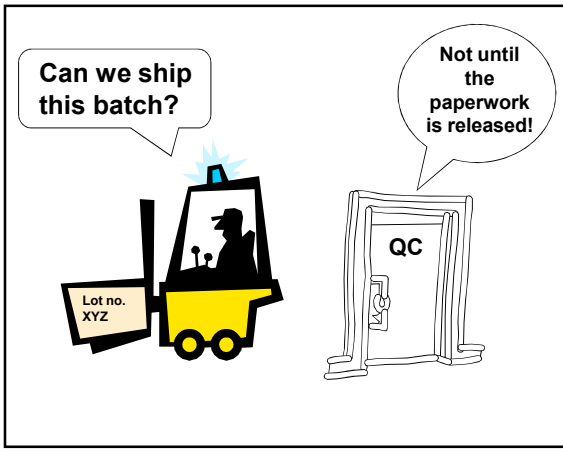
Never leave blank spaces on an official document.

N/A Not applicable

Record Keeping Tip #10

Limit the use of acronyms and abbreviations.

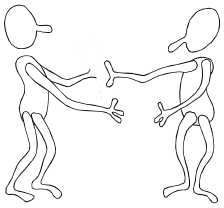




100 % Accuracy

Our customers trust each of us to make sure that our paperwork is 100% accurate.

Our customers don't want us guessing!

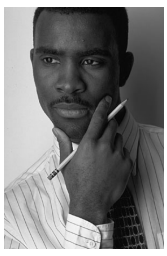


Following our SOP's ensures that we produce consistently good products, that meet all our specifications, all the time.

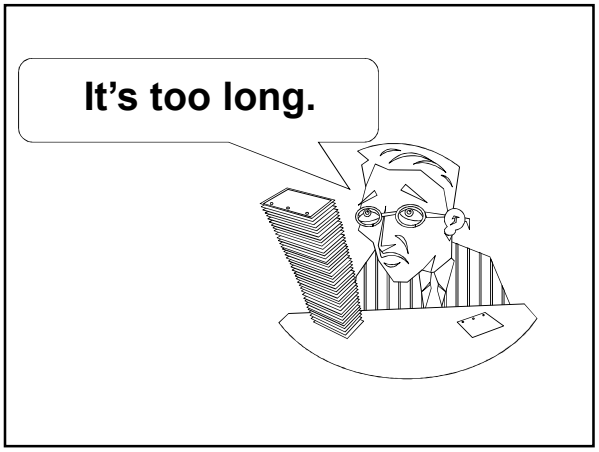
What do you do when you can't follow a written procedure?

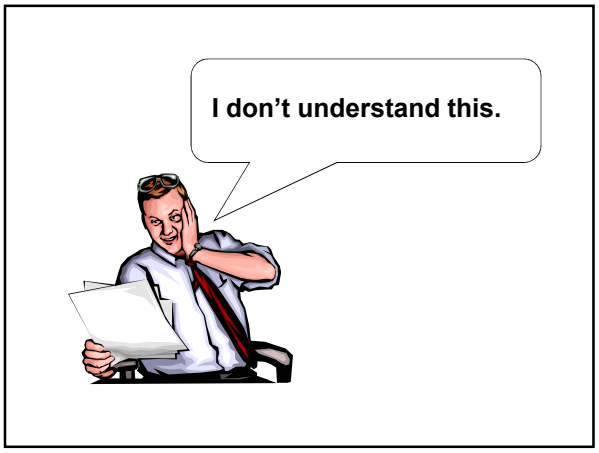
GET HELP!

What are some of the reasons why people don't follow written procedures?

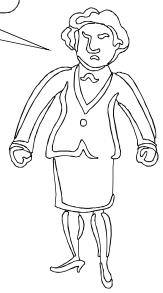



I can’t find it.


It’s too long.

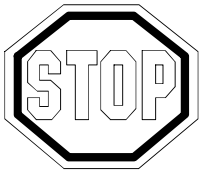

I don’t understand this.

My way is better.



ANY OTHER REASONS?

What do you do when you cannot follow a written procedure?



Get Help!

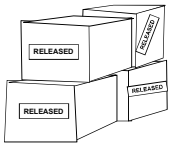
The aim of our written procedures is CONSISTENCY.

