QUALITY MANAGEMENT

ISO 9001: 2015

cGMP

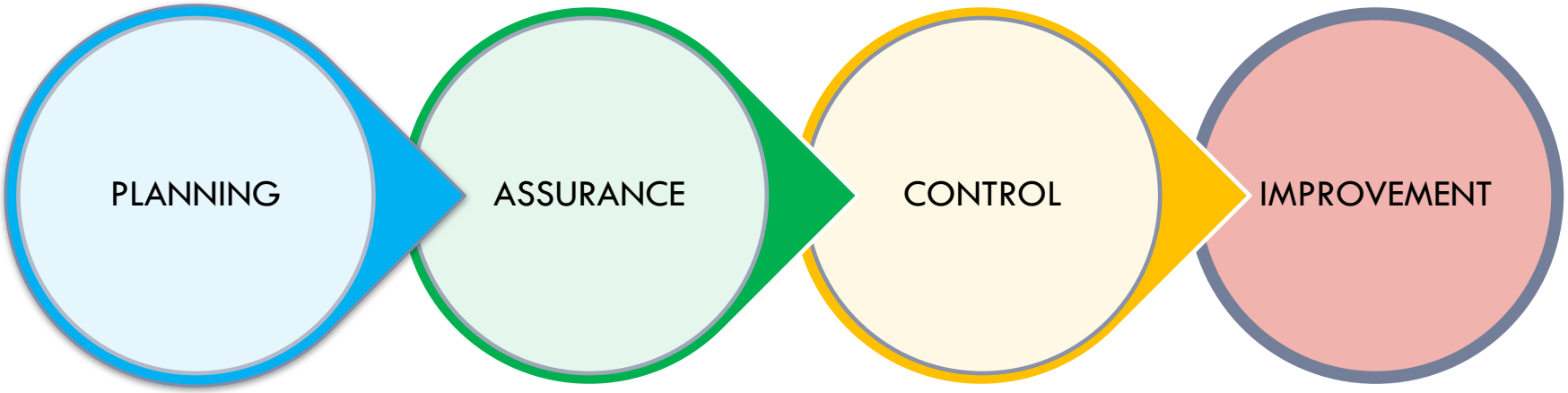
HACCP

INTRODUCTION

- Bioprocessing involves the production, packaging and delivery of biological molecules for human or animal consumption.
- Product Quality is a critical component of the production system.
- Product Quality is driven by customer satisfaction.
- The need for Quality is governed by specific **Quality Standards**.

Quality Systems

- ISO 9001: 2015
- cGMP
- HACCP



QUALITY MANAGEMENT

CURRENT GOOD MANUFACTURING PRACTICE

- What is Quality?
- Why is Quality important in bioprocessing?
- What is a Quality Standard?
- How do we ensure compliance with Quality Standards?

What will you **learn** during the course of this module?

- Develop a plan for which defines the Quality Standard for your specific bioprocess.

