MUTUAL RECOGNITION AGREEMENT

ON CONFORMITY ASSESSMENT IN RELATION TO MEDICINES

GOOD MANUFACTURING PRACTICE INSPECTION AND CERTIFICATION

BETWEEN

THE GOVERNMENT OF CANADA

AND

THE GOVERNMENT OF AUSTRALIA

THE GOVERNMENT OF CANADA AND THE GOVERNMENT OF AUSTRALIA (hereinafter referred to as "the Parties")

CONSIDERING the traditional links of friendship that exist between them,

CONSIDERING their shared commitments to protect, *inter alia*, human health and safety,

CONSIDERING that on the basis of the Trade and Economic Cooperation Arrangement between the Government of Australia and the Government of Canada, both Parties have expressed a desire to establish a more formal framework for collaboration in the field of mutual recognition in relation to Good Manufacturing Practice inspection and certification,

RECOGNISING the importance of maintaining their respective high standards of health and safety,

RECOGNISING their shared commitment to trade facilitation,

DESIRING to conclude an agreement providing for the mutual recognition of inspection and certification activities in relation to Medicines Good Manufacturing Practice required for access into their respective markets,

BEARING IN MIND their status as Contracting Parties to the Marrakesh Agreement Establishing the World Trade Organization, and conscious of their rights and obligations under the Agreement on Technical Barriers to Trade annexed thereto.

HAVE AGREED as follows:

ARTICLE I

Definitions

1. All general terms concerning standards and Conformity Assessment used in this Agreement shall have the meaning given in the definitions contained in ISO/IEC Guide 2:1996 "Standardization and related activities-General vocabulary" of the International Organization for Standardization and International Electrotechnical Commission unless the context requires otherwise. In addition, the following terms and definitions shall apply for the purpose of this Agreement:

(a) *Confidence Building Exercise* means the exercise described in Article 14.

(b) *Conformity Assessment* means any activity concerned with determining directly or indirectly that relevant Mandatory GMP Requirements are fulfilled.

(c) *Good Manufacturing Practice* or *GMP* means that part of quality assurance which ensures that products are consistently produced and controlled during Manufacture to the quality standards appropriate to their intended use and as required by the Marketing Authorisation granted by the importing Party.

(d) *GMP Compliance Certificate* means a certificate issued in accordance with Article 5.

(e) *GMP Compliance Certification* means the issue of a GMP Compliance Certificate following confirmation by on site inspection that a manufacturer of Medicines is in compliance with Mandatory GMP Requirements.

(f) *GMP Compliance Program* means the infrastructure and activities that support the issuance of a GMP Compliance Certificate as detailed in Appendix 4.

(g) *GMP Inspection* means on site inspection or audit of a manufacturer of Medicines to confirm compliance with Mandatory GMP Requirements.

(h) *Inspection Service* means a Regulatory Authority responsible for the inspection of manufacturers of Medicines and the granting of manufacturing licences and/or certificates for Medicines. The Inspection Service for a Party shall be as nominated by that Party in Appendix 2.

(i) *Joint Sectoral Group* means the group of Party representatives established under, and for the purposes specified in, Article 7.

(j) *Joint Sectoral Group's Maintenance Program* means a program developed and managed by the Joint Sectoral Group to provide continuous monitoring of the GMP Inspection procedures and GMP Compliance Programs of the Parties determined by the Joint Sectoral Group to be equivalent at the conclusion of the Confidence Building Exercise.

(k) *Mandatory GMP Requirements* means in relation to a Party, the legislative, regulatory and administrative requirements that apply in relation to the Manufacture of Medicines covered by this Agreement in that Party's territory. The head legislative requirements are detailed in Appendix 3 and all other applicable requirements are specified in the Joint Sectoral Group's Maintenance Program.

(l) *Manufacture* means to produce or engage in any part of the process of producing Medicines or of bringing Medicines to their final state, including engaging in the processing, packaging, labelling, sterilising, testing or releasing for supply of Medicines.

(m) *Manufacturing Authorisation* means the authorisation or approval of a manufacturer to Manufacture Medicines.

(n) *Marketing Authorisation* means the authorisation or approval of Medicines before they are available on the market.

