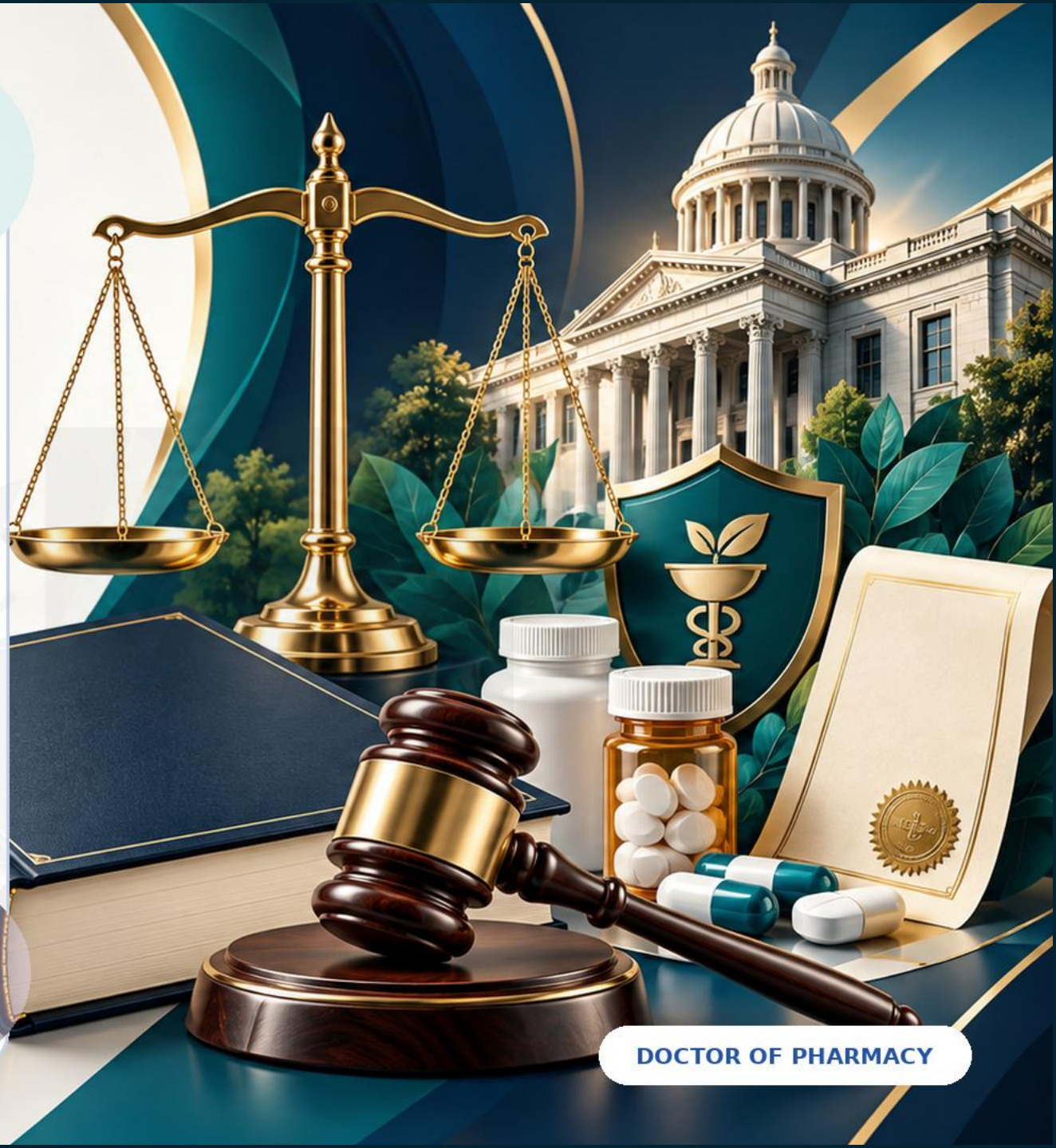
PHARM.D • YEAR 3

Pharmaceutical Analysis

CHAPTER 1

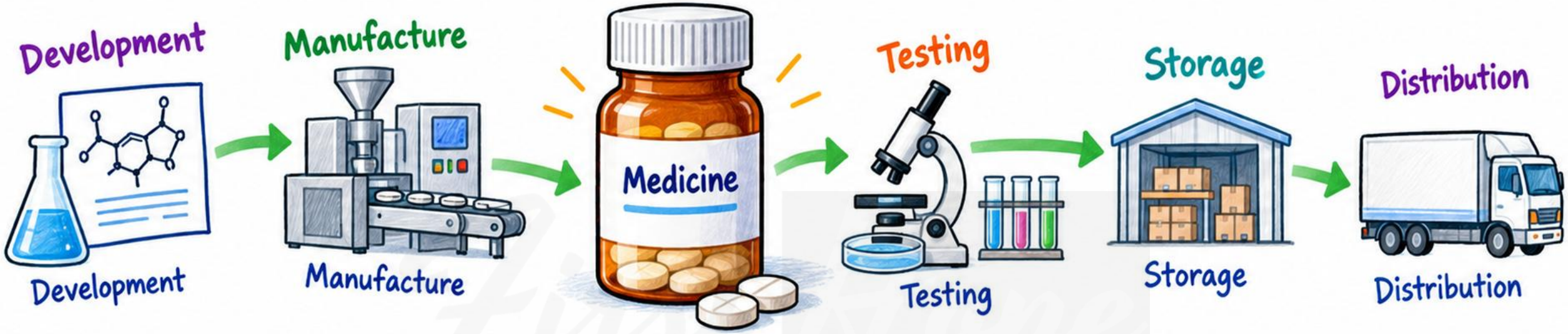
Quality Assurance

PPT CHAPTER COVER



DOCTOR OF PHARMACY

QUALITY ASSURANCE IN PHARMACEUTICALS



What is QA?

- Quality assurance (QA) is the organized system that gives confidence that medicines consistently meet defined quality requirements.
- It covers development, manufacture, testing, storage and distribution.

Prevention is Central

- Approved procedures, trained people and controlled processes reduce defects before they reach a patient.

How QA Connects

- QA connects research, production, quality control and regulatory affairs.
- Product quality depends on the whole organization, rather than a single department.

SOURCES OF QUALITY VARIATION

Materials:

