GACP/GMP Overview
Understanding the Regulatory Requirements
• Learning & Development Director at PharmOut
• Qualified Biological Scientist and Educator
• Over 20 years’ experience in QC, QA and L&D management roles in the Pharmaceutical, Medical Device Manufacturing and Automotive industries in the Asia Pacific Region
• GMP topics include current PIC/S updates, Data Integrity, Quality Risk Management, CAPA, ISO 13485, GACP and more.
• Maria is passionate about program design and competency assessments that align to business strategy and quality culture, and delivers highly-rated courses (onsite, public venues, and Universities).
PharmOut is a leading international consultancy organisation.

• We offer compliance, qualification & validation, regulatory, engineering and architectural consulting services

• We assist the pharmaceutical, blood & tissue, pesticides and veterinary and medical device manufacturers and Medicinal Cannabis cultivators and producers to meet regulatory standards (GACP/GMP) including GMP training

• PharmOut holds ISO 9001:2015 certification from LQRA.

• Our Quality Management System is certified to the ISO 9001:2015 standard for the provision of architectural design and consultancy services.
Our Services

- GxP compliance consulting
- GxP contracting
- GxP training
- Qualification and Validation
- Quality Management Systems
- Project management
- Regulatory submissions
- Continuous improvement consulting
- Temperature mapping
- Architecture
- Engineering
- Master & Strategic planning
Training and Education Announcement | Medicinal Cannabis Industry Courses in Australia | New

The Medicinal Cannabis Academy (MCA) is launching soon, featuring industry-tailored courses for the medicinal cannabis cultivation and production sectors, led by PharmOut.

PharmOut's medicinal cannabis consultants are recognised as having extensive experience in the pharmaceutical manufacturing industry, including validation training, GMP (PIC/S) compliance training, and global medicinal cannabis industry knowledge and medicinal cannabis industry consulting expertise including quality management systems (QMS), site selection, security, workflows and licencing applications.

PharmOut can also assist organisations with TGA audit responses, CAPA systems, upgrades, new sites/designs, FDA audit responses and other industry-specific engineering, validation and employee/contractor GMP (GxP) training requirements.
Global Regulations
Global GMP Regulators

[Map showing global GMP regulators with various abbreviations like MHRA, CFDA, FDA, etc.]

© PharmOut 2019
What is GACP?

Good Agricultural and Collection Practices for Medicinal Plants (or GACP for short) are a set of guidelines developed in 2003 by the World Health Organisation (WHO), aimed at **improving the quality** of medicinal plant material being used in herbal medicines in the market.
Other Guidelines

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

GUIDELINE ON GOOD AGRICULTURAL AND COLLECTION PRACTICE (GACP) FOR STARTING MATERIALS OF HERBAL ORIGIN

ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION | July 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS) | 30 October 2005
AGREED BY HMPC QUALITY DRAFTING GROUP | January 2006
ADOPTION BY HMPC | 12 January 2006
DATE FOR COMING INTO EFFECT | 1 August 2006

Note: the previous Herbal Medicinal Products Working Party Points to consider on GACP is now integrated into this HMPC Guidance. Only minor changes have been made to its content further to the public consultation.

GOOD AGRICULTURAL AND COLLECTION PRACTICE FOR HERBAL RAW MATERIALS
December 2006

Prepared by
the Botanical Raw Materials Committee of the American Herbal Products Association
In cooperation with the American Herbal Pharmacopoeia

American Herbal Products Association
8494 Georgia Ave., #570 • Silver Spring, MD 20910
p: (301) 588-1171 • f: (301) 588-1174 • email: ahpa@ahpa.org

American Herbal Pharmacopoeia
P.O. Box 66809 • Scotts Valley, CA 95067
p: (931) 461-6318 • f: (931) 475-6219 • email: acting@herbal-shp.org
© 2006 American Herbal Products Association
Why is GACP training required?

Concern over the amount of medicinal plant material being produced using **Bad** agricultural and Collection Practices

Adverse events due to poor quality herbal medicines – linked to raw materials

Due to all of this, there is increasing pressure to provide assurance that the herbal products in the market are safe and don’t have a negative impact on the environment
Why is GACP training required?

