



Club Founder  
**Dr. Mahmoud Bahgat**



**International Factories Club**

**PRODUCTION ROLE  
& GMP FUNDAMENTALS**

**Online zoom**

**9 pm EGY-10 pm KSA-11 pm UAE**

**Co-Founder & Host:  
Dr. Ahmed Rafat**

25 كانون الثاني، 25



**Dr. Riham Magdy**  
**Production Manager & GMP Trainer**

**SAT. 25TH JAN. 2025**



PREPARED BY: RIHAM MAGDI



# Dr. Riham Magdi Shaheen

## Education:

**Bachelor of Pharmaceutical science – Ain Shams University 2010**

**Professional TQM Diploma approved from ITS supported by Cambridge University**

**Drug Manufacturing Diploma – Cairo University 2019**

**Teaching Diploma– Cairo University 2020**



## Experience:

**Production Manager**  
March 2024 - Present

Western pharmaceutical industries

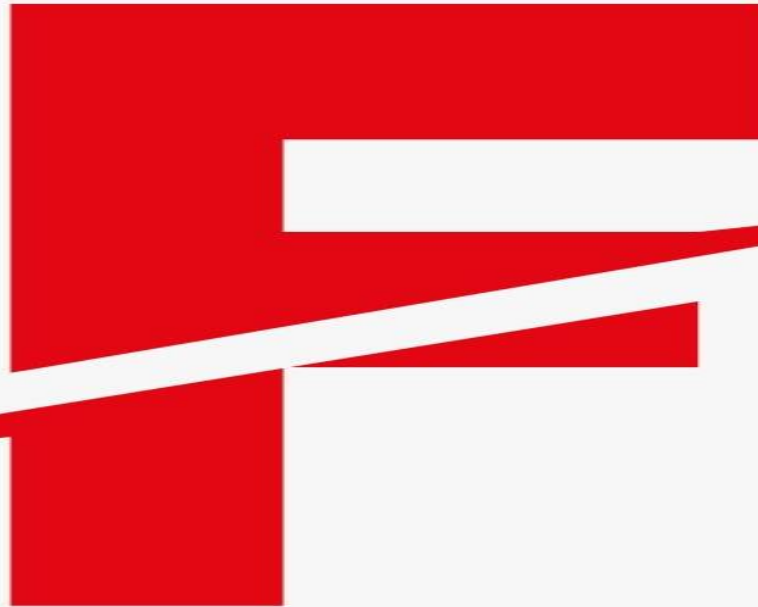
**Solid dosage forms production section head**  
2019 – Feb 2024 Memphis company

**External Trainer for GSK(global for science and knowledge)training academy**  
Present

**External Trainer for Medix training academy**  
Present

**External Trainer for Holdi pharma company**

**International**



**Factories** *Club*

**Sharpen your skills**



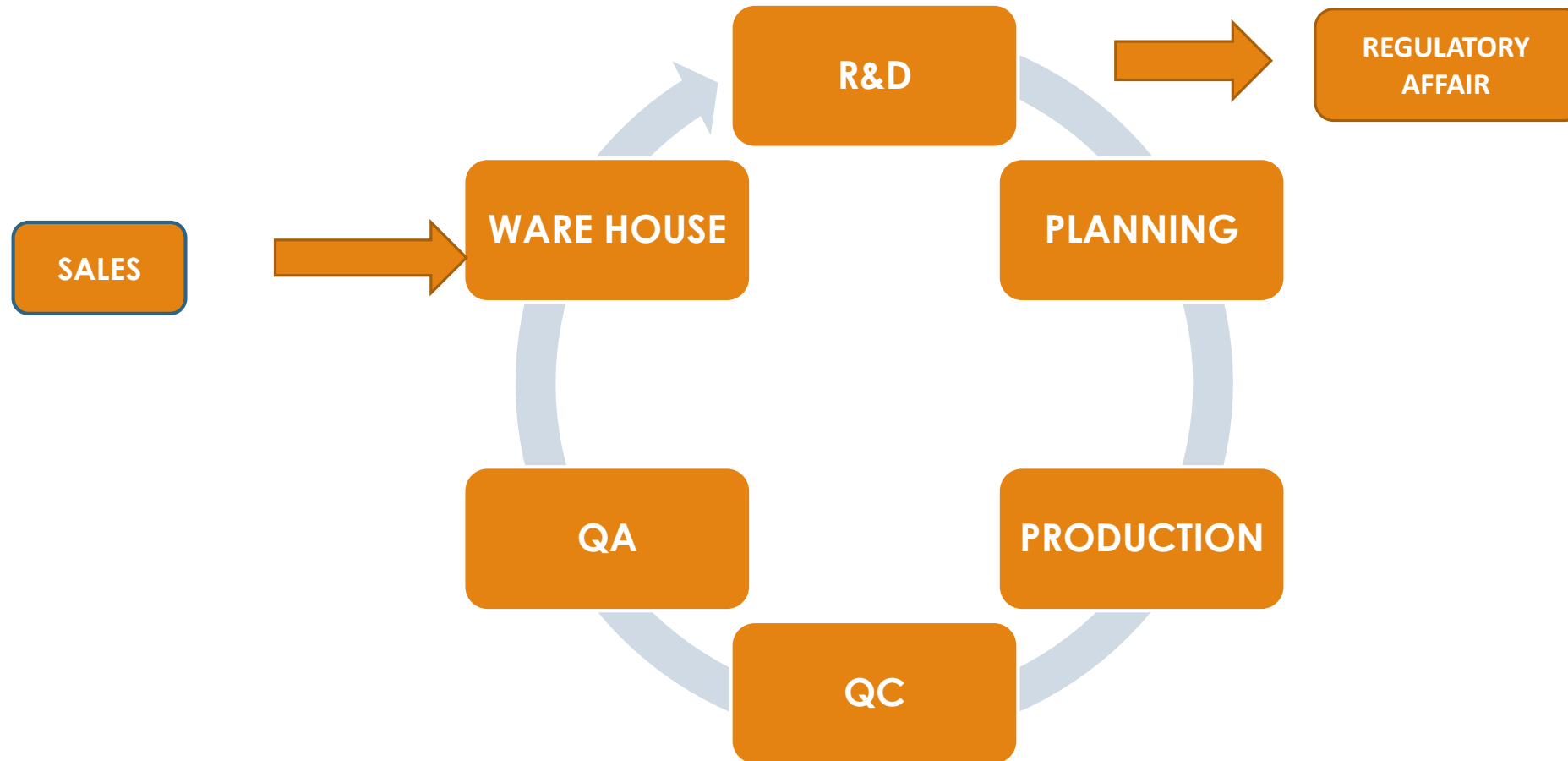
# PRODUCTION ROLES & FUNDAMENTALS OF GMP

