New Zealand Code of
Good Manufacturing Practice
for Manufacture and Distribution
of Therapeutic Goods

Part 3:
Compounding and Dispensing
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Part 3: Compounding and Dispensing
FOREWORD

Codes of good manufacturing practice (GMP) describe proven systems and procedures for the production of quality products. They also contain documentation requirements for providing a traceable history of every end product.

This Code of Practice for Compounding and Dispensing is the third in a series of Codes of GMP produced by the Therapeutics Section of the Ministry of Health during 1993. The code has been written specifically for pharmacists engaged in retail and hospital practice in New Zealand, and for any others involved in compounding and dispensing medicines.

This is the first Code of Practice for Compounding and Dispensing produced for New Zealand use and is the result of a series of consultation meetings between the Ministry and representatives of the pharmacy profession. It reflects what is currently expected of pharmacists nationally and internationally in order to protect the quality of compounded and dispensed medicines.

A code of GMP must be regarded as no more than a minimum standard. Some pharmacists may choose to use alternative systems to those described in the Code. This is acceptable if they achieve the same objectives as the Code. Systems that go beyond the guidelines are encouraged. Every pharmacy employee should be aware of this document.

As a general rule, the relationship between pharmacists and the Department of Health has in the past been an excellent one. Let us continue this partnership between the profession and the new Ministry of Health as we adopt this particular code of GMP and set the mutual goal of excellence in the compounding and dispensing of therapeutic products in New Zealand.

Christopher Lovelace
Director-General
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INTRODUCTION

This part of the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 3, provides the basic requirements necessary to safeguard the quality of compounded and dispensed medicines. The principles in Part 3 have been based on those in Part 1 of the Code: Manufacture of Pharmaceutical Products. Compliance with these Codes will provide a high degree of assurance that the procedures used will result in products of suitable quality.

The basic requirement for good compounding and dispensing practice in pharmacies is that all procedures should be clearly defined and be capable of achieving the specified requirements. It is necessary that appropriate personnel, premises, procedures, equipment and materials are utilised according to the requirements for the individual preparation.

In real terms this means that a pharmacist should not contemplate compounding a medicine unless she/he has a clear idea of what standard the finished medicine has to meet and can ensure that the appropriate facilities are available in which to compound such a product.

Each and every aspect of compounding and dispensing should be carefully considered and developed to ensure that appropriate standards are being achieved.

Application

Part 3 of the Code applies to the preparation of a medicine for an individual person.

Part 3 also applies to the small scale batch preparation and/or repacking of a medicine by a pharmacist in a pharmacy, for retail sale or dispensing, from that pharmacy, where:

i) the size of the batch does not exceed:
   - 2.5 litres of an oral or topical liquid;
   - 2 kilograms of a cream, ointment or powder;
   - 100 capsules, suppositories or other single solid dose forms;
   - 50 repackaged units.
   and

ii) the medicine is not required to be sterile.

and

iii) a batch of medicine is prepared not more than once a week, unless the previous batch has been used in that period.

Repacking requires the same documentation as small scale compounding.

Any preparation of larger size batches than those specified above or any size batches required to be sterile, other than for an individual person, should be done in compliance with Part 1 of the New Zealand Code of Good Manufacturing Practice.

The abbreviation GMP has been left in Part 3 of the Code as it has become a term that reflects a concept rather than just an abbreviation. The concept can be applied to compounding and dispensing as well as manufacturing.

(vi)
GLOSSARY

Definitions given below apply to the words as used in this guide. They may have different meanings in other contexts.

AUTHORISED PERSON
Person recognised by the authority as having the necessary basic scientific and technical background and experience.

BATCH
A defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.

BATCH NUMBER
A distinctive combination of numbers and/or letters which specifically identifies a batch.

BULK PRODUCT
Any product which has completed all processing stages up to, but not including, final packaging.

CALIBRATION
The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.

COMPOUNDING
All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging to its completion as a finished dose form.

CROSS-CONTAMINATION
Contamination of a starting material or of a product with another material or product.

DISPENSARY
A room, rooms or area where dispensing and/or compounding is undertaken.