- The call for greater quality assurance has highlighted the need to improve the quality standards of the medicinal plant growers, collectors and processors.

- It is in this context that the WHO developed the GACP guidelines, aiming to address quality issues in the initial stages of the supply chain.

- WHO did acknowledge, however, that the guidelines were only the first step in achieving this aim and that they would need to be further adapted to meet the specific requirements of different countries and regions.

- They also acknowledged that widespread training would need to be given to farmers, collectors and processors if the guidelines are to make an impact.
Why GACP?

• Interest in herbal medicines has increased substantially in both developed and developing countries over the past three decades.

• The global market for medicinal herbs is growing rapidly and there is a lot of money to be made.

• As a consequence, the safety and quality of herbal medicines have become increasingly important for both the health authorities and the public.
The safety and quality of raw medicinal plant materials and finished products depend on factors that may be classified as:

<table>
<thead>
<tr>
<th>Intrinsic (genetic)</th>
<th>Extrinsic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Environment,</td>
</tr>
<tr>
<td></td>
<td>• Collection methods,</td>
</tr>
<tr>
<td></td>
<td>• Cultivation,</td>
</tr>
<tr>
<td></td>
<td>• Harvest,</td>
</tr>
<tr>
<td></td>
<td>• Post-harvest processing,</td>
</tr>
<tr>
<td></td>
<td>• Transport</td>
</tr>
<tr>
<td></td>
<td>• Storage practices</td>
</tr>
</tbody>
</table>
Objectives

The main aim of the guideline is to:

• Assist in homogenising national and/or regional standards for the cultivation and collection of medicinal plants

• Increase the level of the quality assurance for medicinal plant materials used as the source for herbal products

• Improve the **quality, safety** and **efficacy** of herbal products
NOTE: You are not expected to implement everything in the guidelines!

- Identify which sections are relevant
- Review those sections with respect to your own circumstances
- Implement whichever recommendations are useful and practical for your situation.

Of course, you will be expected to comply with requirements that come with specific certifications, e.g. organic, Kosher, non-GMO standards, etc.

It is also important to check HOW the products will be regulated, e.g. therapeutic goods vs food, because different standards will apply.
Benefits of Implementing GACP

- Credibility
- Reduce waste (costly)
- Ensure Quality of Raw Material
What is GMP?

• The acronym GMP is used internationally to describe a set of **principles** and **procedures** which, when followed by manufacturers of therapeutic goods, **helps ensure** that the products manufactured will have the **required quality**.

• A basic principle of GMP is that quality **cannot be tested into a batch of product** but must be **built into each batch** of product during **all stages** of the manufacturing process.
Why GMP?

1901 – Antitoxin for Diphtheria contaminated with tetanus

1937 – Sulfanilamide “wonder drug” for strep throat and gonorrhoea contained a poison killing 107 people

1955 – Inactivated polio virus in vaccine – 60 people developed polio

1972 – 5 deaths due to contaminated sterile products

1941 – Sulfathiazole tablets tainted with sedative phenobarbital killing nearly 300 people

1960 – Thalidomide marketed as a sleeping pill and to treat morning sickness. 10,000 cases of infant deformities in Europe

1982 – Tylenol cyanide poisoning due to tampering

Syrup “colicky” babies and “tonics” for adults contained alcohol, opium or morphine, which addicted many people who used them
Today’s regulations

The tragedies of the past led to the following standards that are the foundation of the drug, medical device and biologic safety today:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective &amp; safe</td>
<td>Manufacturers had to prove that their drugs were effective as well as safe before release to market.</td>
</tr>
<tr>
<td>Informed consent</td>
<td>Control over clinical investigations improved, including a requirement for informed consent.</td>
</tr>
<tr>
<td>Advertising controls</td>
<td>Regulators have authority to regulate advertising of prescription drugs.</td>
</tr>
<tr>
<td>GMP</td>
<td>Establish good manufacturing practices (GMP) as a means to promote quality assurance.</td>
</tr>
<tr>
<td>Records and process control</td>
<td>Access certain company control and production records to verify production procedures.</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>All drugs introduced between 1938 and 1962 had to be assessed for effectiveness (resulting in findings showing 40% were not!).</td>
</tr>
</tbody>
</table>
Currently **54** authorities have adopted (28 from Europe)

- GMP Guidance’s used as regulatory requirements by EU and Asia-Pacific countries
- Is an informal “Cooperative Arrangement” between GMP regulatory authorities; i.e. not a legal treaty.

