Training Handbook							
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PIC/S GMP Version 14

Training Handbook

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How to use this handbook

The handbook is organized to focus on particular skills and revisions.

These lessons allow you to learn and practice the skills used throughout the course.

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1. What is GMP?

Write down your definition.

2. Quality Definition

- What does quality mean?
- What do you expect from a quality product?

3. PQS/QMS Processes – What's the point?

With your groups, discuss the core PQS/QMS processes listed below and answer the following questions:

1. What is involved in the process?
2. Why is this process needed?

PQS/QMS Process	Discussion Answers
Documentation & Records	
Training	
Change Control	
Non-conformances	
Corrective & Preventive Actions	
Internal Audits	
Complaints & Recalls	
Supplier Assurance	

4. CAPA

There are many problems that you will encounter during your manufacturing processes. In your groups, create a problem scenario.

Scenario:

What would be your Correction(s), Corrective Action(s) and Preventive Action(s)?

Correction(s)

Determine your Root Cause(s)

Root Cause(s)

Corrective Action(s)

Preventive Action(s)

5. Control of Contamination

We have different levels of control based on the requirements of our different products. Prevention of contamination is a critical component of quality compliance.

1. Think about your work area and list the potential sources of contamination/cross-contamination.
2. What controls should be in place to avoid each potential source that you listed?
3. Are the controls working? Or not working?

Potential source of contamination/cross-contamination	Control Strategy / Mitigation	Controls working? Not working?

6. Mind the gap – Chapter 3: Premises & Equipment

In your groups, review the gap analysis spreadsheet and write down some potential ways the new changes may impact your organisation and the tasks you may need to undertake.

7. Mind the gap – Chapter 5: Production

In your groups, review the gap analysis spreadsheet and write down some potential ways the new changes may impact your organisation and the tasks you may need to undertake.

8. Supplier Risk Analysis

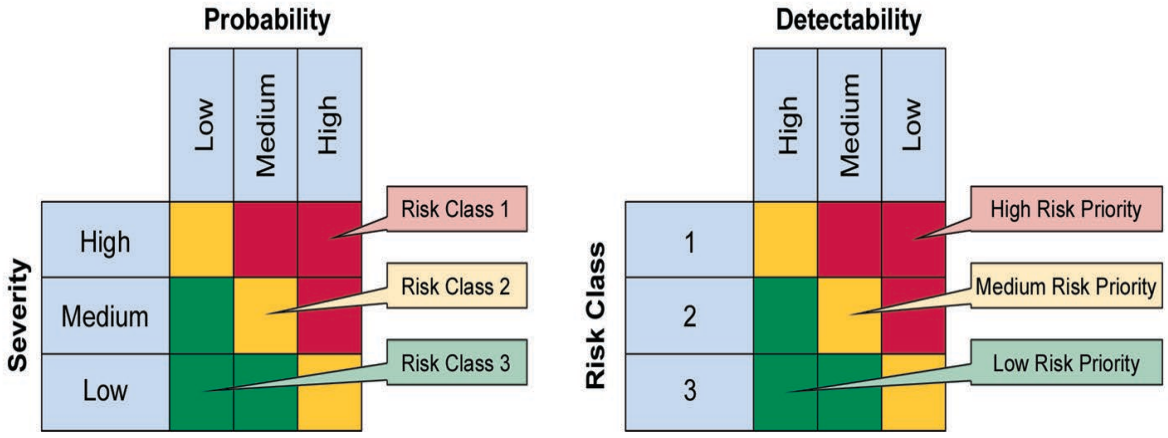
There are various risks associated within our suppliers. These may be risks to the product, risks to the facility, risks to equipment etc.

Within your groups, analyse the risks with your suppliers and fill in the table on the next page.

1. Create a list of some suppliers and rate them low, medium, high risk (Use the Figure below).
2. Why did you give them that rating?

Examples:

- Raw materials
- Equipment
- Pest control
- Security
- Gowning
- Facility maintenance
- Etc.



Severity = Impact on Patient Safety, Product Quality, and Data Integrity (or other harm)
Probability = Likelihood of the fault occuring
Risk Class = Severity × Probability

Detectability = Likelihood that the fault will be noted before harm occurs
Risk Priority = Risk Class × Detectability

Risk Level

Risk Level = Severity x Probability x Detectability

e.g.

H = high

M = medium

L = low

Supplier	Risk Rating (L/M/H)	Justification for Risk Rating
	`	

9. Product Recall

What potential effect did the recall have on the company?

What potential effect can a recall have on your company?

10. Mind the gap – Chapter 8: Complaints & Product Recall

In your groups, review the gap analysis spreadsheet and write down some potential ways the new changes may impact your organisation and the tasks you may need to undertake.

11. Summary: GMP-Ten Golden Rules

Summarise the Ten Golden Rules of GMP in the table below:

Rule No.	Summary
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

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