DISPENSING
The count and pour operation required to fulfill an order for a medicine.

FINISHED PRODUCT
A pharmaceutical product which has undergone all stages of production, including packaging in a final container.

MANUFACTURE
All operations of purchase of materials and products, production, quality control, release, storage, distribution of pharmaceutical products and the related controls.

PHARMACEUTICAL PRODUCT
Any medicine or similar product intended for human use.

PACKAGING
All operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product.

PACKAGING MATERIAL
Any material employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

PROCEDURES
Description of the operations to be carried out, the precautions to be taken and measures to be applied directly or indirectly related to the manufacture of a pharmaceutical product.

PRODUCTION
All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to its completion as a finished product.

QUALITY CONTROL
See Chapter 1.

RECORD
See Chapter 4.

REPACKING
The transfer of a medicine from one container to another as a batch operation limited to 50 containers per batch.

SPECIFICATION
See Chapter 4.

STARTING MATERIAL
Any substance used in the production of a pharmaceutical product, but excluding packaging materials.

VALIDATION
Action of proving, in accordance with the principles of Good Manufacturing Practice, that any procedure, process, equipment, material, activity or system actually leads to the expected results.
CHAPTER 1: QUALITY MANAGEMENT

Principle

The person responsible for the compounding and dispensing of pharmaceutical products must carry out these procedures so as to ensure that the products are fit for their intended use and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of management and requires the participation and commitment by all staff involved. To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of quality assurance incorporating good compounding and dispensing practice and quality control. It should be documented and its effectiveness monitored. All parts of the quality assurance systems should be adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

1.1 The basic concepts of quality assurance, good compounding and dispensing practice and quality control are interrelated. They are described here in order to emphasise their relationships and their fundamental importance to the compounding and dispensing and control of pharmaceutical products.

Quality Assurance

1.2 Quality assurance is a wide ranging concept which covers all matters which individually or collectively influence the quality of a product. It is the sum total of the organised arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates good compounding and dispensing practice plus other factors outside the scope of this Guide.

The system of quality assurance appropriate for the compounding and dispensing of pharmaceutical products should ensure that:

i compounding and dispensing, and control operations are clearly specified and good compounding and dispensing practice adopted;
ii managerial responsibilities are clearly specified;
iii arrangements are made for the supply and use of the correct starting and packaging materials;
iv all necessary validations are carried out;
v the finished product is correctly processed and checked, according to the defined procedures;
vi products are not sold or supplied before an authorised person has checked that each product has been produced and controlled in accordance with any regulations relevant to the production, control and release of pharmaceutical products;
vi the satisfactory arrangements exist to ensure, as far as possible, that the pharmaceutical products are stored and handled so that quality is maintained throughout their shelf life;

Good Compounding and Dispensing Practice for Pharmaceutical Products (GMP)

1.3 Good compounding and dispensing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use.

Good compounding and dispensing practice is concerned with both production and quality control. The basic requirements of GMP are that:

i all compounding and dispensing processes are clearly defined, reviewed in the light of experience and shown to be capable of consistently producing pharmaceutical products of the required quality and complying with their specifications;
ii critical steps of compounding and dispensing processes and significant changes to the processes are validated;
iii all necessary facilities for GMP are provided including:
   a) appropriately qualified and trained personnel;
   b) adequate premises and space;
   c) suitable equipment and services;
   d) correct materials, containers and labels;
   e) approved procedures and instructions;
   f) suitable storage and transport;
iv instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided;
v staff are trained to carry out procedures correctly;
vi records are made, which demonstrate that all the steps required were in fact taken and that the quantity and quality of the product was as expected;
vi records of compounding which enable the history of a finished product be traced, are retained in a comprehensible and accessible form;
vi a system is available to recall any product;
ix complaints about products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent re-occurrence.

Quality Control

1.4 Quality control is that part of good compounding and dispensing practice which is concerned with assessment for use of materials. These materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory.