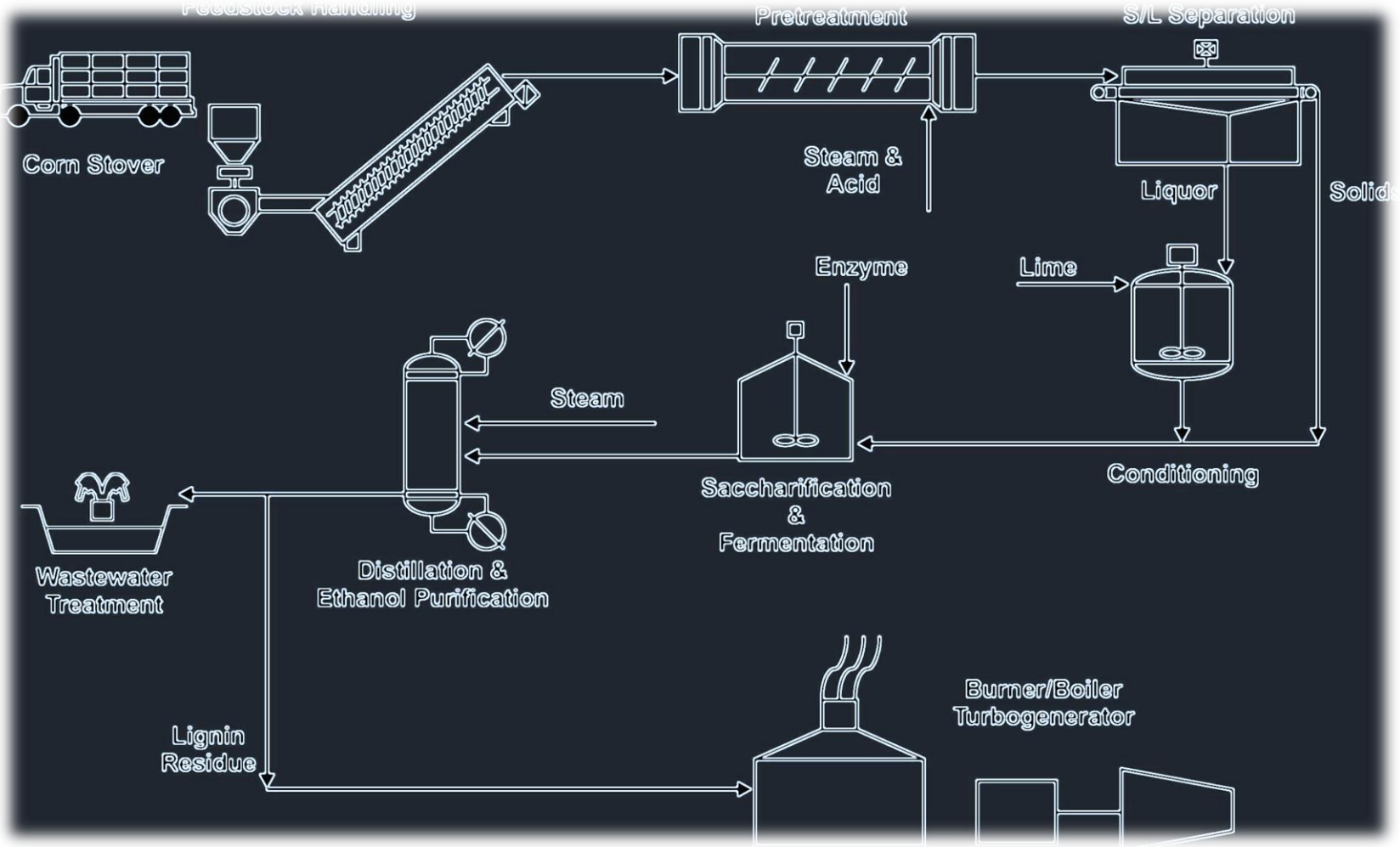
What should you be able to **do** upon completion of this module?

- A working knowledge of cGMP, ISO9001 and HACCP is essential for employment in the bioprocess, pharmaceutical and process biotechnology industry.

How will this module contribute to your **career goals**?

Case Study (cGMP)

- You have decided to establish a manufacturing unit for the production of vaccines for poultry.
- The vaccine has been formulated using a recombinant viral coat protein.
- The formulation contains additional adjuvants.
- Design your process workflow using the principles of industrial molecular biology.
- **How will you ensure that the final product complies with regulatory standards and customer expectations?**



Example of Process Workflow

DISCUSSION BREAK

- Please form a group and discuss how you will resolve the issue of **QUALITY.**
- Assign specific roles and responsibilities to the team.

INTRODUCTION

Good manufacturing practices (GMP) are **the practices** required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages. Cosmetics, pharmaceutical products, dietary supplements, and medical devices. These guidelines provide **minimum requirements** that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

To prevent harm from occurring to the end user.

MAIN PURPOSE

How do we ensure GMP?

- GMP is typically ensured through the effective use of a quality management system (QMS).

What is a QMS?

- A quality management system (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction.

What is **Compliance**?

- In general, compliance means conforming to a rule, such as a specification, policy, standard or law.

Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

Validation

Golden Rules of cGMP

Golden Rule#1 Get the facility design right from the start

Golden Rule#2 Validate processes

Golden Rule#3 Write good procedures and follow them

Golden Rule#4 Identify who does what

Golden Rule#5 Keep good records

Golden Rule#6 Train and develop staff

Golden Rule#7 Practice good hygiene

Golden Rule#8 Maintain facilities and equipment

Golden Rule#9 Build quality into the whole product lifecycle

Golden Rule#10 Perform regular audits

1. **FACILITY DESIGN**

- Get the facility design right from the start.

- Exercise: design a layout of your production facility.
- The location of equipment must be clearly stated.

- Ensure that each process is validated and complies with regulations.

- Which of the processes require compliance with existing laws related to biotechnology in Malaysia?
- How will you build **compliance** into your process?

2. **PROCESS VALIDATION**

- Write procedures and ensure that they are SMART.
- Write down examples of processes that you intend to implement.

3. **PROCEDURES**

- Identify who does what and specify their roles and responsibilities.
- Delegate responsibilities to your team members.

4. DELEGATION

5. DOCUMENTATION

- Ensure that documentation is maintained. This will ensure traceability of processes, personnel and the product.
- How will you ensure that adequate documentation is maintained?
- Exactly what will you document? And why?

6. TRAINING

- Training is part of the CQI cycle. Ensure that training is adequate and specific to organizational needs.
- What specific training do your team members need?

7. HYGEINE

- Practice good hygiene during the production cycle.
- What specific procedures will you implement to ensure that your final product is sterile?

8. MAINTENANCE

- Maintain facilities and equipment in order to ensure that processes comply with standard operating procedures.

- How will you maintain your equipment? What are the criteria for maintenance?

9. QUALITY

- Build quality into the process.
- State how you will ensure that the quality of your process is maintained and improved upon?

10. AUDITS

- Perform regular audits to ensure compliance and for the purpose of product improvement.

- What are the essential elements of an audit?
- How will you decide upon the periodicity of yours audits?

HACCP

ISO 22000 FSMS 2011

- Hazard
- Analysis and
- Critical
- Control
- Points

What is HACCP

- A HACCP System requires that potential hazards are identified and controlled at specific points in the process. This includes biological, chemical or physical hazards.

Case Study (HACCP)

- You have decided to establish a manufacturing unit for the production of probiotics for human consumption.
- The process consists of fermenting three (3) types of bacteria for a specific period of time.
- The bacteria are then lyophilized and encapsulated.
- **How will you conduct a Hazard Analysis?**

- Principle 1 - Conduct a Hazard Analysis.
- Principle 2 - Identify the Critical Control Points.
- Principle 3 - Establish Critical Limits.
- Principle 4- Monitor CCP.
- Principle 5 - Establish Corrective Action.
- Principle 6 - Verification.
- Principle 7 - Recordkeeping

What are the 7 principles of **HACCP**?

- **Hazard** is a biological, chemical or physical property that may render an item unfit for human consumption.

1. Conduct a hazard analysis

- Critical Control Point (CCP) is the point where the failure of Standard Operation Procedure (SOP) could cause harm to the consumer of the final product.

2. Identify Critical Control Points

- A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce that hazard to an acceptable level.

3. Establish critical limits for each critical control point

- Monitoring activities are necessary to ensure that the process is under control at each critical control point.

4. Establish critical control point monitoring requirements

- These are actions to be taken when monitoring indicates a deviation from an established critical limit.

5. Establish corrective actions

- Validate your controls in order to ensure that they are doing that which they were intended to do.

6. Establish procedures for ensuring the HACCP system is working as intended

- Hazard analysis,
- Written HACCP plan.
- Monitoring records of CCPs

7. Establish record keeping procedures

ISO9001

The next module will focus on the IS09001:2015

- ISO 9001 is the international standard that specifies requirements for a **quality management system (QMS)**. Organizations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements.

Reflections

- How will you apply the principles of Quality Management if you are assigned the role of a **Quality Assurance Manager** in a facility which manufactures probiotics for human consumption?