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By: Dr. Riham Magdi

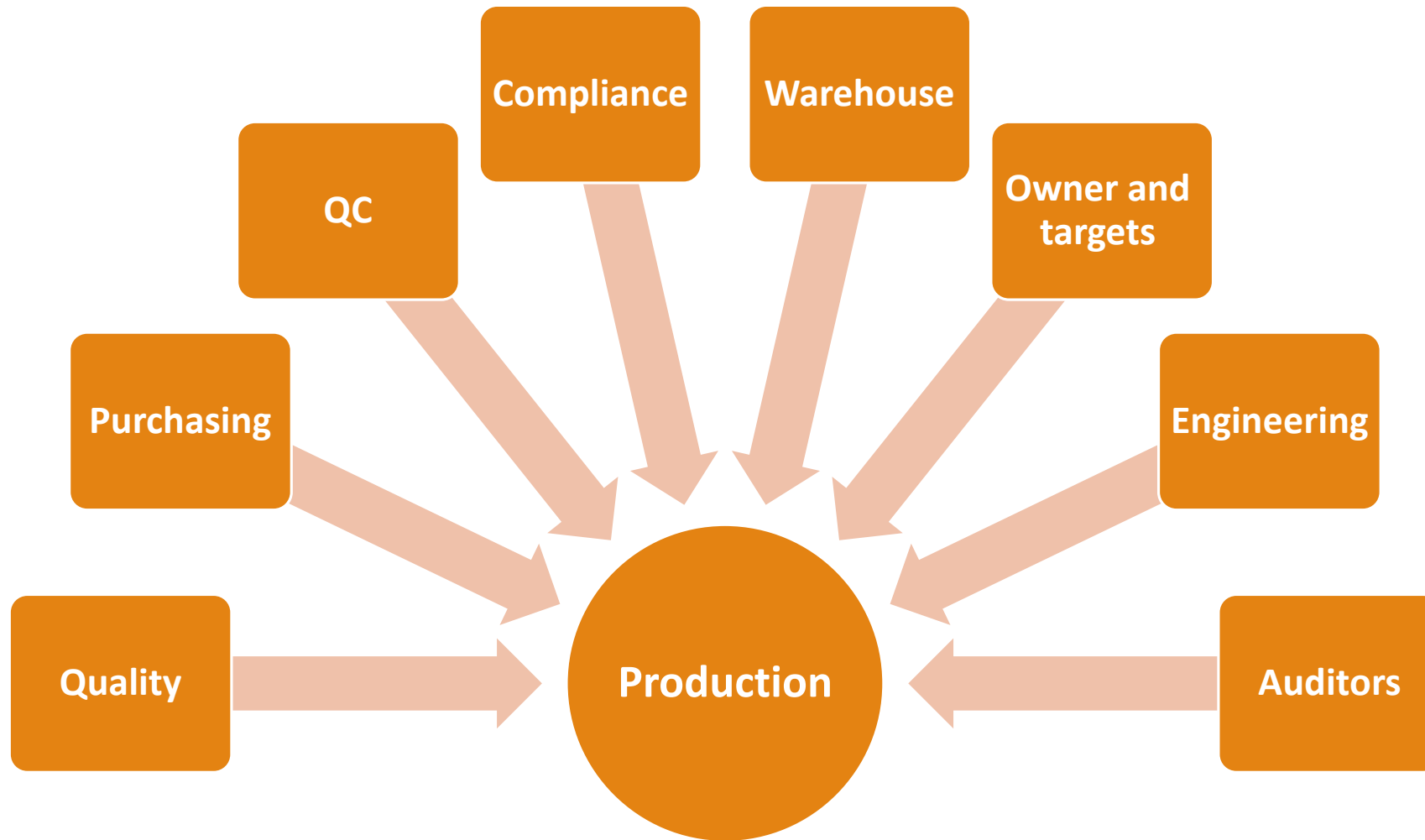


# Pharmaceutical Factory Organization

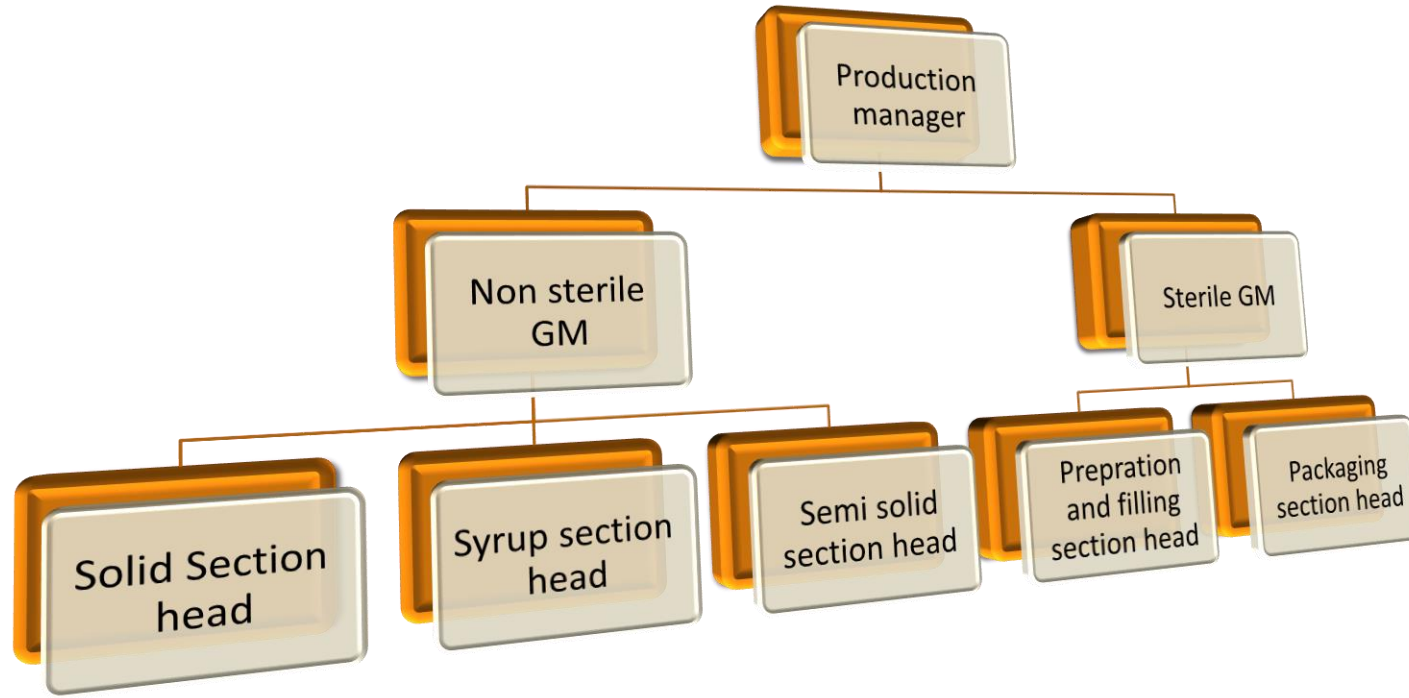


# What is the role of Production Pharmacist????





# Production Organogram



# ***PRODUCTION MAPPING***

***Raw material  
preparation***



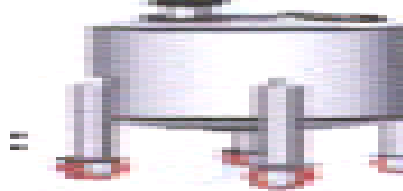
***Weighing***



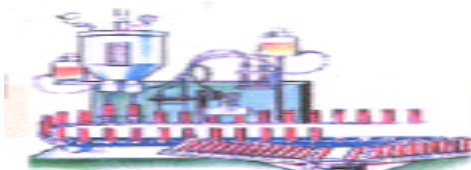
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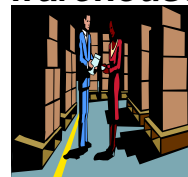
***Bulk storage***