- API impurities, variable excipients and unsuitable packaging can alter product quality.



Process:

- inconsistent mixing, drying, granulation or compression can change the finished dosage form.



Mixer

Mixing
↓
Drying
↓
Granulation
↓
Compression



Finished dosage form

Equipment:

- faulty operation or calibration adds variation.



Instrument
(e.g. balance)

Proper calibration and operation are essential.

People:

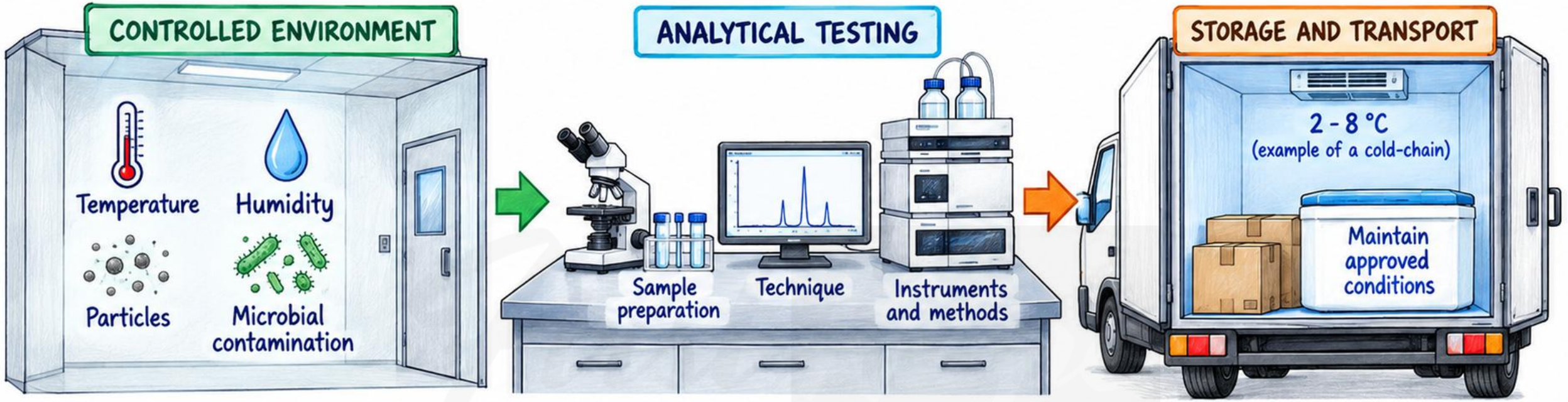
- inadequate training, fatigue and departure from SOPs increase errors.



Operator

These sources can cause failed batches, recalls and risks to patients.
A deviation investigation should identify the actual cause instead of assuming operator error.

ENVIRONMENT, TESTING AND DISTRIBUTION



1. ENVIRONMENTAL VARIATION

- Environmental variation includes uncontrolled temperature, humidity, particles and microbial contamination.