No obligation for member authorities to accept inspection reports of other members.
54 PIC/S member authorities

4 Partners
EDQM
EMA
UNICEF
WHO

EUROPEAN UNION Member States Agencies (29)
We are here

PE009-8
- 15 Jan 2008
- Annexe 3

PE009-9
- 01 Sep 2009
- Chap. 4

PE009-10
- 01 Jan 2013
- Annex 6, 7, 11 & 13

PE009-11
- 01 Mar 2014
- Part II (QRM)
- Annex 2 & 14

PE009-12
- 01 Oct 2015
- Annex 15

PE009-13
- 01 Jan 2017
- Chap. 1, 2, 6 & 7 (Part I)

PE009-14
- 01 Jul 2018
- Chap. 3, 5 & 8
- Annex 17

PE009-??
- Chap. 4
- Annexes 1, 2, 11, 13, 16, 21
PIC/S PE 009 Guide to Good Manufacturing Practices is in 3 parts:

- Guide to Good Manufacturing Practice for Medicinal Products **Part I**
- Guide to Good Manufacturing Practice for Medicinal Products **Part II** (API manufacturing)
- Guide to Good Manufacturing Practice for Medicinal Products **Annexes**
1. Pharmaceutical Quality System
2. Personnel
3. Premises and Equipment
4. Documentation
5. Production
6. Quality Control
7. Outsourced Activities
8. Complaints and Product Recall
9. Self Inspection
PIC/S PE 009-13 Part II

1. Introduction
2. Quality Management
3. Personnel
4. Buildings and Facilities
5. Process Equipment
6. Documentation and Records
7. Materials Management
8. Production and In-Process Controls
9. Packaging and ID Labelling of APIs and Intermediates
10. Storage and Distribution
11. Laboratory Controls
12. Validation
13. Change Control
14. Rejection and re-use of Materials
15. Complaints and Recalls
16. Contract Manufacturers (including laboratories)
17. Agents, brokers, traders, distributors, repackers and relabellers
18. Specific guidance for APIs manufactured by cell culture/fermentation
19. APIs for use in clinical trials
20. Glossary
Application of this guide to API Manufacturing

<table>
<thead>
<tr>
<th>Type of Manufacturing</th>
<th>Application of this Guide to steps (shown in grey) used in this type of manufacturing</th>
</tr>
</thead>
</table>
| Chemical Manufacturing | Production of the API Starting Material  
Introduction of the API Starting Material into process  
Production of Intermediate(s)  
Isolation and purification  
Physical processing, and packaging |
| API derived from animal sources | Collection of organ, fluid, or tissue  
Cutting, mixing, and/or initial processing  
Introduction of the API Starting Material into process  
Isolation and purification  
Physical processing, and packaging |
| API extracted from plant sources | Collection of plant  
Cutting and initial extraction(s)  
Introduction of the API Starting Material into process  
Isolation and purification  
Physical processing, and packaging |
| Herbal extracts used as API | Collection of plants  
Cutting and initial extraction  
Further extraction  
Physical processing, and packaging |
| API consisting of comminuted or powdered herbs | Collection of plants and/or cultivation and harvesting  
Cutting/comminuting  
Physical processing, and packaging |
| Biotechnology, fermentation / cell culture | Establishment of master cell bank and working cell bank  
Maintenance of working cell bank  
Cell culture and/or fermentation  
Isolation and purification  
Physical processing, and packaging |
| "Classical" Fermentation to produce an API | Establishment of cell bank  
Maintenance of the cell bank  
Introduction of the cells into fermentation  
Isolation and purification  
Physical processing, and packaging |