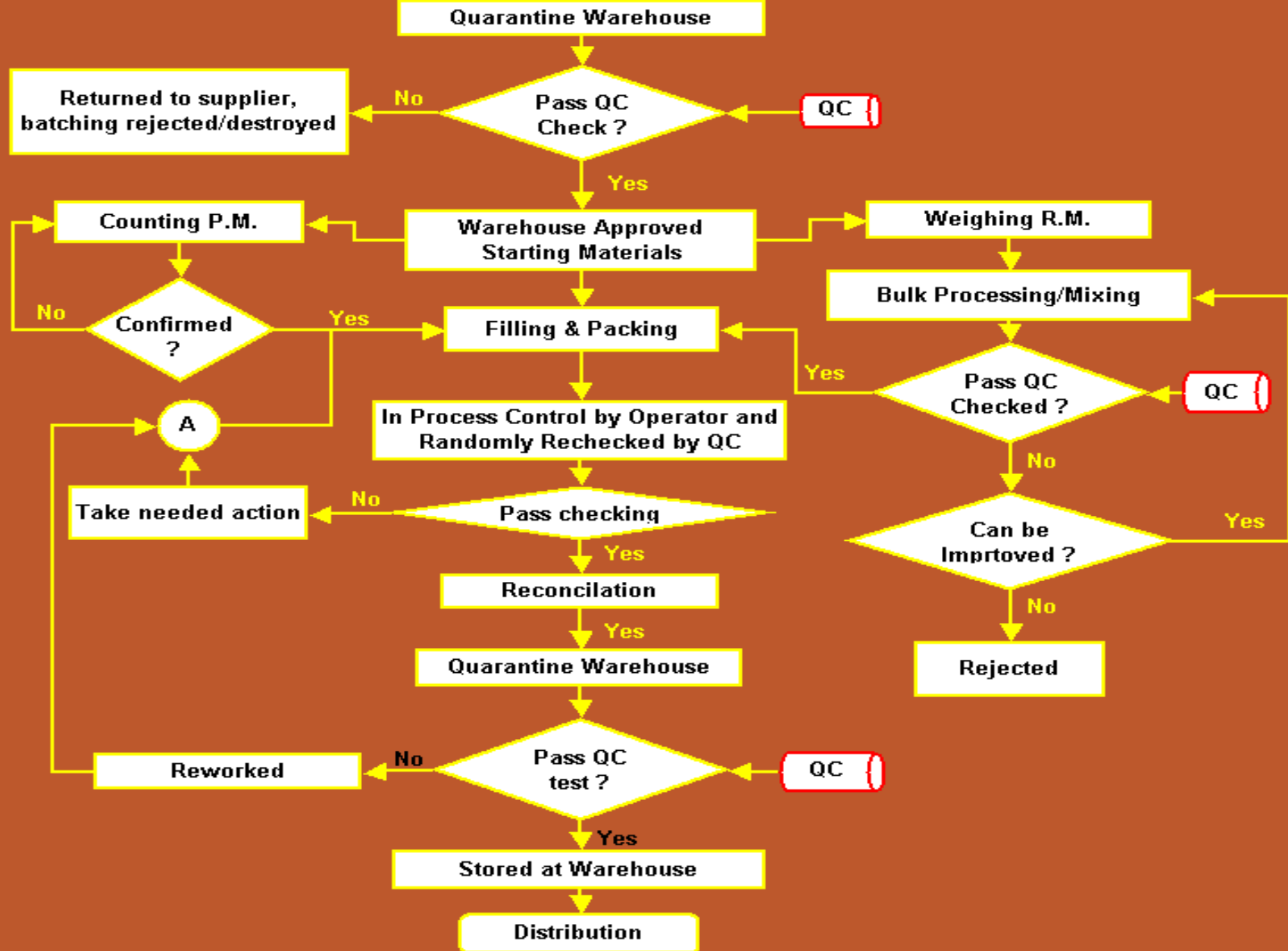


***Filling & packing***



***Delivery to  
warehouse***





# Solid manufacturing process

Advantages/disadvantages of different processes:

Wet granulation	Dry granulation	Directcompression
Good powder flow	Good powder flow	Simple process?
Limited segregation	Limited segregation	Few machines needed
Good distribution of drug and excipients	Drug not in contact water no high temperatures	Little process stress no water no high temperatures