(o) *Medicines* means those products which are defined as drugs under Section 2 of the *Food and Drugs Act* in Canada and those defined as medicines under the *Therapeutic Goods Act 1989* in Australia as those Acts are amended from time to time, excluding vitamins, minerals, herbal remedies and homeopathic medicines.

(p) *Pre-Approval Inspection* means a product or process orientated inspection conducted prior to the issue of a Marketing Authorisation.

(q) *Regulatory Authority* means an entity that has a legal right to control the import, export, re-analysis or supply of products within a Party's jurisdiction and that may take enforcement action to ensure that products marketed within its jurisdiction comply with that Party's Mandatory GMP Requirements.

(r) *Site Master File* means all documents compiled by a manufacturer of Medicines which verify to the Inspection Service that the factory, equipment, processes, products and personnel at the site of Manufacture are as documented by the manufacturer.

2. For the purposes of this Agreement the singular should be read to include the plural and vice-versa when appropriate.

ARTICLE II

Scope of this Agreement

1. This Agreement shall apply, on the one hand, to the territory of Australia and, on the other hand, to the territory of Canada.

2. This Agreement shall apply to GMP Inspections carried out in the territories of the Parties.

3. This Agreement shall apply to all Medicines which in Australia and/or Canada are subject to a GMP Compliance Program. These include:

(a) human pharmaceuticals such as prescription and non-prescription Medicines and medical gases;

(b) human biologicals including vaccines, immunologicals and biotherapeutics; and

(c) human radiopharmaceuticals.

4. This Agreement does not apply to the following products/processes:

(a) blood and blood components;

(b) tissues and organs of animal and human origin;

(c) official batch release of biologicals;

(d) stable Medicines derived from human blood or plasma; or

(e) veterinary pharmaceuticals, including sterile and non-sterile veterinary pharmaceuticals.

5. This Agreement shall not apply to Pre-Approval Inspections.

6. The Mandatory GMP Requirements covered by this Agreement are the Mandatory GMP Requirements of the Parties.

7. Agreements concluded by either Party with a third party shall not impose any obligation on the other Party to accept the results of a GMP Inspection undertaken by the third party, save where there is an express agreement between the Parties to do so.

ARTICLE III

Exchange of information

1. The Parties shall exchange information concerning their Mandatory GMP Requirements and GMP Compliance Programs, including any new technical guidance or inspection procedure.

2. Each Party shall inform the other Party of any significant changes to its Mandatory GMP Requirements and GMP Compliance Program including any new technical guidance or inspection procedure. Except where considerations of health, safety and environmental protection warrant more urgent action, each Party shall notify the other Party of the changes within at least 60 calendar days before the changes enter into force. Concerns about non-equivalency shall be addressed to the Joint Sectoral Group.

3. The Parties shall exchange any information necessary for the mutual recognition of GMP Inspections.

ARTICLE IV

Obligations

1. Australia shall accept GMP Compliance Certification by Canada's Inspection Service in accordance with Article 5, without re-control at import.

2. Canada shall accept GMP Compliance Certification by Australia's Inspection Service in accordance with Article 5, without re-control at import.

3. Where:

(a) Medicines are covered by the Mandatory GMP Requirements of the importing Party but not the exporting Party; or

(b) the Mandatory GMP Requirements of both Parties have not been determined to be equivalent in accordance with Article 14 of this Agreement,

then GMP Compliance Certification by the Inspection Service of the exporting Party, if that Inspection Service is willing, shall be in relation to the Mandatory GMP Requirements of the importing Party.

4. Where the Mandatory GMP Requirements of both Parties have been determined to be equivalent in accordance with Article 14 of this Agreement, GMP Compliance Certification by the Inspection Service of the exporting Party shall be in relation to the Mandatory GMP Requirements of the exporting Party.

ARTICLE V

GMP Compliance Certification

1. The Inspection Service of the exporting Party shall at the request of an exporter or importer of Medicines, or the Regulatory Authority of the importing Party, where appropriate, issue a GMP Compliance Certificate that certifies that a manufacturer of a Medicine located in the territory of the exporting Party:

(a) is appropriately authorised to Manufacture the relevant Medicines or to carry out the relevant specified manufacturing operation;

(b) is regularly inspected by the Regulatory Authority of the exporting Party; and

(c) (i) in cases to which Article 4, paragraph 3 applies, complies with the Mandatory GMP Requirements of the importing Party; or

(ii) in cases to which Article 4, paragraph 4 applies, complies with the Mandatory GMP Requirements of the exporting Party.