Our customers expect our products to be consistent from dose to dose, from batch to batch, week to week, year to year.

With our products, consistency is measured at the molecular level. It's how our products work, how our products perform, that's critical to the health of our customers.

Managing our Materials to Prevent Contamination, Mix-ups, and Errors

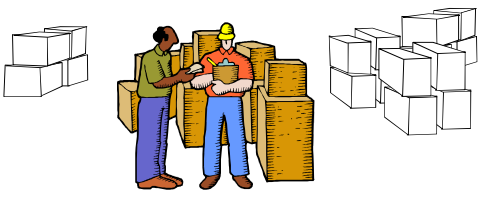
GMP Training Program



Our Materials

Our materials consists of our:

- **raw materials**
- **packaging materials**
- **labels**



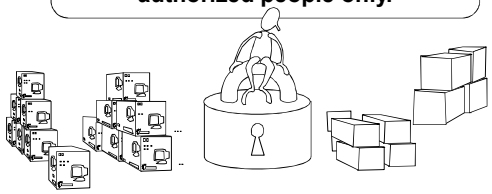
RECEIVING

Upon receipt, raw materials, packaging materials, and labels must be:

- Identified,
- Inspected, and
- Placed into Quarantine.

QUARANTINE

Quarantine areas are to be kept secure, with access limited to authorized people only.

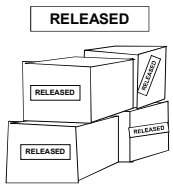


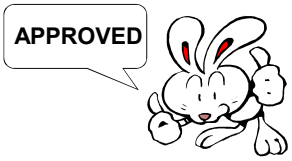
This reduces the risk of mix-ups and errors!

Quality Control takes samples and tests all incoming raw materials.

They also check packaging materials and labels to ensure that they meet our specifications.

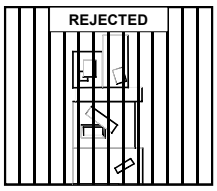
If materials meet our specifications, they are APPROVED and RELEASED for use by Quality Control.





If materials DO NOT meet our specifications, they are REJECTED.

They are placed in a secure area until disposition is determined.



ALWAYS check materials you use to make sure that they are APPROVED and RELEASED for use.

ALL Work-in-Process (WIP) shall be properly identified and labeled during storage.

WIP storage area

This reduces the risk of mix-ups and errors!

ALL Finished Goods (FG) shall be properly identified and labeled during storage.

FG storage area

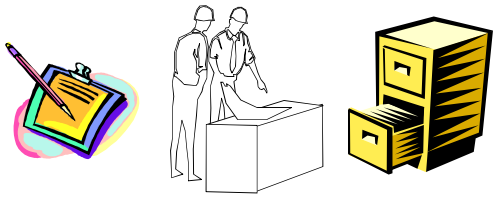
This also reduces the risk of mix-ups and errors!

ALL Finished Goods (FG) shall be sampled and tested by Quality Control BEFORE they are shipped.

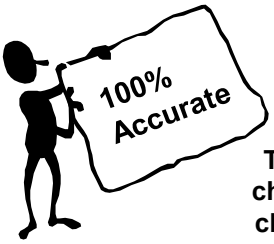
The Final Product CANNOT be shipped until:

All testing is complete and confirmed that the product meets all specifications
AND
All paperwork is complete and accurate
AND
Signed off by Quality

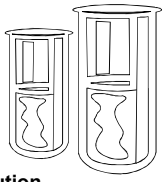
We must keep accurate records of all our shipments.



Check and Double Check



Take the time to check and double check your work.



Solution A

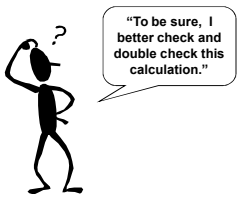
Solution B

Many materials look similar, although they are very different.

Many labels look similar, although they are very different.

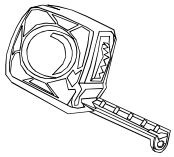
1,347 grams
X 25

33,675 grams
or
33.675 kilograms

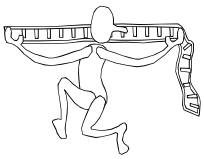


Check and double check your calculations.