Suitable for all concentrations of drug	Complex process	Robust process
Compaction behavior determined by process	Poor process control, compaction behavior	Segregation change poor distribution
Binder substance in the powder	Dust!	Limited concentration range (0.5-25%)
Complicated process many ipc's, difficult validation		Dependence of flow and compaction behavior of excipient
Unsuitable for drugs sensitive to moisture		
And health.		

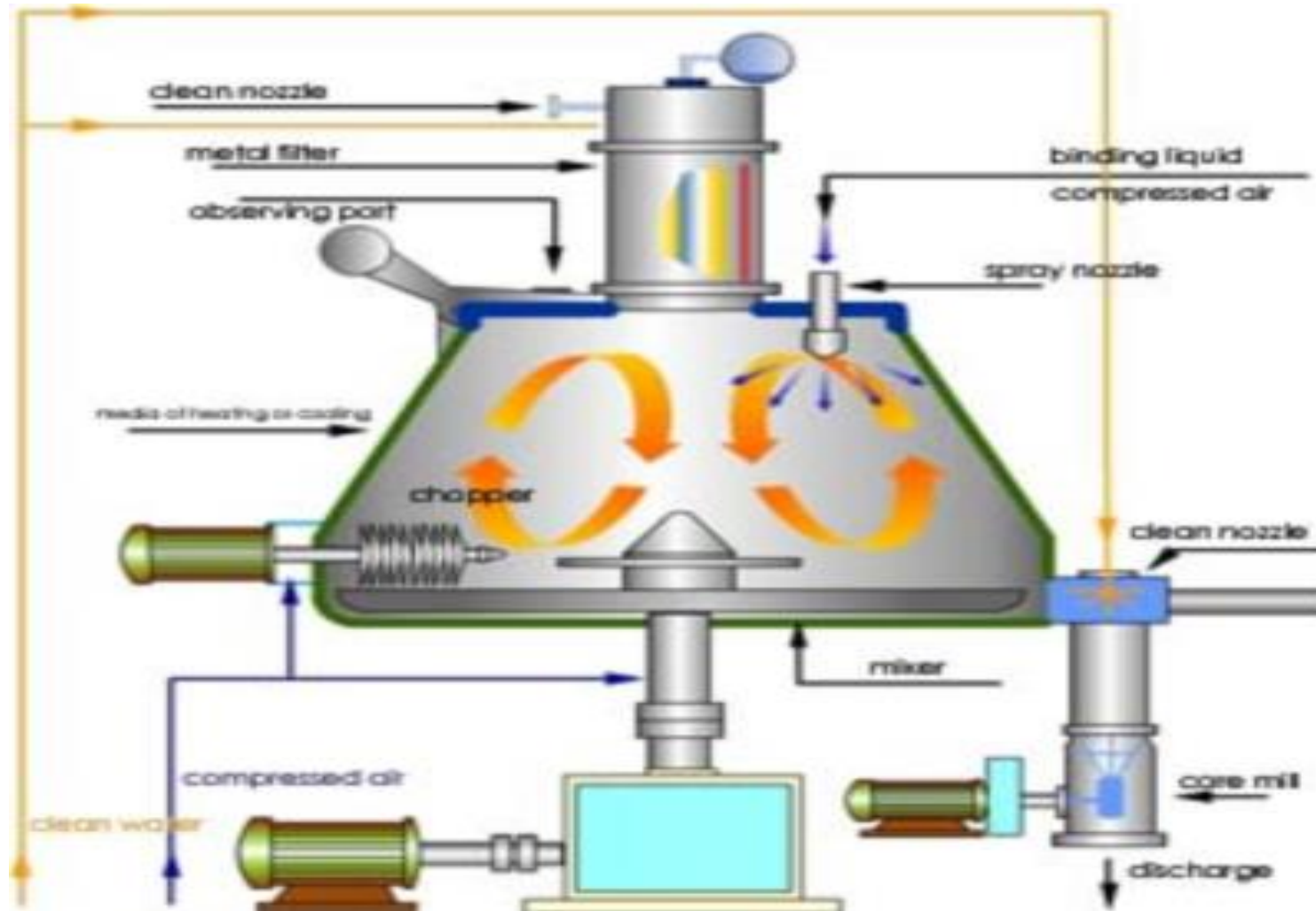
- **The requirements for fill material for tablet making**

