GUIDELINES FOR SELECTION OF AUTHORIZED PERSON IN THE PHARMACEUTICAL AND CHEMICAL INDUSTRY

Preamble and Scope

In pursuance of **Section 115 subsection 1(a) of the Public Health Act 2012, Act 851** these guidelines are hereby made to provide guidance to applicants wishing to apply for approval as a qualified person to supervise the manufacture of any drug or chemical substance

1. Interpretation:

1.1 In these guidelines, unless the context otherwise states: -

a) 'Qualified person' means - a person among key personnel of a manufacturing establishment responsible for the release of batches of finished products for sale.

2. Authorized Person Status

2.1 The Authority shall confer authorized person status on an individual who has a degree or its equivalent in the following disciplines and possesses the requisite experience in the pharmaceutical, herbal medicine or chemical industry,

Name of Discipline	Experience in the pharmaceutical or chemical industry
1. Pharmacy	2 years
2. Chemistry	3 years
3. Pharmaceutical Sciences	3 years
4. Chemical Engineering	4 years
5. Biological Science	5 years
6. Biomedical Sciences	5 years

These not withstanding the following shall also apply.

2.2. Authorized person certification shall be conferred on an individual after the Authority is satisfied that the individual is conversant with provisions of current Good Manufacturing Practices.

2.3. Authorized Persons shall have a personal and professional duty to keep their knowledge and experience up to date. It is expected that this will cover the current state of pharmaceutical quality management regulatory, aspects and GMP guideline standards, products manufacturing and control technology and general work practices.

2.4. Authorized Persons shall regularly review the skills and knowledge required for their field of practice and undertake a programme of continuing professional development structured to meet their personal needs and to be able to provide evidence of such.

2.5 In organizations that do more than one dosage form, there shall be authorized persons in charge of the release of each of these dosage forms.

3. Responsibilities of an authorize person

3.1 Authorized persons shall have routine duties, some of which may be delegated. Before certifying a batch prior to release the Qualified Persons doing so shall ensure that the following requirements have been met.

3.1.1 The marketing authorization requirements of the product have been met for the batch concerned.

3.1.2 Guidelines of GMP has been followed during manufacture of the product.

3.1.3 Principal manufacturing and testing processes have been validated or verified.

3.1.4 All the necessary quality control checks and tests have been performed and account taken of the manufacturing and packaging conditions.

3.1.5. The batch records has been reviewed and found to be satisfactory.

3.1.6 Any changes or deviations in manufacturing, packaging or quality control have been identified and qualified.

3.1.7. All necessary manufacturing packaging and associated documentation have been completed and endorsed by a suitably qualified staff.

3.1.8 All relevant factors have been considered including any not specifically associated with the output batch directly under review (e.g. Calibration and maintenance records, environmental monitoring).

4. In the event of an Authorized Person making a major change in job responsibilities for example from a company making only sterile dosage forms to ones with a wider range of products including solid dosage forms, the authorized person shall seek clearance from the Authority.