Increasing GMP requirements
Annexes

- Annex 11 – Computer System Validation
- Annex 15 – Qualification and Validation
- Annex 20 – Quality Risk Management
- Annex 7 – Herbal medicinal products
Regulators have the power to:

- Impose Fines
- Send to Jail
- Close down facilities
- Suspend licence
Regulators, regulations, standards & guidance's

- ISPE
- GAMP
- ICH
- US FDA
- Part 11
- CFRs
- 600
- 211
- 606
- PDA
- 820
- Annex 11

- ISO
- Q9
- Q10
- 13485
- WHO
- 14971
- EMA
- GACP
- Part 1
- TGA
GACP & GMP Overview
Where does GACP and GMP fit into the process?
Pharmaceutical Quality System (PQS) aka QMS

The holder of a Manufacturing Authorisation must manufacture medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the Marketing Authorisation or Clinical Trial Authorisation, as appropriate, and satisfy, quality or efficacy. The attainment of safety, quality, efficacy requires the participation and commitment by staff in many different departments and at all levels within the company, by the company’s suppliers and by its distributors. To achieve this quality objective reliably there must be a comprehensive designed and effectively implemented Pharmaceutical Quality System that requires the participation and commitment by staff in many different departments, at all levels of the company.
GMP requires that any changes that can affect product quality must be controlled.

- Planned
- Approved
- Controlled & coordinated
- Communicated & trained
- Documented
- Checked for effectiveness
What is a deviation, non-conformance? (Incident, Issue, Defect)

1. Non-conforming materials, product, test result that deviates from approved specifications
2. Deviating from a QMS procedure, test method, specification, or using an unauthorised document
3. Deviating from mandatory regulations or standards
4. Any other deviation within the facility or associated with services, utilities, or computer systems
5. When an adverse trend has occurred
6. Planned deviations from a QMS procedure, test method, specification or manufacturing instruction
Deviations – typical process

1. Identify deviation
2. Stop operation
3. Report to assigned personnel/person
4. Assess the immediate risk.
   - Take immediate CA and PA
   - Fill out Form & submit
5. Correction
6. Register
What is CAPA?

A Continuous Improvement (CI) tool used within Quality Management system

Aims to prevent a recurrence (corrective action) or to prevent issue occurrence (preventive action)

CAPA is the core of continuous improvement systems and better quality of product or service

“... CAPA is a quality assurance system, which addresses quality events, which have occurred or could be anticipated to occur during healthcare products manufacturing.”
Key CAPA Definitions

**Correction**

Corrections typically are one-time fixes. A correction is an immediate solution such as segregate, quarantine, repair or rework.
- Also known as remedial or containment action.

**CAPA - Corrective and Preventive Action**

A systematic approach that includes actions needed to correct (correction), avoid recurrence (corrective action), and eliminate the cause of potential non-conforming product and other quality problems (preventive action).
The value of CAPA

- Helps determine the actions needed to correct or fix the causes of identified problems
- A structured approach to eliminate the causes of problems that affect systems, processes and products
- Mechanism to recognise existing or potential quality issues, take steps to investigate them, resolve the issues, and stop the issues from occurring again.
- CAPA systems can help to identify gaps in the QMS and assist in recognising and resolving important quality issues
PIC/S 1.12 & 1.13 Quality Risk Management

- Systematic process for the assessment, control communication and review of risks.

- Risk must be assessed based on scientific knowledge and patient safety.