**1) Flowability ( free-flowing from the hopper into the dies)**

**2) Compressibility**

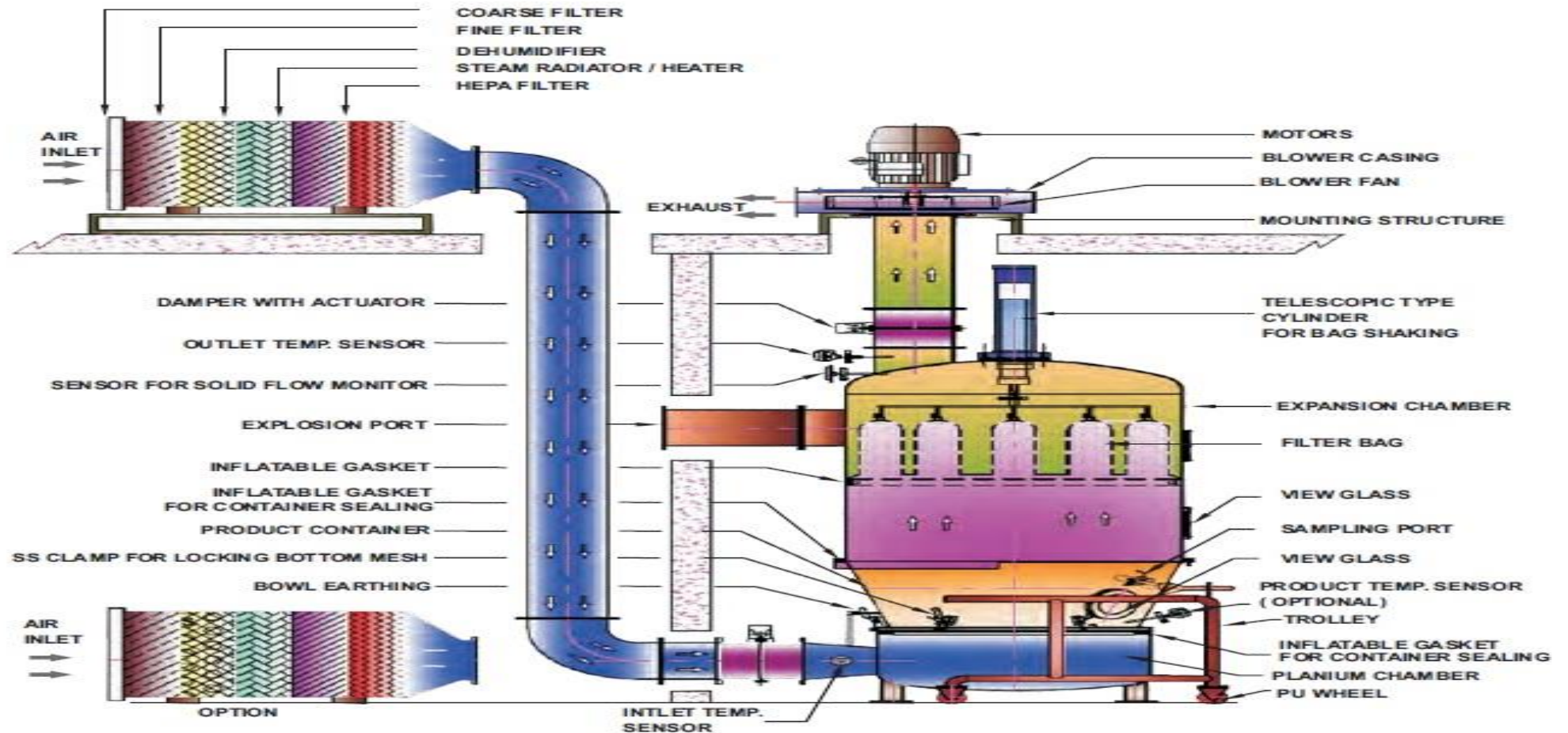


