

# Good Manufacturing Practices

(PHAR 533)

Fifth Grade – Spring Semester

Faculty of Pharmacy

Pharmacy Department

Tishk International University



## Lecture 2

# Quality Management Systems and Risk Management

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11/2/2026



# Outlines

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- Quality Management Systems
- Quality Risk Management
  1. Risk Assessment
  2. Risk Control
  3. Risk Communication
  4. Risk Review
- Quality System Inspections



# Learning Outcomes

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**At the end of this chapter, you will be able to:**

1. Explain the structure and purpose of Quality Management Systems in pharmaceutical manufacturing.
2. Identify and differentiate the types and stages of Quality Risk Management.
3. Apply basic risk-based thinking to pharmaceutical operations and inspections by recognizing common risks and regulatory inspection priorities.

# Quality Management Systems (QMS)

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**QMS:** a structured and documented management system describing the **policies, objectives, principles, organizational authority, responsibilities, accountability,** and **implementation plan** of an organization for ensuring quality in its work processes, products (items), and services.





# Quality Management Systems (QMS)

The quality systems are organized into four sections:

## **1. Management Responsibilities**

(e.g., leadership, organizing, establishing policies and objectives, planning ...)

## **2. Resources**

(e.g., develop personnel, facilities, equipment ...)

## **3. Manufacturing Operations**

(e.g., design and develop products and processes, monitor packaging and labeling processes, address nonconformities ...)

## **4. Evaluation Activities**

(e.g., analyze data, conduct internal audits, corrective action, risk assessment ...)



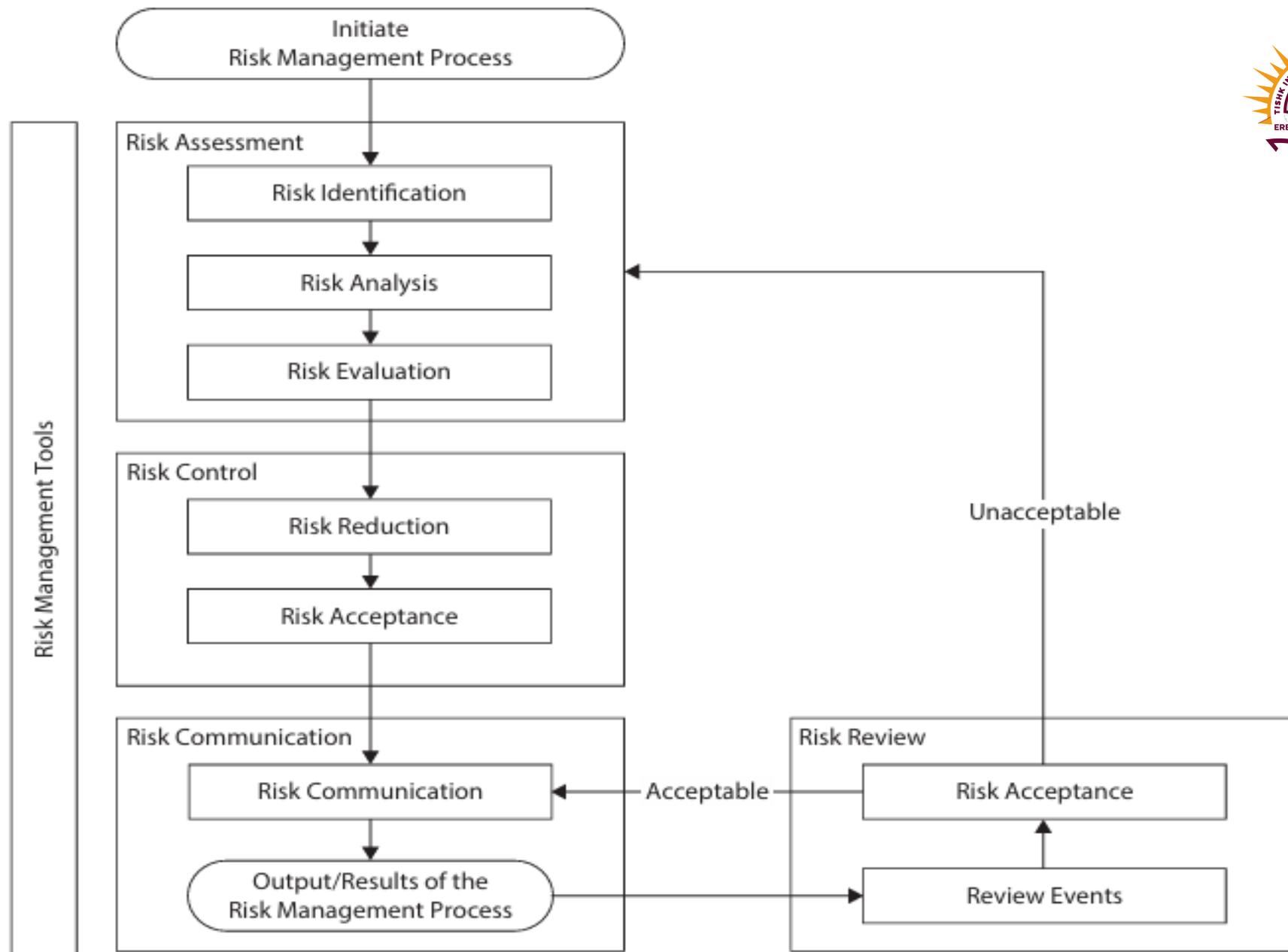
# Quality Risk Management

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**Risks** are **uncertain future events** that have the potential to affect the achievement of a company's goals and objectives.

