ANNEX 7: AUTHORIZED PERSONS

7.1 The authorized person is defined as a person (among key personnel of a manufacturing establishment) responsible for the release of batches of finished products for sale.

The role and position of the authorized person in the company

7.2 The authorized person as the overall quality controller will be a member of a team whose function includes the following major areas:

- implementation (and, when needed, establishment) of the quality system;
- participation in the development of the company's quality manual;
- supervision of the regular internal audits or self-inspections;
- oversight of the quality control department;
- participation in external audit (vendor audit);
- participation in validation programs.

7.3 Although authorized persons may not have line management responsibility for many activities within this function (although they should be involved in these activities as much as possible), they must be aware of any changes that may affect compliance with technical or regulatory requirements related to the quality of finished products. When any aspect of the company's operations is not in accordance with GMP guidelines or relevant legislation in force, the authorized person must bring this to the attention of senior management. This duty should be reflected in the authorized person's job description.

7.4 The availability of an authorized person should be a prerequisite for issue of a manufacturing license (authorization). The authorized person (as well as persons responsible for production and quality control) must be approved by the NMRA. The marketing authorization holder is obliged to inform the NMRA, or other responsible authority depending on national (regional) regulations, immediately if the authorized person is replaced unexpectedly. Such provisions will assure to a considerable degree the independence of the authorized person from the management of the company in the fulfillment of his or her duties even when under pressure to depart from professional and technical standards.

7.5 More than one authorized person may be designated A company may have a complex structure, or operate at several locations, or both, and sometimes a separate authorized person may be designated who is responsible for the manufacture of clinical trial materials. Consequently, it may be necessary to

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nominate several authorized persons, one of them having the responsibilities of the overall quality controller and the others responsible for site or branch operations or specific products. The person authorizing batch release should be independent from production and quality control activities.

7.6 The drug regulatory authority should approve the authorized person on the basis of his or her professional curriculum vitae. Authorized persons have duties not only to their employer but also to the competent authorities such as the drug regulatory authority. They should establish good working relations with inspectors and as far as possible provide information on request during site inspections.

7.7 The authorized person depends upon many working colleagues for the achievement of quality objectives, and may delegate some duties to appropriately trained staff while remaining the overall quality controller. It is therefore of paramount importance that he or she establish and maintain a good working relationship with other persons in positions of responsibility, especially those responsible for production and quality control.

Implementation of the quality system

7.8 Authorized persons have a personal and professional responsibility for ensuring that each batch of finished products has been manufactured in accordance with the marketing authorization, GMP rules and all related legal and administrative provisions. This does not necessarily mean that they must have directly supervised all manufacturing and quality control operations. They must be satisfied either directly or, more usually, by proper operation of quality systems that manufacturing and testing have complied with all relevant requirements. Therefore, it is required that the manufacturer establishes and maintains a comprehensive quality management system, covering all aspects of GMP.

7.9 The Authorized person must ensure that there is a *quality manual* describing the *quality policy* and objectives (commitment to quality) of the company, the organizational structure, responsibilities and authorities, together with a description of or references to documented quality system procedures.

7.10 The Authorized person must ensure that Research and development activities and the transfer of results of the developmental work to routine manufacture, including original product design, formulation, processes development and validation, should

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observe GMP principles as guidance. Batches produced for clinical trials must follow applicable GMP. It is of vital importance that the quality of routine production batches corresponds to a specification derived from the composition of development batches. The quality and safety of a pharmaceutical product depend on the application of appropriate procedures, based on GMP, leading to a product within the recognized specification. Standard procedures and recognized specifications cannot be separated.

Routine duties of an authorized person

7.11 Before approving a batch for release the authorized person doing so should always ensure that the following requirements have been met:

- The marketing authorization and the manufacturing authorization requirements for the product have been met for the batch concerned.
- The principles and guidelines of GMP have been followed.
- The principal manufacturing and testing processes have been validated, if different.
- All the necessary checks and tests have been performed and account taken of the production conditions and manufacturing records.
- Any planned changes or deviations in manufacturing or quality control have been notified in accordance with a well-defined reporting system before any product is released. Such changes may need notification to and approval by the drug regulatory authority.
- Any additional sampling, inspection, tests and checks have been carried out or initiated, as appropriate, to cover planned changes and deviations.
- All necessary production and quality control documentation has been completed and endorsed by supervisors trained in appropriate disciplines.
- Appropriate audits, self-inspections and spot-checks are being carried out by experienced and trained staff.
- Approval has been given by the head of the quality control department.
- All relevant factors have been considered, including any not specifically associated with the output batch directly under review (e.g., subdivision of output batches from a common input, factors associated with continuous production runs).

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7.12 In certain circumstances the authorized person may be responsible for the release of intermediates manufactured on contract.

Education and training

7.13 The basic qualifications of a scientific education and practical experience for key personnel, including authorized persons, are outlined in chapter 2 (Personnel).

Professional Experience

7.14 Depending on the type of activity and professional knowledge, the required experience shall range from a minimum of 1 year up to 4 years.

The experience expected includes primarily the following points:

7.14.1 technical know-how of the processes an authorized person will be responsible for,

7.14.2 for manufacturing, import and wholesale including market release of pharmaceutical products: knowledge and experience of GMP,

7.14.3 for the import, wholesale, export and trade in foreign countries: knowledge and experience of GDP,

7.14.4 for manufacturing, import and wholesale of blood and blood products including market release of labile blood products: knowledge and experience of blood collection for transfusion, haematology or blood transfusion.

This experience can be acquired:

- by activities where the individual is in charge of, or partially responsible for, the manufacturing of medicinal products or transplant products (GMP), or the wholesale of medicinal products (GDP),

- by involvement in quality assurance work within a company that manufactures medicinal products or transplant products,

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- or possibly by means of experience with regulatory issues, such as the drafting of the quality modules of the CTDs /eCTDs within the framework of authorization procedures,

- by executing advisory or inspectory activities in the respective field.

7.15 Additional requirements may include subjects such as principles of quality assurance and GMP, principles of good laboratory practice as applicable to research and development as well as to quality control, detailed knowledge of the authorized/qualified person's duties and responsibilities, of International Standards ISO 9000–9004 and relationships with suppliers, principles and problems of formulation of pharmaceutical preparations, pharmaceutical microbiology, and principles and practice of sampling and testing of starting materials, packaging components and finished dosage forms.