



## Training Handbook

<b>Department</b>	TRG	<b>Project No.</b>	200102_PHA	<b>Document No.</b>	HBK001	<b>Doc Rev.</b>	01
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# PIC/S GMP Laboratories Version 14

## Training Handbook

**Presented By  
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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?

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### 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?

<b>PQS/QMS Process</b>	<b>Discussion Answers</b>
<b>Training</b>	
<b>Documentation &amp; Records</b>	
<b>Change Control</b>	
<b>OOS/OOT</b>	
<b>Corrective &amp; Preventive Actions</b>	
<b>Internal Audits</b>	
<b>Complaints &amp; Recalls</b>	
<b>Supplier Assurance</b>	

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#### 4. CAPA

There are many problems that you will encounter in the laboratory. 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)

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## 5. Control of Contamination

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?

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## 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.



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## 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.



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## 9. 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.

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10. **Summary: GMP-Ten Golden Rules**

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

<b>Rule No.</b>	<b>Summary</b>
<b>1</b>	
<b>2</b>	
<b>3</b>	
<b>4</b>	
<b>5</b>	
<b>6</b>	
<b>7</b>	
<b>8</b>	
<b>9</b>	
<b>10</b>	

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