2. A GMP Compliance Certificate shall also include the following information:

(a) Name and address of the establishment to whom the certificate is issued;

(b) Site(s) of Manufacture;

(c) Certificate number;

(d) Category of Medicine (refer to Article 2, paragraph 3 for examples) and dosage form (eg tablets, small volume parenterals);

(e) Steps of Manufacture;

(f) Standards used to certify compliance with requirements;

(g) Date of last inspection;

(h) Period of validity of the certificate;

(i) Date of issuance of the certificate;

(j) Name of the representing Regulatory Authority; and

(k) Signature of the representing Regulatory Authority.

3. A GMP Compliance Certificate shall be issued expeditiously and the time taken shall not exceed 30 calendar days. In exceptional cases, such as when a new GMP Inspection has to be carried out, this period may be extended to 60 calendar days.

4. The decision to suspend or revoke a GMP Compliance Certificate shall rest with the issuing Inspection Service.

ARTICLE VI

Batch Certification of Medicine

1. Each batch of Medicines covered by a GMP Compliance Certificate issued in accordance with Article 5 that is exported shall be accompanied by a batch certificate issued by the manufacturer ("self certification") after a full qualitative and quantitative analysis of all active constituents to ensure that the quality of the Medicines complies with the requirements of the Marketing Authorisation.

2. The batch certificate shall be signed by the person responsible for releasing the batch for sale or supply. The format of the batch certificate is attached at Appendix 1 and may be modified by decision of the Joint Sectoral Group.

ARTICLE VII

Joint Sectoral Group

1. A Joint Sectoral Group shall be established.

2. The Joint Sectoral Group shall be led by co-chairs representing the Parties and shall comprise an equal number of senior representatives from both Parties with an understanding of this Agreement, its objectives and application and with the relevant expertise. A representative:

(a) may be accompanied by advisers at meetings of the Joint Sectoral Group; and

(b) shall not hold a position which may give rise to a conflict of interest.

3. The Joint Sectoral Group shall:

(a) be responsible for administering and facilitating the effective functioning of this Agreement including:

(i) developing, managing and assessing the Confidence Building Exercise;

(ii) resolving any questions or differences relating to the interpretation, operation or application of this Agreement;

(iii) developing and managing the Joint Sectoral Group's Maintenance Program;

(iv) specifying all applicable Mandatory GMP Requirements in the Joint Sectoral Group's Maintenance Program;

(v) consideration of proposed amendments to this Agreement; and

(vi) the discharging of such other functions as provided for in this Agreement.

(b) be the primary contact point for the Parties;

(c) determine its own rules of procedure;

(d) make its decisions and adopt its recommendations by consensus; and

(e) meet as and when required for the discharge of its functions, including upon the request of either Party.

4. The Joint Sectoral Group may establish ad hoc groups to undertake specific tasks, where necessary.

5. The Parties shall bring into effect the relevant decisions of the Joint Sectoral Group.

ARTICLE VIII

Confidentiality

1. A Party shall not be required to disclose confidential proprietary information to the other Party except where such disclosure would be necessary for the Party to demonstrate the competence of its Regulatory Authority to conduct GMP Inspection and GMP Compliance Program activities.

2. A Party shall, in accordance with its applicable laws, protect the confidentiality of any proprietary information disclosed to it in connection with GMP Inspection and GMP Compliance Program activities.

3. Subject to paragraphs 1 and 2 of this Article, each Party reserves the right to make public the results of any GMP Inspection, including the conclusions of GMP Inspection reports provided by the other Party, in situations in which public health and safety may be affected.

ARTICLE IX

Safeguards

1. Each Party retains all authority under its laws to interpret and implement its Mandatory GMP Requirements.

2. This Agreement does not limit the authority of a Party to determine the level of protection it considers necessary with regard to health, safety and the environment.

3. This Agreement does not limit the authority of a Party to take all appropriate measures whenever it ascertains that Medicines may not conform with its Mandatory GMP Requirements. Such measures may include withdrawing Medicines from the market, prohibiting their placement on the market, restricting their free movement, initiating a Medicine recall, and initiating legal proceedings or otherwise preventing the recurrence of such problems, including through a prohibition on imports. If a Party takes such measures, it shall notify the other Party within 15 calendar days of taking the measures, providing its reasons.