**Risks are categorized into:**

- 1. Strategic Risks** (e.g., entering a new market without understanding local regulatory frameworks, leading to product rejection or market withdrawal).
- 2. Operational Risks** (e.g., equipment breakdown causing batch delays or losses).
- 3. Financial Risks** (e.g., sudden increase in the cost of API).
- 4. Hazard Risks** (e.g., handling live microorganisms in vaccine production).



# 1- Risk Assessment

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## **A- Risk Identification:**

What might or could go wrong?

## **B- Risk Analysis :**

What is the probability or likelihood that it will go wrong?

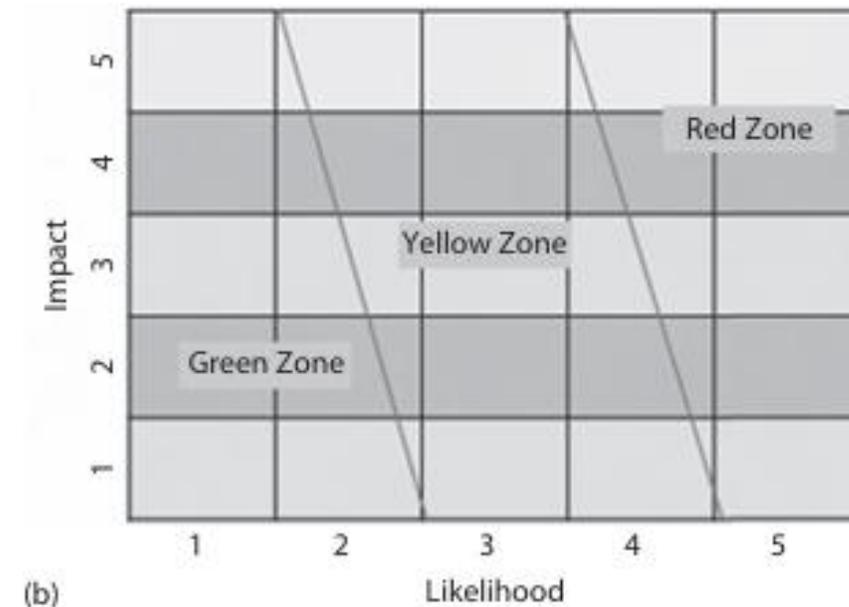
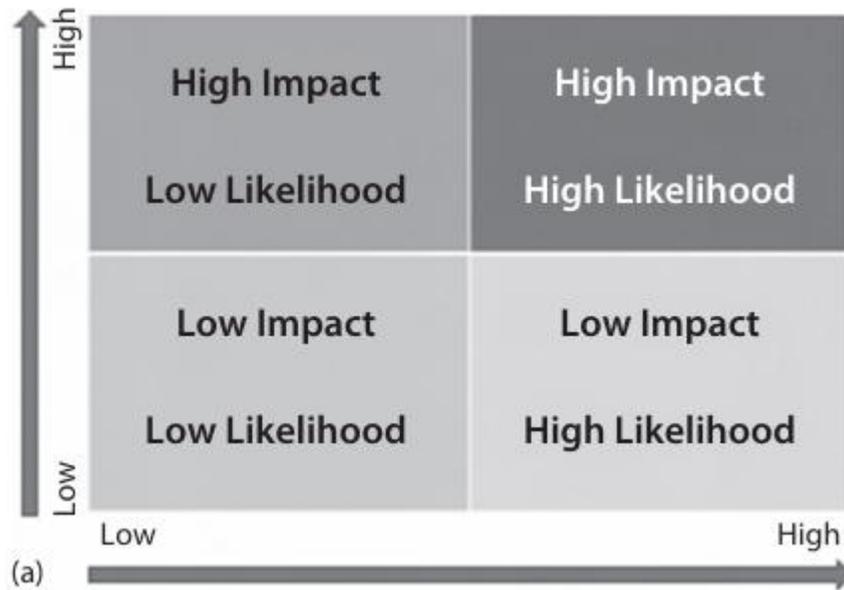
What is the severity or consequence if the event happens?



# 1- Risk Assessment

## C- Risk Evaluation:

Can involve a **qualitative** (high to low) or **quantitative** (numerical probability) approach.





## 2- Risk Control

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**A- Risk reduction:** actions taken to mitigate or avoid the risk.

**B- Risk acceptance decision.**

In some cases, it may not be possible to eliminate the risk, but short-term remedial actions may reduce it to an acceptable level or make sure it is detected.

1. Is the risk above an acceptable level?
2. What can be done to reduce, control, or eliminate the risk?
3. What is the correct balance between risk, benefits, and resources?

# 3- Risk Communication

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If a team has been working together on the problem, there should have already been communication between the **decision-makers** and **stakeholders**.

However, there may be a need for a more formal process of notification for **other parties** involved in or impacted by the decisions and changes.





# 4- Risk Review

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The output and results should be reviewed for new knowledge and lessons learned.

The changes and results should be monitored, and if needed, the risk management process can be re-engaged to handle planned or unplanned events.



# Quality System Inspections

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**The FDA determined the top three priorities for their inspection program:**

- Firms that produce sterile products
- Firms that produce prescription drugs
- Firms that have not been inspected previously

# References

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**Bunn, G. P. (Ed.). (2015). *Good manufacturing practices for pharmaceuticals* (7th ed.). John Wiley & Sons.**