The basic requirements of quality control are that:

i adequate facilities, trained personnel and approved procedures are available for inspecting and assessing for use starting materials, packaging materials and finished products, and where appropriate for monitoring environmental conditions for GMP purposes;
ii records are made which demonstrate that all the required inspecting and assessing procedures were actually carried out. Any deviations are fully recorded and investigated;
iii the finished products contain active ingredients of a quantity and quality required, and are enclosed within their proper container and correctly labelled;
iv no product is released for sale or supply prior to checking by an authorised person that it is in accordance with the requirements.
CHAPTER 2: PERSONNEL

Principle

Staff involved in compounding and dispensing must have theoretical pharmaceutical training, acquired practical skills and an appreciation of the importance of hygiene. The possibility of analytical control of the finished product is limited. The competence of the staff is therefore of crucial importance for the quality of the end product. Tasks and areas of responsibility should be clearly defined.

Staff

2.1 A registered pharmacist must have overall responsibility for the dispensing and compounding of medicines.

2.2 An authorised person should have overall responsibility for the quality management of the pharmacy.

2.3 An adequate number of qualified and experienced personnel is required to maintain a satisfactory compounding and dispensing service. The pharmacy manager should ensure that responsibilities placed on any staff member should not be so extensive as to compromise the quality of the pharmacy's products.

2.4 A staff handbook/manual should be available. It should be regularly reviewed and updated.

2.5 A written job description should be available for each staff member. The job description should be regularly reviewed and updated.

Training

2.6 The pharmacy manager should define the level of qualification, competence, experience, training and supervision required by a staff member to work in a particular area.

2.7 The pharmacy manager should ensure that appropriate training is provided for all staff to enable them to be competent in performing their particular jobs within the pharmacy.

2.8 An introductory staff orientation and training programme should be available for all new staff members. Continuing training should also be given and training records kept.

2.9 Participation by staff in appropriate continuing education programmes should be encouraged.

2.10 The concept of quality assurance and ways of improving its understanding and implementation should be included in staff training and review sessions.

2.11 Staff involved in aseptic/sterile work require special training.

Personal Hygiene

2.12 The pharmacy manager should ensure that procedures related to health, hygiene practices and clothing are established. These procedures should be understood and practised by each staff member. Special attention should be accorded to hand hygiene and to the wearing of appropriate clothing.

2.13 External staff who are working in the pharmacy (e.g., tradespersons, cleaners) or visitors to the pharmacy should be carefully supervised to ensure they do not compromise the hygiene procedures of the pharmacy.

2.14 In general, any unhygienic practice (including, eating, drinking, chewing and smoking or the storage of food, drink, smoking materials and personal medication) should not occur in the dispensing, compounding and pharmaceutical storage areas of the pharmacy.

2.15 Staff members with an infectious disease, open skin lesions on exposed surfaces of the body or a condition that would present abnormal microbiological hazards to products should not be involved in compounding and dispensing or have direct contact with pharmaceuticals until the condition is corrected.
CHAPTER 3: PREMISES AND EQUIPMENT

Principle

Premises and equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out. Their layout and design must aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build up of dust or dirt and, in general, any adverse effect on the quality of products.

Premises

General
3.1 Each part of the premises should be suitable for its particular function.
3.2 Each part of the premises should be maintained in a good and hygienic condition. There should be written cleaning schedules for all parts of the premises.
3.3 All parts of the premises should have appropriate and effective means of heating, lighting and ventilation.
3.4 Premises should be designed and equipped so as to afford maximum protection against the entry of insects or other animals.
3.5 The premises should provide adequate space for the orderly placement of materials and equipment.
3.6 Products and starting and packaging materials should be protected from theft, adulteration and contamination.
3.7 Suitable systems should be in place to deter and detect unauthorised access to the premises. If windows are capable of being opened they must be securely locked when the pharmacy is closed.
3.8 Other than in a supervised sales area, the public should not have access to areas where drugs, medicines and raw materials are stored. If it is necessary to allow someone through a medicine storage area, then that person should be escorted by a staff member. This restriction should be considered when designing access routes for goods delivery or public access to toilet facilities.