ARTICLE X

Civil Liability

1. Nothing in this Agreement is intended to change or modify the law in the territory of either Party applicable to civil liability of manufacturers, distributors, suppliers, Regulatory Authorities or governments, to consumers or among each other, in respect of the design, Manufacture, testing, inspection, distribution or sale of Medicines that have undergone Conformity Assessment pursuant to this Agreement.

2. Each Party shall promptly notify the other Party of any proceedings in the territory of such Party arising from or in connection with Conformity Assessment performed by the other Party pursuant to this Agreement.

3. Each Party shall, at the other Party's request, take reasonable steps to cooperate with the other Party in any proceedings which arise from or relate to a Conformity Assessment undertaken pursuant to this Agreement. Such cooperation shall include, subject to limits imposed by their respective laws, rendering reasonable assistance in obtaining relevant documents and in gaining access to material witnesses.

ARTICLE XI

Requests for and Transmission of GMP Inspection Reports

1. Upon written request by the Regulatory Authority of one Party, the Inspection Service of the other Party shall forward a copy of the last GMP Inspection report of a manufacturing site or contract testing laboratory in the case where analytical operations are contracted out. Such a request may be for:

   (a) a "full inspection report" comprising a Site Master File (compiled by the manufacturer and verified by the Inspection Service) and a narrative report by the Inspection Service; or

   (b) a "detailed report" responding to specific queries about a manufacturer by the other Party.

2. If the manufacturing operations of the Medicines in question have not been inspected within two years, or a particular need to inspect has been identified, a specific and detailed inspection may be requested.

3. Parties shall ensure that GMP Inspection reports are forwarded within 30 calendar days. Should a new inspection be carried out, this period may be extended to 60 calendar days.

ARTICLE XII

GMP Inspections

1. In accordance with this Agreement, and by mutual agreement between the Inspection Services, joint GMP Inspections may be conducted. These inspections are intended to develop common understandings and interpretations of practice and requirements.

2. The fee for a joint GMP Inspection shall be charged only by the Regulatory Authority of the Party in whose territory the inspection is carried out if the Inspection Service of the other Party participates in the joint GMP Inspection.

3. The Regulatory Authority of a Party may, subject to the laws and regulations of the other Party, conduct its own GMP Inspection of manufacturers in the other Party's territory for reasons identified to the other Party. Such GMP Inspections shall be notified in advance to the other Party, which has the option of joining the GMP Inspection. Recourse to this safeguard clause shall only be exercised in exceptional circumstances for the purpose of health and safety and shall only occur with the consent of the manufacturer.

ARTICLE XIII

Inspection Services and Contact Points

1. For the purposes of this Agreement, the Inspection Service of each Party is identified in Appendix 2 – Inspection Services. The contact points for each Party's Inspection Service shall be specified in the Joint Sectoral Group's Maintenance Program.

ARTICLE XIV

Confidence Building Exercise

1. The Parties shall conduct a Confidence Building Exercise in accordance with a confidence building program developed by the Joint Sectoral Group to determine:

   (a) the equivalency or otherwise of their respective Mandatory GMP Requirements in relation to particular Medicines; and

   (b) the equivalency and capabilities of the GMP Inspection procedures and the GMP Compliance Programs of the Regulatory Authorities.

2. The Confidence Building Exercise shall commence upon the entry into force of this Agreement and should be completed within 12 months.

3. Each of the Parties to the Agreement shall be responsible for the costs of its participation in the Confidence Building Exercise.

4. Before the end of the Confidence Building Exercise, the Joint Sectoral Group shall undertake a joint assessment of the equivalency and capabilities of the GMP Inspection procedures and the GMP Compliance Programs of the Regulatory Authorities.

5. If following the joint assessment referred to in paragraph 4 of this Article the Parties' GMP Inspection procedures and GMP Compliance Programs are determined to be equivalent by the Joint Sectoral Group, the Confidence Building Exercise is completed.

6. If following the joint assessment referred to in paragraph 4 of this Article the Parties' GMP Inspection procedures and GMP Compliance Programs are determined not to be equivalent by the Joint Sectoral Group, the Confidence Building Exercise shall continue until the GMP Inspection procedures and GMP Compliance Programs are determined to be equivalent by the Joint Sectoral Group.