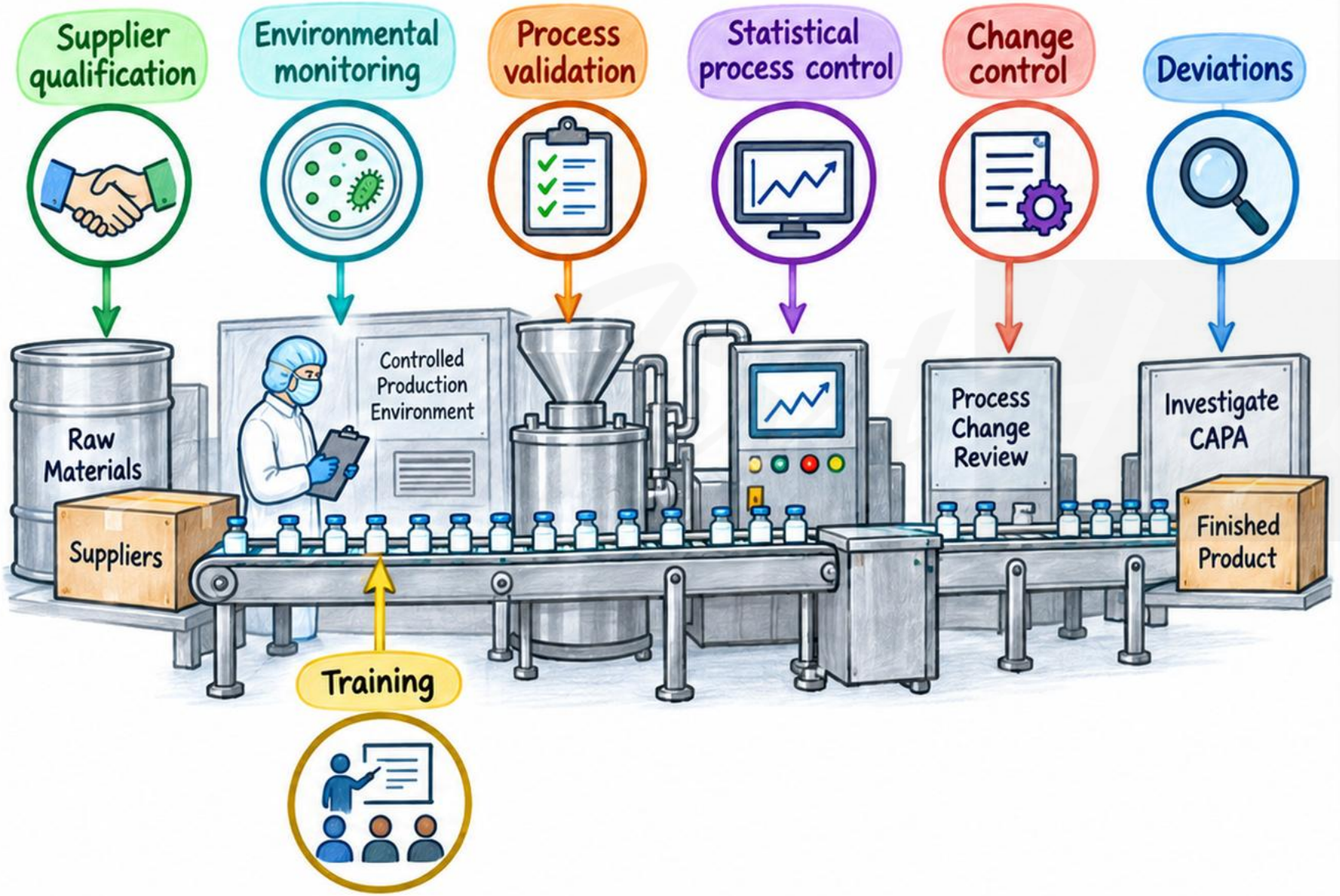
2. TESTING VARIATION

- Laboratory variation may arise from sample preparation, technique, unqualified instruments or unsuitable methods.

3. STORAGE AND DISTRIBUTION

- Storage and transport can expose products to heat, light or moisture.
- Maintain the storage conditions approved for each product.
- The 2-8 °C range is a cold-chain example, not a universal storage requirement.
- Records and monitoring help connect a quality failure with its source.

CONTROLS FOR QUALITY VARIATION



Process validation
provides evidence that a process can consistently produce acceptable quality.

Change control
evaluates proposed changes before implementation.

Deviations
require investigation and appropriate corrective and preventive action (CAPA).

Training
confirms that personnel can follow current procedures.

Supplier qualification
controls incoming materials.

Environmental monitoring
checks relevant particles and microorganisms.

Statistical process control
uses trends to detect changes in process behavior.

These controls work together throughout routine production.

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