Dispensary

3.9 The dispensary should be a distinct identifiable area separate from any sales or customer waiting areas.
3.10 The dispensary should be designed and used only for dispensing and compounding.
3.11 Public access to the dispensary should be prohibited except for persons authorised for a specific purpose. Dispensary design should discourage uninvited access.
3.12 The dispensary should be large enough to have adequate bench space and floor space as a dedicated dispensing and compounding area. Size and layout of the dispensary should allow efficient flow of work and direct staff supervision.
3.13 The dispensary should be uncluttered and should not contain anything that is not required for dispensing.
3.14 All working surfaces, cupboards and shelves should be finished with smooth, impervious and washable materials. Floors should be finished with a material that is impervious and washable.
3.15 Dispensary stock should be stored in a logical and orderly manner. If there are windows in the dispensary, direct sunlight should not shine upon stock items.

3.16 For aseptic compounding and manipulation and preparation of products for final sterilisation see Annex 1.

Storage Areas

3.17 Storage areas should be sufficient to permit the effective separation and identification of the various stored materials and products.
3.18 Materials should be protected from the adverse effects of temperature extremes, light and dampness.
3.19 Pharmaceutical products requiring refrigerated storage should be stored in a way which prevents cross-contamination. A suitable maximum/minimum thermometer should be kept in each such refrigerator. The temperature should be monitored and recorded to ensure maintenance of correct temperature.
3.20 The medicines refrigerator should be sited in a suitable area.

Ancillary Areas

3.21 Rest and refreshment rooms should be separate from other areas.
3.22 Adequate toilet facilities should be provided.
3.23 All pharmacies should have their own handwashing facilities in addition to any shared facility. The dispensary sink should not be used for handwashing.
3.24 Toilets must not open directly into the dispensary/compounding area.
3.25 Toilet areas should not be used for storage nor as a source of water for dispensing.
3.26 There should be a notice recommending hand washing after using the toilet. Disposable towels or hot air dryers should be used for drying hands.

Equipment

3.27 Dispensary equipment should normally not be used for any other purpose than the preparation and dispensing of medicines.
3.28 Balances, measuring and other equipment and utensils should be appropriate and adequate to carry out the operations of the pharmacy.
3.29 Equipment and utensils should be thoroughly cleaned and maintained, and adequately stored.
3.30 Equipment and utensils should be designed and constructed so that they are suitable for their purpose and easy to clean, in order to prevent contamination of products.
3.31 Measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests should be maintained.
CHAPTER 4: DOCUMENTATION

Principle

Good documentation is an essential part of quality assurance. The purpose of written procedures is to prevent errors and misinterpretation, to ensure that processes are carried out in the same way each time, to ensure that facilities and equipment are maintained to appropriate standards and to record the processing of each product.

General

4.1 Documentation should be simple, unambiguous and easy to read. Each master document should:
   
   a) state the title, nature and purpose of the document and identify the pharmacy;
   b) have instructions that are clear, precise and unambiguous;
   c) be prepared by an authorised person who signs the document;
   d) be checked by a second authorised quality control person, if available;
   e) when requiring the entry of data, provide sufficient space for the data and for the signature (initials) of the person confirming the entry.

All documents should be kept up to date and be revised as necessary. Any amendments should be formally authorised and signed. Outdated or superseded documents should be removed from active use and the master retained for reference.

Documents Required

Master Formula

Where a standard formula is used frequently it is advisable to have a Master Formula. A photocopy or reprint of the Master Formula should be used to make the record for the small-scale compounded batch and repackaged batch or product.

4.2 The Master Formula should be dated and include:

   a) the name of the product;
   b) a description of the pharmaceutical form and strength of the product;
   c) a list of the ingredients together with the amount of each;
   d) a step by step description of the compounding procedure;
   e) a list of the packaging material to be used;
   f) a sample of the label and any advisory/auxiliary labels;
   g) the assigned expiry date.

Record of compounding

4.3 A copy of the Master Formula should be used to make the record. The following information should be recorded:

   a) the date of the preparation;
   b) the name of the compounding;
   c) quantities of ingredients used;
   d) total quantity prepared;
   e) batch numbers of ingredients used;
   f) a unique identifying batch number;
   g) expiry date of the finished product;
   h) label sample.