7. At the end of the Confidence Building Exercise, the Joint Sectoral Group shall issue its findings with respect to the equivalency of the Mandatory GMP Requirements in relation to Medicines.

ARTICLE XV

Alert System

1. The Joint Sectoral Group shall ensure that an efficient and effective "two-way" alert system is in place at all times. The contact points for each Party's alert system will be specified in the Joint Sectoral Group's Maintenance Program.

2. The Regulatory Authority of one Party shall inform the Regulatory Authority of the other Party with appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch.

3. The Parties shall ensure that any suspension or withdrawal (total or partial) of a Manufacturing Authorisation, based on non-compliance with Mandatory GMP Requirements and which could affect the protection of public health, is communicated to each other with the appropriate degree of urgency.

ARTICLE XVI

Settlement of Differences between the Parties

1. Any differences between the Parties concerning the interpretation, operation or application of this Agreement shall in the first instance be discussed in the Joint Sectoral Group. Should the Joint Sectoral Group be unable to resolve such differences, then the Parties shall settle them through direct bilateral discussions.

ARTICLE XVII

Entry into Force and Termination

1. This Agreement shall enter into force on the first day of the second month following the date on which the Parties have exchanged notes confirming the completion of their respective procedures for the entry into force of this Agreement.

2. The operational phase of this Agreement shall commence on the first day of the month following the successful completion of the Confidence Building Exercise.

3. Either Party may terminate this Agreement in its entirety by giving the other Party six months advance notice in writing.

4. Following termination of this Agreement, a Party shall continue to accept the results of GMP Compliance Certification obtained prior to termination, unless that Party decides otherwise based on health, safety and environmental protection considerations.

ARTICLE XVIII

Final Provisions

1. Any amendment to this Agreement shall be by mutual agreement.

2. Such amendments shall enter into force on the date on which the Parties have exchanged notes confirming the completion of their respective procedures for the entry into force of the amendments.

3. The Appendices shall form an integral part of this Agreement.

4. This Agreement is drawn up in two originals in the English and French languages, each text being equally authentic.

IN WITNESS WHEREOF the undersigned, being duly authorised by their respective Governments, have signed this Agreement.

DONE at on 2005.

FOR THE GOVERNMENT OF CANADA	**FOR THE GOVERNMENT OF AUSTRALIA**
_____	_____

Appendix 1

Content of the Manufacturer's Batch Certificate for Medicines Exported to Countries under the Scope of a Mutual Recognition Agreement (MRA)

[LETTER HEAD OF EXPORTING MANUFACTURER]

1. **Name of Medicine**

   Proprietary, brand or trade name in the importing country.

2. **Importing Country**

3. **Marketing Authorization Number**

   The Marketing Authorisation number of the Medicine in the importing country.

4. **Strength/Potency**
   Identity (name) and amount per unit dose required for all active ingredients/constituents.

5. **Dosage form** (pharmaceutical form)

6. **Package size** (contents of container) and **type** (e.g. vials, bottles, blisters)

7. **Lot/batch number**

   As related to the Medicine.

8. **Date of manufacture**

   In accordance with national (local) requirements.

9. **Expiry date**

10. **Name and address of Manufacturer(s) - Manufacturing site(s)**

    Name and address of all sites involved in the Manufacture including packaging and quality control of the batch. The name and address to correspond to the information provided on the Manufacturing Authorisation/Establishment Licence.

11. **Number of Manufacturing Authorisation, Licence or Certificate of GMP Compliance of a Manufacturer**

    Number for each site listed under item 10.

12. **Results of analysis**

To include the authorized specifications, all results obtained and the methods used (may refer to a separate certificate of analysis which must be dated, signed and attached).

13. Comments

Any additional information that can be of value to the importer and/or inspector verifying the compliance of the batch certificate (e.g. specific storage or transportation conditions).

14. Certification statement

Statement to cover the fabrication/manufacturing, including packaging and quality control. The following text shall be used: "I hereby certify that the above information is authentic and accurate. This batch of Medicine has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the Mandatory GMP Requirements of the Regulatory Authority in the importing/exporting* country and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with the Mandatory GMP Requirements of the importing/exporting* country".
(*strike out whichever not applicable)

15. Name and position/title of person authorizing the batch release

Including his/her company, site name and address, if more than one company is mentioned under item 10.