- Level of effort of risk management needs to be commensurate with the level of risk.
Quality Risk Management overview

1. Initiate Quality Risk Management Process
   - Risk Assessment
     - Risk Identification
     - Risk Analysis
     - Risk Evaluation
   - Risk Control
     - Risk Reduction
     - Risk Acceptance
   - Output / Result of the Quality Risk Management Process
2. Risk Review
   - Review Events
3. Risk Communication
4. Risk Management tools
Benefits of QRM

- Better understanding of processes and controls.
- Increased awareness by staff of risk concepts, leading to better compliance with GACP, GMP and product safety, quality and efficacy.
- Cost savings from reduction in defects and poor quality.
- Greater likelihood of passing regulatory inspections.
Quality Metrics
Demonstrating the Health of your QMS/PQS

Management Reviews and Product Quality Reviews
• Assessment of performance indicators that can be used to monitor the effectiveness of processes within the pharmaceutical quality system, and the product such as:
  • Complaints and recalls
  • Deviations, CAPA, Changes
  • Suppliers & Technical agreements
  • Audits
  • Starting and packaging materials
  • Stability monitoring programme
  • Equipment and Utilities qualification status
Personnel

• General Requirements
  • Organisation charts
  • Job Descriptions

• Training
  • Initial and ongoing training
  • Demonstrated competence
  • Extra training where specific hazards exist

• Personal Hygiene
• Consultants
Premises and Equipment

- Control of materials
- Facility – Design and segregation of starting materials, quarantined/rejected/returned products, final products
- Control of environment
  - Lighting, temperature, humidity
- Pest Control
- Protection against unauthorised personnel entry to authorised areas
- Prevention of cross-contamination
What are some potential sources of contamination?

- Air quality
- Irrigation water
- Fertiliser
- Growth media & substrate
- Drying methods
Sources of contamination

**Facility**
- Flow of Personnel
- Material/Waste
- HVAC

**Equipment**
- Assembly
- Cleaning
- Validation

**Materials**
- Raw materials
- Filters
- Chemicals
Sources of contamination

**Processes:**
- Open vs Closed

**Personnel:**
- Clothing
- Personal hygiene

**Utilities:**
- Water
- Gas
The main source of contamination is?
Equipment documentation requirements

- Calibration and maintenance requirements documented in the SOP for the equipment
- Records of usage, repairs and routine maintenance should be retained
- Cleaning, calibration and maintenance activities must be documented in a logbook
- Logbooks must be controlled
Calibration

Appropriate calibration frequency

Calibration frequency and procedure dependant on the criticality of the data generated

Also ask the supplier what they recommend
Calibration

Impact of a calibration failure

Risk Assessment
Scheduled Maintenance

- Regular maintenance reduces the risk of breakdown
- If requires routine maintenance, should have maintenance frequencies documented and therefore scheduled
- Maintenance contracts with vendors should be considered
- Proposed maintenance activities should be reviewed and approved before entering into a service agreement
Unscheduled Maintenance

Nature or details of breakdown are required to be recorded in the instrument logbook.

External service providers should provide a service report – their activities should also be recorded in the log book.

On completion of the repair, the performance of the instrument requires verification.

This can be done by calibration or performance verification procedures.
Equipment

- Validated (Fit for purpose)
- Periodically inspected
- Cleaned
- Maintained
- Calibrated
Documentation and Records

External standards:
- EU
- PIC/S
- Order No. 916
- cGMP
- US FDA
- ISO
- GxP

Training modules and records
Good Documentation Practice

Always use indelible blue/black ink pens

Never use pencil or pen that can be erased

Never use white-out

Never use post-it notes or similar products to record GMP information

Electronic Signatures should be authenticated and secure. They hold the same weight as a written signature.
Computerised Systems

GMP related computerised systems should be validated.

The depth and scope of validation depends on the diversity, complexity and criticality of the computerised application.

Computerised systems should have sufficient controls to prevent unauthorized access or changes to data.

There should be controls to prevent omissions in data (e.g. system turned off and data not captured).

There should be a record of any data change made, the previous entry, who made the change, and when the change was made.
Computerised Systems

Where critical data are being entered manually, there should be an additional check on the accuracy of the entry.

This can be done by a second operator or by the system itself.

If system breakdowns or failures would result in the permanent loss of records, a back-up system should be provided.