# WET GRANULATION

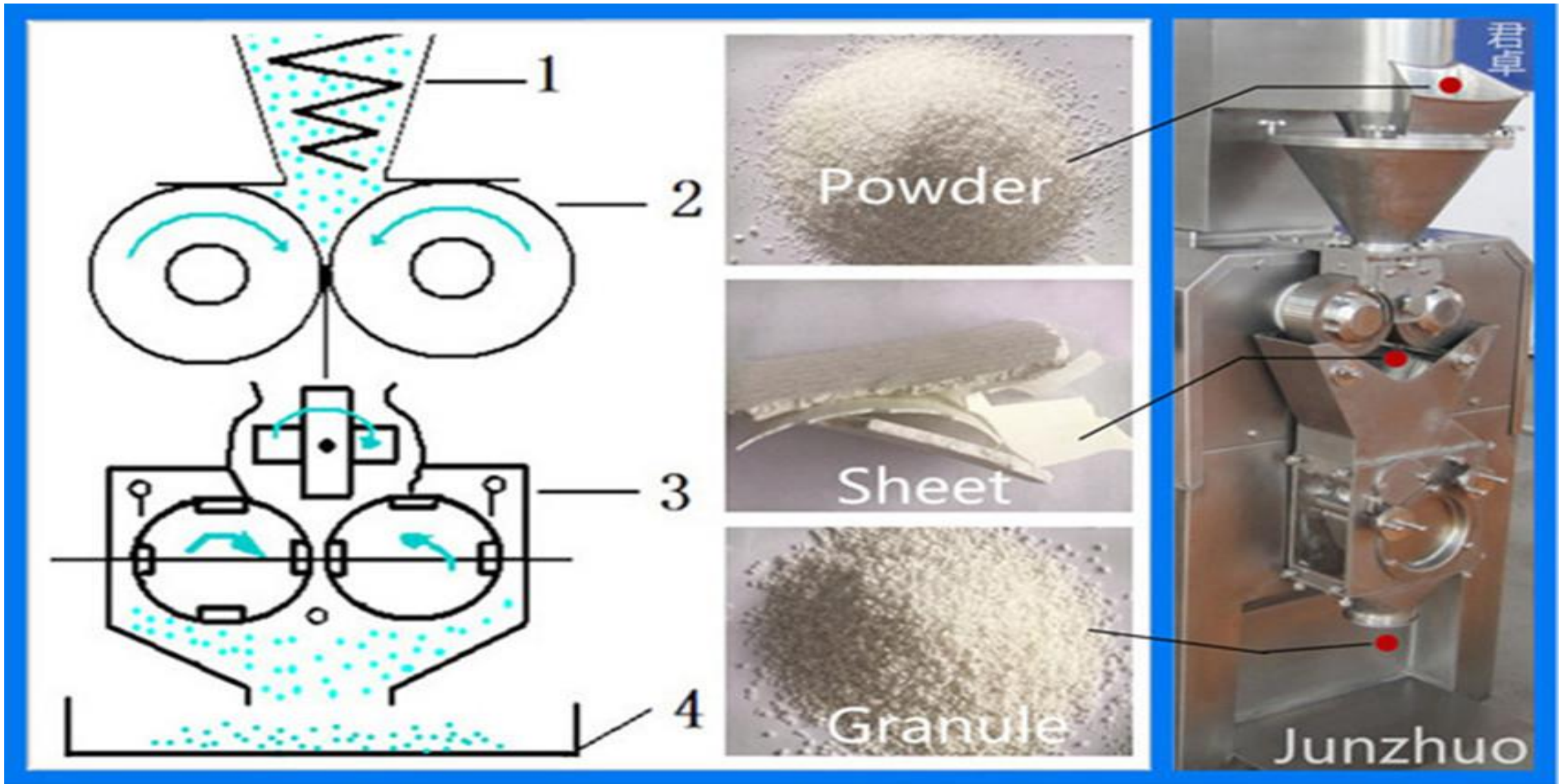


# FLUIDIZED BED DRYER

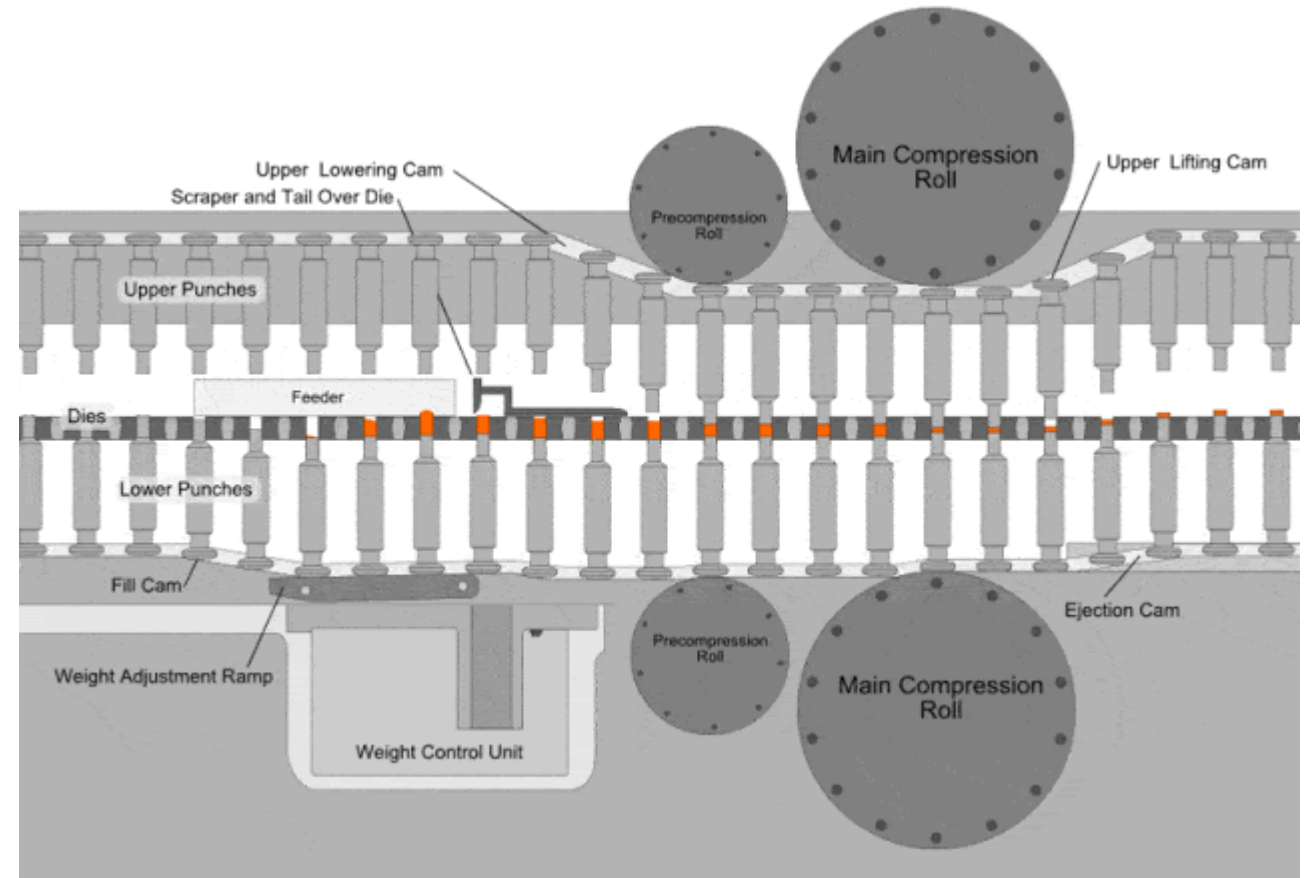
## SCHEMATIC DIAGRAM OF FLUID BED DRYING SYSTEM