16. Signature of person authorizing the batch release

17. Date of signature

Appendix 2

Inspection Services

1. For the purpose of this Agreement, Australia's Inspection Service shall be:

   Therapeutic Goods Administration (TGA)
   Department of Health and Ageing
   PO Box 100
   WODEN ACT 2606
   AUSTRALIA

2. For the purpose of this Agreement, Canada's Inspection Service shall be:

   Health Products and Food Branch Inspectorate
   Health Canada
   11 Holland Avenue, Tower A, Second Floor
   Address Locator: 3002C
   OTTAWA, ONTARIO
   KIA OK9
   CANADA

Appendix 3

Mandatory GMP Requirements

LIST OF APPLICABLE LEGISLATIVE PROVISIONS.

For Australia:

- Therapeutic Goods Act 1989
- Therapeutic Goods Regulations
- Therapeutic Goods (Charges) Act 1989
- Therapeutic Goods (Charges) Regulations

For Canada:

- Food and Drugs Act (R.S. 1985, c F-27)
- Food and Drug Regulations (C.R.C., c.870)

Appendix 4

The 11 Components of a Good Manufacturing Practice (GMP) Compliance Program

1. Legislative and Regulatory Requirements and Scope

   – Empowering legislation and regulations including authority to enforce laws and regulations, powers given to inspectors to conduct inspections and authority to remove violative products from the market; and

   – Suitable controls on conflict of interest.

2. Regulatory Directives and Policies

   – Procedures for designating inspectors;

   – Enforcement policies/guidelines/procedures (inspection, re-inspection, corrective action);

   – Codes of conduct/ethics;

   – Training/certification policies/guidelines;

   – Alert/crisis management policies/procedures/guidelines; and

   – Organizational structure, including roles, responsibilities and reporting relationships.

3. Good Manufacturing Practices (GMP) Standards

   – Scope/details of GMPs necessary for the control of the manufacturing of Medicines; and

   – Process validation requirements.

4. Inspection Resources

   – Staffing – initial qualifications, certification of inspectors;

   – Number of inspectors in relation to size of industry (in-house, contract, third Party);

   – Training/certification programs/processes (e.g., frequency of training); and

   – Quality assurance mechanisms to ensure effectiveness of training programs.

5. Inspection Procedures (pre-inspection, inspection, and post-inspection activities)

   – Inspection strategy (type, scope, scheduling, focus of inspection, notification of inspections, risk-based inspections);

   – Pre-inspection preparation/requirements;

   – Format and content of inspection reports (including support tools and hardware);

- Inspection methodology (including access to and review of firm's files and databases, collection of evidence, data review, sample collection, interviews);
- Standard Operating Procedures (SOPs) for inspection;
- Post-inspection activities (including procedures for report issuance, follow-up and decision making); and
- Storage of inspection data.

6. Inspection Performance Standards

- Frequency/number of inspections, quality and timeliness of inspection reports, norms/frequency/procedures for re-inspection and corrective action.

7. Enforcement Powers and Procedures

- Provision of written notices of violation to firms;
- Noncompliance management procedures/mechanisms (including recall, suspension, quarantine of Medicines, licence revocation, seizure and prosecution);
- Appeal mechanisms; and
- Other measures to promote voluntary compliance by firm.

8. Alert and Crisis Systems

- Alert mechanisms;
- Crisis management mechanisms; and
- Alert performance standards (appropriateness and timeliness of alert).

9. Analytical Capability

- Access to laboratories with capacity to handle necessary analysis;
- Standard Operating Procedures (SOPs) for analytical support; and
- Processes for validation of analytical methods.

10. Surveillance Program/Measures (used by firm and by Regulatory Authority)

- Sampling and audit procedures;
- Recall monitoring (including effectiveness controls and verifications of procedures);
- Consumer complaint system/procedures;
- Adverse reaction reporting system/procedures; and
- Medicines defect reporting system/procedures.

11. Quality Management Systems

- Quality management/assurance system/procedures to ensure the ongoing suitability and effectiveness of policies, procedures, guidelines and systems used to achieve the objectives of the GMP Compliance Program, including the establishment of standards and annual audit and review.