In the case of individual compounding where a copy of a Master Formula is not used as the record, a record must be kept which enables the history of the finished product to be traced and an expiry date to be recorded.

Specifications

Where appropriate there should be specifications for starting and packaging materials, and finished products.

Specifications for starting and packaging materials

4.4 Specifications for starting materials and packaging material should include:

   a) a description of the material and the name and reference, if any, to a Pharmacopoeial monograph;
   b) the approved suppliers, and if possible, the original producer of the material;
   c) a specimen of printed materials;
   d) storage conditions;
   e) the maximum period of storage before expiry or the need for reexamination.

Specifications for finished products

4.5 Specifications for finished products should include all the checks the product has to conform with before release for sale or distribution and should include:

   a) a description of the product with reference to an official compendium if appropriate;
   b) a suitable expiry date.

Standard Operating Procedures (SOPs)

4.6 Handling of pharmaceuticals should follow standard operating procedures.

Some examples of especially important activities which require standard operating procedures are:

   a) aseptic process validation;
   b) cleaning procedures for compounding and dispensing areas;
   c) cleaning and maintenance of equipment;
   d) operation of equipment.
CHAPTER 5: COMPOUNDING

Principle

Compounding should be carried out in accordance with systematic and precise routines, which support security in the operation. The aim of systematic routines is to achieve products that are safe, of an acceptable and consistent quality.

General

5.1 Frequently used methods of preparation should be written down as SOPs. Frequently prescribed formulas should be written down as master formulas.

5.2 All incoming materials should be checked to ensure that they correspond to the order. Containers should be cleaned where necessary.

5.3 Any damage or contamination must be considered by a pharmacist and appropriate action taken.

5.4 Incoming materials should only be used if they meet predetermined specifications.

5.5 Finished products should only leave the pharmacy when the products meet predetermined specifications.

5.6 All materials and products should be stored under appropriate conditions and in an orderly fashion.

5.7 In extemporaneous compounding the risk of a mix-up is of particular concern and steps should be taken to minimise this. Products should not be prepared simultaneously or consecutively in the same area unless there is no risk of mix-up or cross-contamination.

5.8 At every stage of compounding, preparation techniques should be used which protect the starting materials and finished products from microbial and other contamination. Special procedures are required for aseptic / sterile preparation. These are outlined in Annex 1.

5.9 When working with dry materials and products, precautions should be taken to prevent the generation and spreading of dust. This is particularly important when handling highly active or sensitising materials.

5.10 All products should have an expiry date assigned to them and this should be stated on the label.

5.11 Precautions must be taken to ensure that mistakes do not occur during labelling.

5.12 Access to the compounding area during compounding should be restricted, for hygienic reasons.

5.13 Normally the preparation of non-pharmaceutical products should not take place in areas intended for the preparation of pharmaceutical products.

5.14 Equipment used in the preparation of non-pharmaceutical products should normally not be used in the preparation of pharmaceutical products.

Cross-contamination

The significance of the risk of contamination varies with the type of contaminant and the product being made. Amongst the most hazardous contaminants are highly sensitising materials, biological preparations containing living organisms, certain hormones, and other highly active materials. Products in which contamination is likely to be most significant are those administered by injection, those given in large doses and/or over a long time.

5.15 Adequate precautions should be taken to prevent contamination, cross-contamination and product mix-up in all stages of preparation eg by:

   a) using segregated areas for reconstitution of antibiotics or making sure nothing else is at risk of being contaminated at the time, followed by appropriate cleaning;
   b) using effective cleaning. Ineffective cleaning of equipment is a common source of cross-contamination;
   c) keeping protective clothing inside areas where products with special risk of cross-contamination are processed.

Validation

5.16 When a new method of preparation is adopted, steps should be taken to demonstrate that it achieves the expected result.

Expiry Dates

5.17 The expiry dates for extemporaneously compounded medicines will in most cases be arbitrary as no physical and chemical stability data will be available. The responsibility lies with the pharmacist to assess the time to expiry and the storage conditions.