# ROLLER COMPACTOR



# TABLETING CYCLE



# Tablet Coating



- ❑ Why coat tablets?

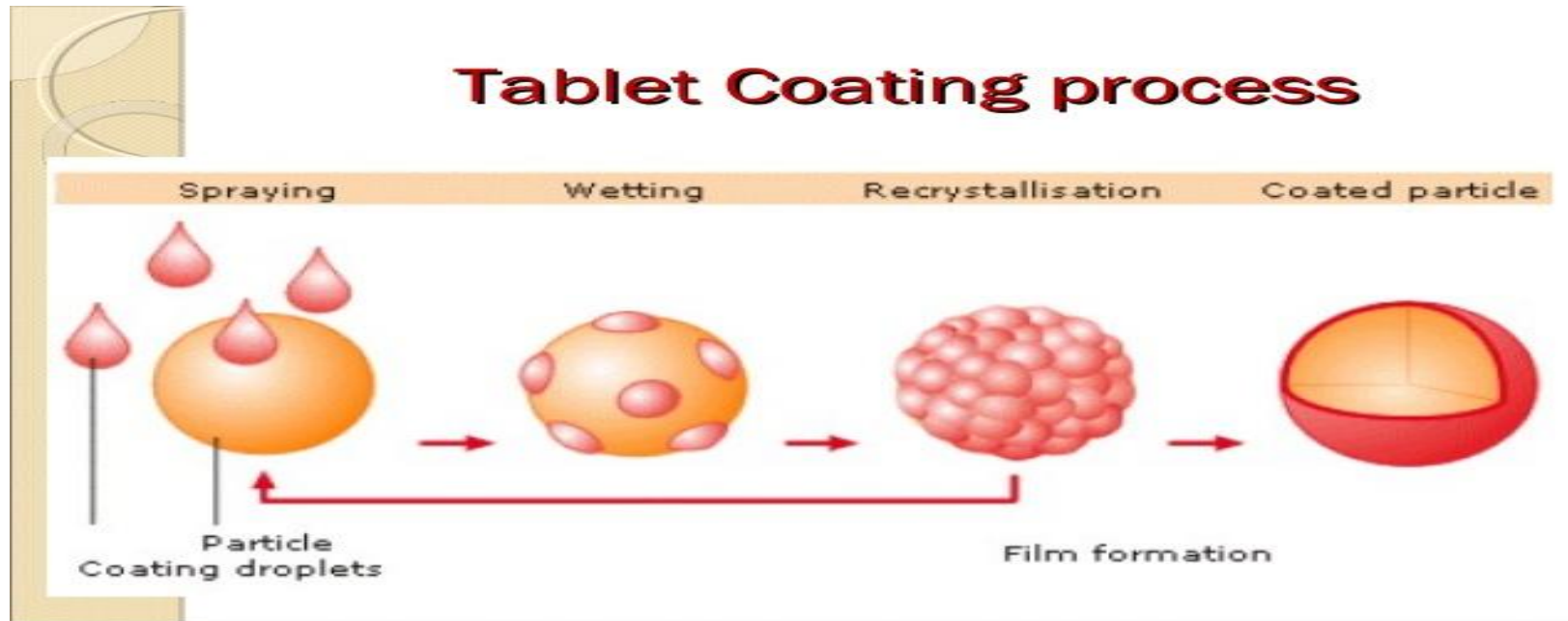
- ❑ Types of coatings

  - ❑ sugar coating

  - ❑ film coating

  - ❑ press coating (compression coating)

## Tablet Coating process



# Coating Machine



# Semisolid Dosage Forms

➤ Semisolid dosage forms meant for external application

➤ Semisolid dosage forms subcategorized are as-

I) ointment

II) creams

III) paste

IV) Jellies

V) Suppositories



# Semisolid Dosage Forms



**Ointment**



**Creams**



**Pastes**



**Gels**



**Suppositories**

# Syrup

- ❑ It is a concentrated or saturated solutions of sucrose in purified water.
- ❑ The concentration of sucrose is **66.7% w/w** & due to that it is a viscous preparations.
- ❑ The syrup which contains medical substance called as a **medicated syrup** & those containing aromatic or flavored substance known as a **flavored syrup**