Check and double check for decimal point errors.



Remember to check and double check your work.



Keeping Things Clean Guarding Against Contamination

GMP Training Program

What is contamination?

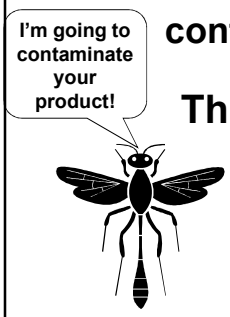
Anything that causes our products to be:

Impure

Unclean

Unfit for use

What are sources of contamination?



Think WASPP

- Water
- Air
- Surfaces
- Pests
- People

Water

Water is a potential source of microbial contamination.

Microbes are microscopic living organisms, commonly referred to as "germs."

Clean up any standing water.

This eliminates this source of contamination.

Air

Air is a potential source of microbial and particulate contamination.

Particulates are tiny pieces of dirt, dust, fibers, hair, lint, and anything else which can float through air.

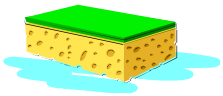
Keep doors closed to prevent outside contamination from entering our workplace.

Surfaces

Surfaces are potential sources of particulate and microbial contamination.

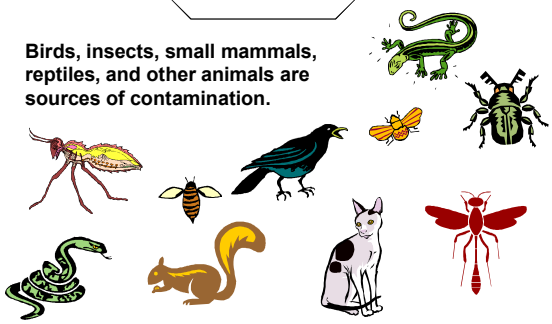
Particulates on surfaces are tiny pieces of glass, metal, dirt, dust, fibers, hair, lint, and anything else which can rest on surfaces.

Keep surfaces and equipment clean, neat, and orderly to prevent particles from contaminating our products.

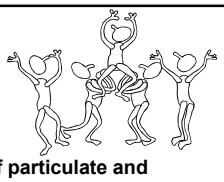


Pests

Birds, insects, small mammals, reptiles, and other animals are sources of contamination.



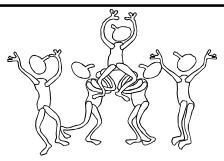
People



People are potential sources of particulate and microbial contamination.

- Clothing that sheds fibers.
- Hair, dandruff, scalp or skin particles.
- Sneezing, runny noses, open lesions.
- Articles falling out of pockets.

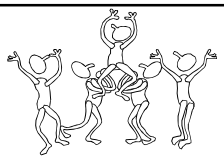
People



We prevent people contamination by following our policies and procedures regarding:

- Head coverings.
- Facial hair coverings.
- Gowns and lab coats.
- Gloves.
- Arm coverings.
- Masks and other protective gear.

People



We prevent people contamination by following our policies and procedures regarding:

- Personal hygiene.

Wash your hands thoroughly with soap and warm water.

Report any health condition that may have an adverse effect on our products.

Cross contamination

One product being mixed with another product.

Cross contamination can occur:

- when containers are not tightly sealed.
- when equipment and utensils have not been properly cleaned.

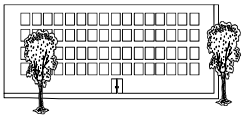
Be on Guard!

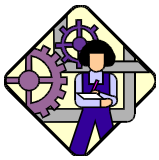
Report any conditions you see which could lead to contamination.

Always be alert and on the look-out for potential contamination.