Starting Materials

5.18 Starting materials should be of a quality suitable for use in products intended for therapeutic use in humans.

5.19 Starting materials should be purchased from suppliers who know the origin of the material and who are recognised as reliable, based on a history of deliveries which meet specifications.

5.20 At the point of receipt, the containers should be checked for integrity of package and seal, legibility of labelling and for correlation between the delivery note and the supplier's labels.

5.21 A system should be set up to ensure that all materials meet the required specifications at the time of purchase and throughout the period of use.

5.22 There should be appropriate procedures or measures to assure the identity of the contents of each container of starting material.

5.23 The starting materials should be stored under appropriate conditions.

5.24 Only starting materials which meet required specifications, have been identified and are within their shelf-life should be used.

Water

5.25 Water to be used as a starting material should be of a quality appropriate for the finished product and be handled as other starting materials.

Packaging Materials

5.26 Packaging material should be selected with regard to its suitability for the product it will contain.

5.27 The purchase and handling of packaging material should be accorded attention similar to that given to starting materials.
Packaging Procedures

5.28 The packing area should only contain materials associated with the process being carried out.

5.29 Containers should be clean before filling. If the containers are washed on site, the washing procedure has to be validated.

5.30 Labels should be printed so that containers can be labelled as soon as filled.

Finished Product

5.31 There must be a defined step where the finished product is compared with its specifications and released or rejected.

5.32 This decision must be made by the person taking responsibility for quality and must be recorded.

Rejected and Returned Materials

5.33 Rejected materials and products should be stored separately. They should either be returned to the supplier or destroyed.

5.34 Products returned from patients/customers should be destroyed.

CHAPTER 6: QUALITY CONTROL

Principle

Quality Control (QC) involves sampling, specifications and testing and also documentation and procedures that ensure that starting materials are not used and finished products not sold or supplied unless they are safe and of an acceptable quality. Quality Control involves all decisions which relate to the quality of a product.

It is considered fundamental when manufacturing medicines that the Quality Control function is independent from production. While this is desirable also when compounding and dispensing in reality this is often not possible. The pharmacists responsible for quality control are usually also involved in compounding. In this situation if is of utmost importance that the quality aspects of compounding are not outweighed by other matters.

Functions

6.1 A Quality Control pharmacist should be involved in:
   a) approval or rejection of starting and packaging materials, and finished products;
   b) evaluation of documentation;
   c) ensuring all appropriate testing is carried out;
   d) approval of specifications, test methods and other QC procedures;
   e) ensuring that appropriate validation is carried out;
   f) calibration of instruments, scales and other equipment.

Quality Control Laboratories

6.2 Some hospital pharmacies have control laboratories. These should meet the requirements and follow the appropriate laboratory practice set down for Quality Control Laboratories in the New Zealand Code of Good Manufacturing Practice Part 1.

6.3 The use of outside laboratories should be in conformity with the principles outlined in chapter 7 on Contract Compounding and Analysis.

Documentation

6.4 The following details should be available to the QC person:
   a) specifications;
   b) testing procedures and records;
   c) certificates of analysis and other analytical reports;
   d) data from environmental monitoring;
   e) procedures for and records of the calibration of instruments and maintenance of equipment;
   f) compounding records;
   g) any documentation relating to an extemporaneously compounded product should be kept for one year after the expiry date.
CHAPTER 7: CONTRACT COMPOUNDING AND ANALYSIS

Principle

If a pharmacy decides to buy the services of an outside supplier of extemporaneously compounded medicines or of a control laboratory it is the responsibility of the pharmacy to assess the competence of that supplier or laboratory.

It is also important to clarify the division of responsibilities between the buyer of the service and the provider of it.

For further information refer to the New Zealand Code of Good Manufacturing Practice Part 1, Chapter 7.

CHAPTER 8: SELF INSPECTION

Principle

Self inspection should be conducted in order to monitor the implementation of and compliance with Good Compounding and Dispensing principles and to propose necessary corrective measures.

Self inspections should be recorded. Statements on any action taken as a result of the inspection should also be recorded.