# Syrup Preparation Line



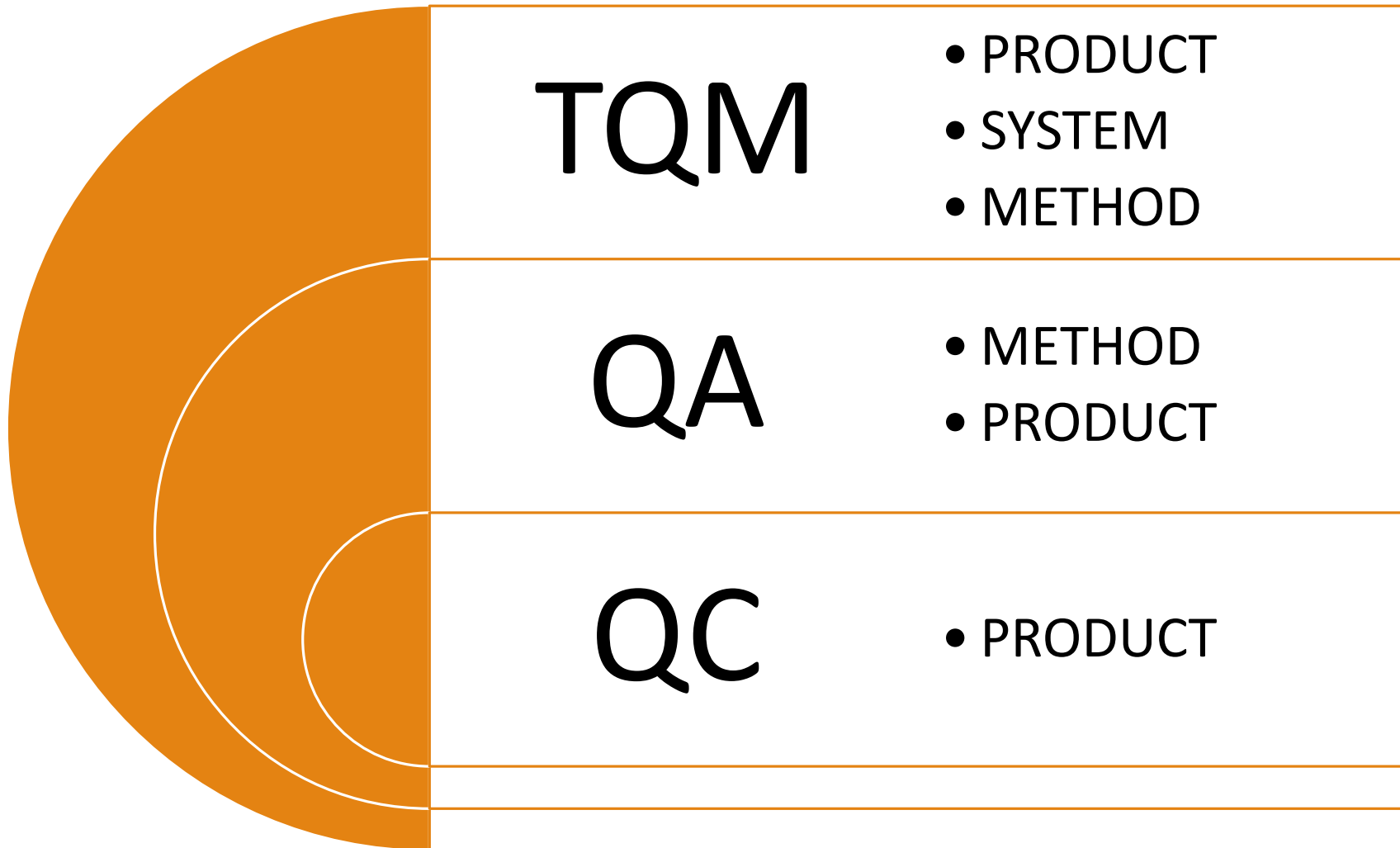
# GMP

## Quality Standards



# What is the difference between GMP certificate and ISO Certificate?





**GMP :**

is that **part** of Quality Assurance which ensures that products are consistently produced and controlled to the quality standard appropriate to their intended use and as required by the marketing authorization.



# Good Manufacturing Practices (GMPs)

are regulations that describe the methods, equipment, facilities, and controls required for producing:

- ☐ Human and veterinary products
- ☐ Medical devices
- ☐ Processed food&cosmetics



## EVOLUITON OF GMP

1-sant Louis 1901 horse  
Use its blood for difterrhea vaccine  
jem(infected by tetnous)  
13 children died  
Leads to:  
Biological control act 1902



2-1905 a book called THE  
JUNGLE

Family death slowly because of  
unsafe work conditions in  
meatpacking

1906 purue of chemistry that  
becom food and drug act FDA



**3-sulfanilamide 1937 diethylene  
glycol as solvent  
107 kids died  
1938FDA**

**4-sulfathiazole 1941  
contaminated with  
phenolphthalein**



**5-1956 thalidomide**

**Anti vomiting in**

**In 1962 discover the side effect**

**GOOD MANUFACTURING PRACTICE 1967**



# **1969 WORLD HEALTH ORGANISATION GMP accepted by WHO BECOME WORLDWIDE**



# Why GMP?

- ❑ **Final testing** of the product cannot ensure the Quality efficiency and safety.
- ❑ Conformance to the **predetermined specification**.
- ❑ To **minimize contamination** eg:- microbial contamination.
- ❑ To **eliminate error**.
- ❑ To produce product of **consistent quality** Government requirement.
- ❑ Reduce rejects, recalls.
- ❑ Satisfied customers.
- ❑ Company **image** and reputation



# GMP is global

**It is influenced by international bodies**

- **ICH**
- **International Organization for Standardization (ISO)**
- **cGMP Harmonization Analysis working group (FDA 2003) Modify 21CFR 210 and 211 to meet**



## 10 PRINCIPLES OF GMP:

1. **Design and construct the facilities and equipment properly**
2. Write procedure
3. Follow written procedures and Instructions
4. Document work
5. Validate work
6. Monitor facilities and equipment
7. Design ,develop(تطوير الكفاءة) and demonstrate job competence
8. Protect against contamination(be clean)
9. Control components and product related processes
10. Conduct planned and periodic audits