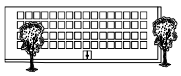
Keeping Our Buildings and Equipment in Good Shape

GMP Training Program





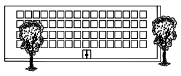
Our Facilities



GMP requires that our facilities shall be laid out and constructed in a way that makes them easy to:

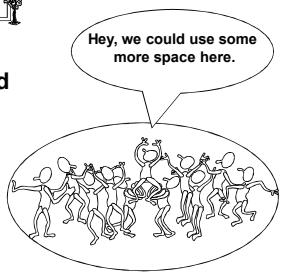
Clean
Maintain
Operate

Our Facilities



Our facilities shall be laid out and constructed in a way that it:

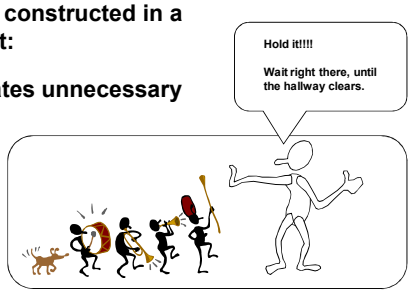
Provides adequate space.



Our Facilities

Our facilities shall be laid out and constructed in a way that:

Eliminates unnecessary traffic.



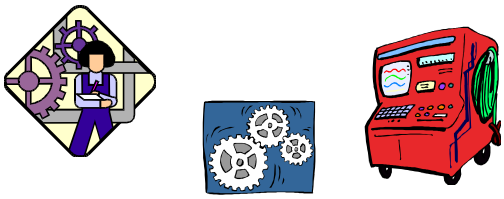
Inadequate space and unnecessary traffic may result in:

Contamination,
Mix-ups,
Errors,
Accidents.

Our buildings shall be maintained in a good state of repair.

Report any conditions that needs attention to your supervisor.

Our equipment shall be designed for the particular purpose for which it is intended.



Our equipment shall be made of materials that WILL NOT react with or ABSORB any of the components they contact.

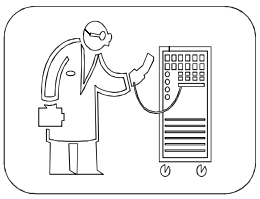
Our equipment shall be maintained and cleaned properly.

This includes maintaining a Cleaning Log for each piece of equipment.

Calibration records shall be maintained.

Each piece of equipment that requires calibration must be calibrated on a regular schedule.

This calibration shall be documented.



Be on Guard!

Report any conditions you see which could lead to mix-ups, errors, or contamination.

Always be alert and keep our buildings and equipment working in their best condition.

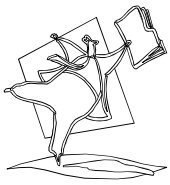
How Am I Doing?
Performing Self-Audits

GMP Training Program

Who performs audits?

- FDA
- state agencies
- customers
- consultants we hire
- internal auditors
- ourselves

Self-audits benefit everyone



Conducting self-audits help keep us on our toes and alert to our entire work environment.

We benefit from a safer workplace and our customers benefit from knowing that they will receive the best possible quality products.

People – The Key to Success!

GMP Training Program

Our customers trust us.

They trust us to always follow our procedures.

They trust us to ask when we're not sure.

They trust us to have the right education, training, and experience.

21CFR Parts 210 and 211

Current Good Manufacturing Practice for the Manufacture, Processing, Packing, or Holding of Drugs

National Archives and Records Administration

code of federal regulations

211.25

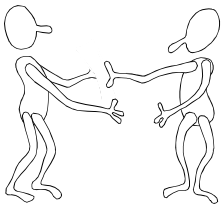
Training shall be in the particular operations that the employee performs and in current good manufacturing practice as they relate to the employee's functions.

Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them

100 % Right

Our customers trust each of us to make sure that we know our jobs, and that we do our jobs right 100% of the time.

Our customers don't want us guessing!



Let's follow GMPs!

Our customers are counting on us.

QUALITY ASSURANCE 19 KEY ELEMENTS

QUALITY SYSTEM OVERVIEW

- **We manage Quality Assurance as a system.**
- **The Key Elements describe the component parts of the Quality Assurance System.**
- **QA Capability is our process measure of the health of our Quality Assurance System.**

Key Elements

History

- **Initially established in 1994**
- **Consistent with general contents of various GMPs and ISO. & considering the specific regulatory requirements for location where we operate.**
- **Includes additional material to incorporate Total Quality thinking**

Key Elements

- **Level 1 – Key Element**
- **Level 2 – Systems and Objectives**
- **Level 3 - Requirements**

LEVEL 1 → **1. Leadership**

Leadership demonstrates a commitment to the establishment and maintenance of a quality culture within each site and the organization as a whole. They set clear operating standards for site operations and ensure that these standards are communicated to individuals and reinforced through personal example, defined responsibility and clear accountability. Leadership ensures that the organization is designed and developed to deliver the consumer and customer expectations in terms of product and package development, execution and delivery.