A means of ensuring data protection should be established for all computerised systems.
Data Integrity (ALCOA)

Good Documentation Practices
Clauses 4.7-4.9

A – Attributable
L – Legible/Permanent
C – Contemporaneous
O – Original
A - Accurate
Production

- Production is controlled at all stages by procedures
- Processes are validated
- Consistently produce products of the designated (required) quality
Quality Control

- Independent group responsible for product testing
- All products and materials are tested as necessary
- No product is released to customers until its quality is judged as satisfactory
Conforming with TGO 93 (Standard for Medicinal Cannabis)

• Unapproved medicinal cannabis products imported into and supplied/manufactured in Australia must conform with TGO 93.

• TGO 93 is a standard that specifies minimum quality requirements for medicinal cannabis products.

• Sponsors (importers) are expected to demonstrate compliance with a number of conditions in obtaining an import licence under the SAS or AP. The sponsor is responsible for products conforming with TGO 93.

• It is an offence under the Therapeutic Goods Act 1989, to import, export, or supply therapeutic goods that do not conform to an applicable standard.
## TGO 93 Standard for Medicinal Cannabis

- Requirements for testing

### Schedule 1 Specified tests

(subsection 12(1))

1. **Interpretation**
   1. For each item specified in column 1 of this table, the parameter specified in column 2 must comply with the limits specified in column 4 under the test method from the European Pharmacopoeia specified in column 3.
   2. With the exception of item 2 of this table, each limit specified in column 4 applies on a dried basis.

2. **Table of specified tests**

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Parameter</td>
<td>Test method</td>
<td>Limits</td>
</tr>
<tr>
<td>1</td>
<td>Alkaloids</td>
<td>Ph Eur 2.8.18</td>
<td>Not more than 2 (\mu)g kg(^{-1}) and not more than 2 (\mu)g kg(^{-1}) for the sum of alkaloids B1, B2, G1, G2</td>
</tr>
<tr>
<td>2</td>
<td>Foreign matter</td>
<td>Ph Eur 2.8.2</td>
<td>Not more than 2.0%</td>
</tr>
<tr>
<td>3</td>
<td>Heavy metals</td>
<td>Ph Eur 2.4.27</td>
<td>Not more than 30 ppm of arsenic Not more than 0.5 ppm of cadmium Not more than 5 ppm of lead Not more than 0.1 ppm of mercury</td>
</tr>
<tr>
<td>4</td>
<td>Ochretones A</td>
<td>Ph Eur 2.8.22</td>
<td>Not more than 20 (\mu)g kg(^{-1})</td>
</tr>
<tr>
<td>5</td>
<td>Pesticides</td>
<td>Ph Eur 2.8.15</td>
<td>Not more than the limits specified in Ph Eur 2.8.12</td>
</tr>
<tr>
<td>6</td>
<td>Total ash</td>
<td>Ph Eur 2.4.16</td>
<td>Not more than 20.0%</td>
</tr>
</tbody>
</table>

Out Of Specification (OOS)

- Generation of a result that is **outside the specification limit**
- The investigation should be **thorough, timely, unbiased, well-documented, and scientifically sound**
- **Cannot average** an in spec result and an OOS result to get an in spec overall result

**Useful references:**
- **MHRA:** Out Of Specification Investigations

The laboratory should convey its data, findings, and supporting documentation to the manufacturing firm’s Quality Control Unit (QA), who should then initiate the full-scale OOS investigation.
Out of specification process

A typical OOS process:

1. Initiation
2. Initial investigation
3. Plan / test hypothesis: retesting / resampling
4. Detailed investigation
5. Root cause
6. Conclusion(s) / hypothesis confirmed?
7. Corrective actions / Preventive actions
Testing

- Testing materials should be prepared in accordance with written procedures
- Calculations should be critically examined
- Records of testing should be retained
- Analytical methods should be validated and performed as described in Marketing Authorisations
Outsourced Activities

Principle

• “Any activity covered by the GMP Guide that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality.”

• The scope of this chapter includes oversight of all outsourced activities that may have an impact on quality operations and ultimately the quality of the medicinal product.

• It is expected that manufacturers manage and control those relationships in accordance with existing principles in order to manage risks, ensure compliance and ultimately ensure product quality.
Warning!