LEVEL 2 → **1.1. Leadership is accountable for quality results and quality assurance of the site. Leadership ensures that the organization is designed, staffed and capable of delivering intended quality product, data and results.**

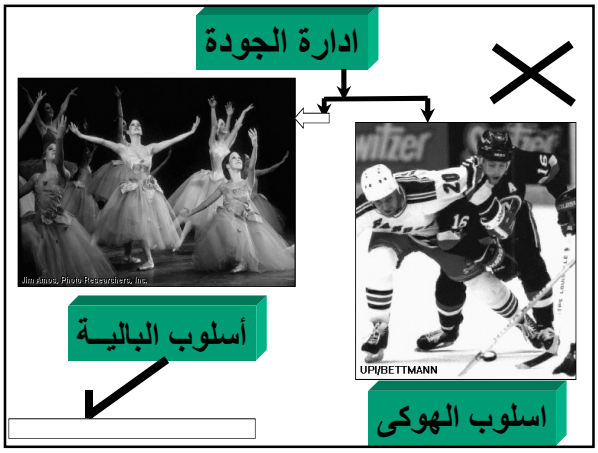
LEVEL 3 → **1.1.1. Leadership considers physical design, product complexity, process capability, initiative load and organization capability in the design of the system and organization to deliver key element requirements. The leadership ensures that there are enough qualified individuals available to perform the required tasks for specific operations.**

الجودة مبدأ قديم و راسخ في الشركة منذ نشأتها

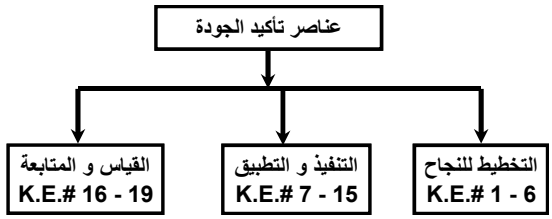
إذا لم تستطع صنع منتجات نقية

و بأوزان كاملة، فاعمل بأي شيء آخر
حتى و إن كان تكسير الحجارة

جيمس جامبل



تنظيم عناصر الجودة



عناصر تأكيد الجودة
للتخطيط والنجاح

1- القيادة
2- التدريب
3- التصميم ، البناء، والتركيب
4- الفورمة التركيبية، والمواصفات القياسية
5- التعليمات المكتوبة
6- الأجراءات التـأكيدية

عناصر تأكيد الجودة
"التنفيذ والتطبيق"

7- الترتيب ، مكافحة الآفات، والصيانة
8- المواد الأولية
9- عمليات التصنيع
10- عمليات التعبئة
11- تخزين ومناولة المنتجات
12- نظم المختبر
13- نظم التحكم في العمليات التشغيلية
14- نظم التحكم والفسح للمنتجات
15- السجلات

عناصر تأكيد الجودة
"القياس والمتابعة"

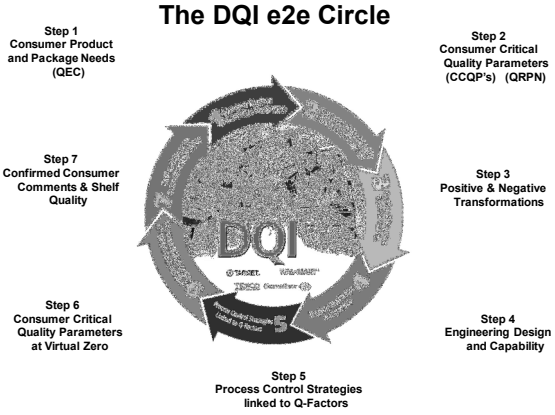
16- برنامج التطوير الذاتي

17- نظام فحص شكاوى المستهلكين

18- متابعة نتائج الجودة

19- متابعة ولاء المصنعين المتعاقدين

The DQI e2e Circle



Questions?