As a Contract Giver, you do not delegate your regulatory responsibilities!
The Contract Giver is responsible for:

- Assessing competence of the contract accepctor
- Ensuring the principles of GMP are followed
- Providing information
- Awareness of potential hazards
- Ensuring product meets specifications
How do you effectively assess competence?

- Auditing the Contract Acceptor
  - Review their QMS/PQS
  - Review their performance with medicinal products or GMP Services
  - Review their industry history/experience
- Verify relevant certifications/registrations i.e. ISO, GMP, Industry certifications, etc.

As the Contract Giver, it is your responsibility to ensure they are suitable to provide the GMP function to meet your standards and industry regulations.
The **Contract Acceptor** is responsible for:

- Adequate premises and equipment
- Knowledge and experience
- Competent personnel
- Ensuring products or materials are suitable for their intended purpose
- Not passing work to a third party without approval
The Contract should specify:

- Responsibilities for:
  - manufacture and control of product
  - Purchasing materials
  - Testing and releasing materials
  - Production and quality control
  - In-process controls
  - Sampling and analysis

- Record management and availability
- Permission for the contract giver to visit the facility
Complaints and Product Recall

PRINCIPLE
• All complaints and other information concerning potentially defective products must be carefully reviewed according to written procedures. In order to provide for all contingencies, a system should be designed to recall, if necessary, promptly and effectively products known or suspected to be defective from the market.
Self-inspections must be conducted by an independent person from the company or external experts.

Self-inspections must be recorded with observations and proposals for corrective actions. Subsequent actions must also be recorded.

Scope
- Personnel matters
- Premises
- Equipment
- Documentation
- Production
- Quality control
- Distribution of product
- Complaints and recall process
- Self-inspection process
Inspection “hot spots”

Corrective and Preventive Actions (CAPA)

- Data Integrity – ALCOA
- Cross-Contamination Prevention
- Supplier Management
- Quality Risk Management
Ten Golden Rules

Rule 1 • Build Quality In

Rule 2 • Validation (equipment, methods, process, cleaning, facility etc.)

Rule 3 • Develop procedures
Ten Golden Rules

Rule 4
- Follow procedures

Rule 5
- Record in real time

Rule 6
- Clear responsibilities and train staff

Rule 7
- Personal hygiene/contamination control
Ten Golden Rules

Rule 8 • Calibration and Maintenance

Rule 9 • Control starting materials and process

Rule 10 • Self-Inspections
How to Maintain your “Quality” Mindset
How to Maintain your “Quality” Mindset

Open your eyes and read available resources

Don’t keep your blinkers on, know what is happening in other industries and around the world

Listen to the experts sharing their knowledge. Attend forums, dinner updates, webinars etc.
Medicinal Cannabis Conferences and Events in 2020 | International Cannabis Conferences

Register for the 2020 Medicinal Cannabis Conference

Conference dates: 23rd & 24th March, 2020 (Australia)

Featuring international experts in regulated manufacturing and production sectors including cannabis cultivation standards of operation for GMP compliant production, architecture/facility design for cleanrooms and processing plants, GMP engineering, greenhouse climate controls to reduce crop issues (yeast, mould, wastage), economical growing systems, validation, security, waste management/resource management and other GMP (EU GMP) and PIC/S requirements for medicinal cannabis cultivation and export businesses in the newly growing sector of Australian Medicinal Cannabis production for domestic supply and exportation.

2020 Medicinal Cannabis Conferences | International Conferences and Australia/New Zealand

The 2020 Australian Cannabis Conference is scheduled for March 2020 in Melbourne, and we're expecting another record turnout. The annual Medicinal Cannabis Forum is suitable for pharmaceutical businesses, engineers, validation professionals, engineering students, bio-medicine researchers/new generation medicines, cultivation employees, licence holders, regulatory experts and policy makers and others with an interest in the
Thank you for your time. Questions?

Maria Mylonas
Learning & Development Director
maria.mylonas@pharmout.net
www.pharmout.net