QUALITY ASSURANCE

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Synthon

AGENDA

1. Background
2. Department tasks and responsibilities
   - Quality Assurance
   - Qualified Person
3. Importance of the department inside the pharmaceutical industry
4. Career development
5. Personal skills

1. Background

G M P

Good Manufacturing Practice for medicinal products for human and veterinary use

European Guidelines that each laboratory should implement in order to ensure the quality of products manufactured, for it must take all appropriate measures to ensure that medicines possess the necessary quality according to their intended use.

GMP applies to the lifecycle stages from the manufacture of investigational medicinal products, technology transfer, commercial manufacturing through to product discontinuation.

1. Background

- Part I: Basic requirements for Medicinal Products
- Part II: Basic requirements for Active Substances used as starting materials Products
- Part III: GMP related documents
- Annexes

Europa (Eudralex):

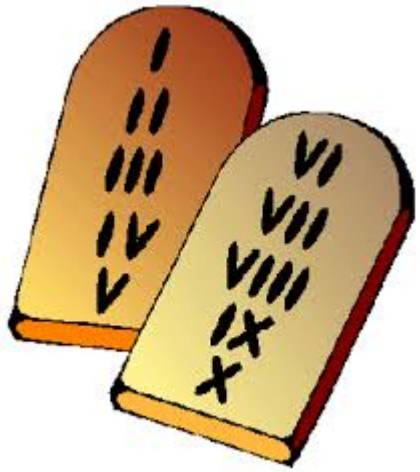
https://ec.europa.eu/health/documents/eudralex/vol-4_en

Spain (AEMPS):

http://www.aemps.gob.es/industria/inspeccionNCF/guiaNCF/home.htm

1. Background

There are 10 Commandments:



1. Write all the procedures and standards
2. Follow written procedures
3. Record all the working activities
4. Validate all the process
5. Design and build the facilities and equipment
6. Maintain facilities and equipment
7. Keep facilities and equipment clean
8. Control the quality
9. Be competent (as a result of education, training and experience)
10. Train and examine the staff to comply with the above points

1. Background

Quality Management 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 organized arrangements made with the objective of ensuring that medicinal products are of the quality required for their intended use. Quality Management therefore incorporates Good Manufacturing Practice.

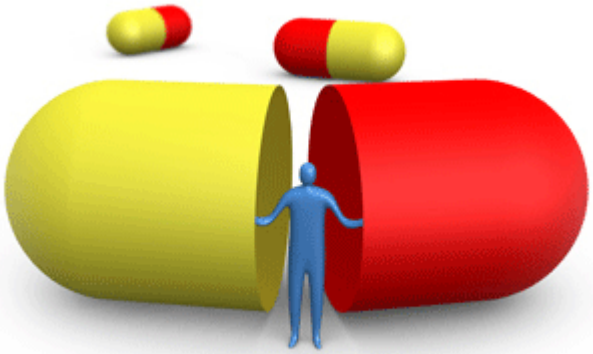
Chapter 1: Pharmaceutical Quality system

1. Background

2. Department tasks and responsibilities: Quality Assurance dpt

Quality Assurance **aims to ensure greater reliability and security to the end users of the drugs** analyzed, manufactured and condition following quality criteria according to the rules described in the Guide of Good Manufacturing Practices and international recommendations.

Quality Assurance is **involved in all stages of the manufacturing process** as well as upstream and downstream manufacturing and marketing of products **to ensure that all planned activities comply with regulations** and **also provide tools for improvement**.



2. Department tasks and responsibilities: Quality Assurance dpt

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Is GMP application only part of the tasks and responsibilities of Quality Assurance?

2. Department tasks and responsibilities: Quality Assurance dpt

1. Draft quality assurance policies and procedures
2. Responsible for document management systems
3. Implement and evaluate the quality assurance standards
4. Review and approve testing, inspection of materials, production records of products to ensure finished product quality
5. Perform internal audits
6. Coordinate and support on-site audits: Health Authorities, customers.
7. Evaluate audit findings and implement appropriate corrective actions
8. Assure ongoing compliance with quality and industry regulatory requirements
9. Investigate customer complaints and non-conformance/deviations issues
10. Develop, recommend and monitor (CAPA) corrective and preventive actions
11. Compile statistical quality data and perform Annual Produt Review
12. Analyze data to identify areas for improvement in the quality system
13. Identify training needs and organize training interventions to meet quality standards
14. .....

2. Department tasks and responsibilities: Qualified Person

The **Qualified Person** is Responsible for carrying out the release of the products according to the quality of the compliance and GMP and ensure that the manufacturing process meets with Manufacturing Authorization.

2. Department tasks and responsibilities: Qualified Person

Requirements:

1. In possession of a diploma, extending over a period of at least **four years** of theoretical and practical study in one of the following scientific disciplines: **pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology**.
2. The course shall include theoretical and **practical study** bearing upon at least the following basic subjects:
   -General and inorganic chemistry
   -Organic chemistry
   -Analytical chemistry
   -Pharmaceutical chemistry, including analysis of medicinal products
   -General and applied biochemistry (medical)
   - Physiology
   -Microbiology
   -Pharmacology
   -Pharmaceutical technology
   -Toxicology
   -Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin).

2. Department tasks and responsibilities: Qualified Person

Requirements:

3. The qualified person shall have acquired **practical experience over at least two years, in one or more undertakings which are authorized to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products**. The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years

2. Department tasks and responsibilities: Qualified Person

Responsibilities:

Responsibilities are also regulated by in Artcle 18 : *Real Decreto 824/2010, de 25 de junio, por el que se regulan los laboratorios farmacéuticos, los fabricantes de principios activos de uso farmacéutico y el comercio exterior de medicamentos y medicamentos en investigación.*

Artículo 18. *Responsabilidades del director técnico.*

1. El director técnico será el responsable de que:

a) En el caso de medicamentos fabricados en España, cada lote de medicamentos haya sido fabricado y controlado con arreglo a la legislación vigente y en la observancia de las exigencias requeridas para la autorización de comercialización.

b) En el caso de los medicamentos procedentes de terceros países, aunque hayan sido fabricados en la Unión Europea, que cada lote de fabricación importado haya sido objeto, en un Estado miembro, de un análisis cualitativo completo, de un análisis cuantitativo de, al menos, todos los principios activos y de todas las demás pruebas o verificaciones necesarias para garantizar la calidad de los medicamentos, en observancia de las exigencias requeridas para la autorización de comercialización.

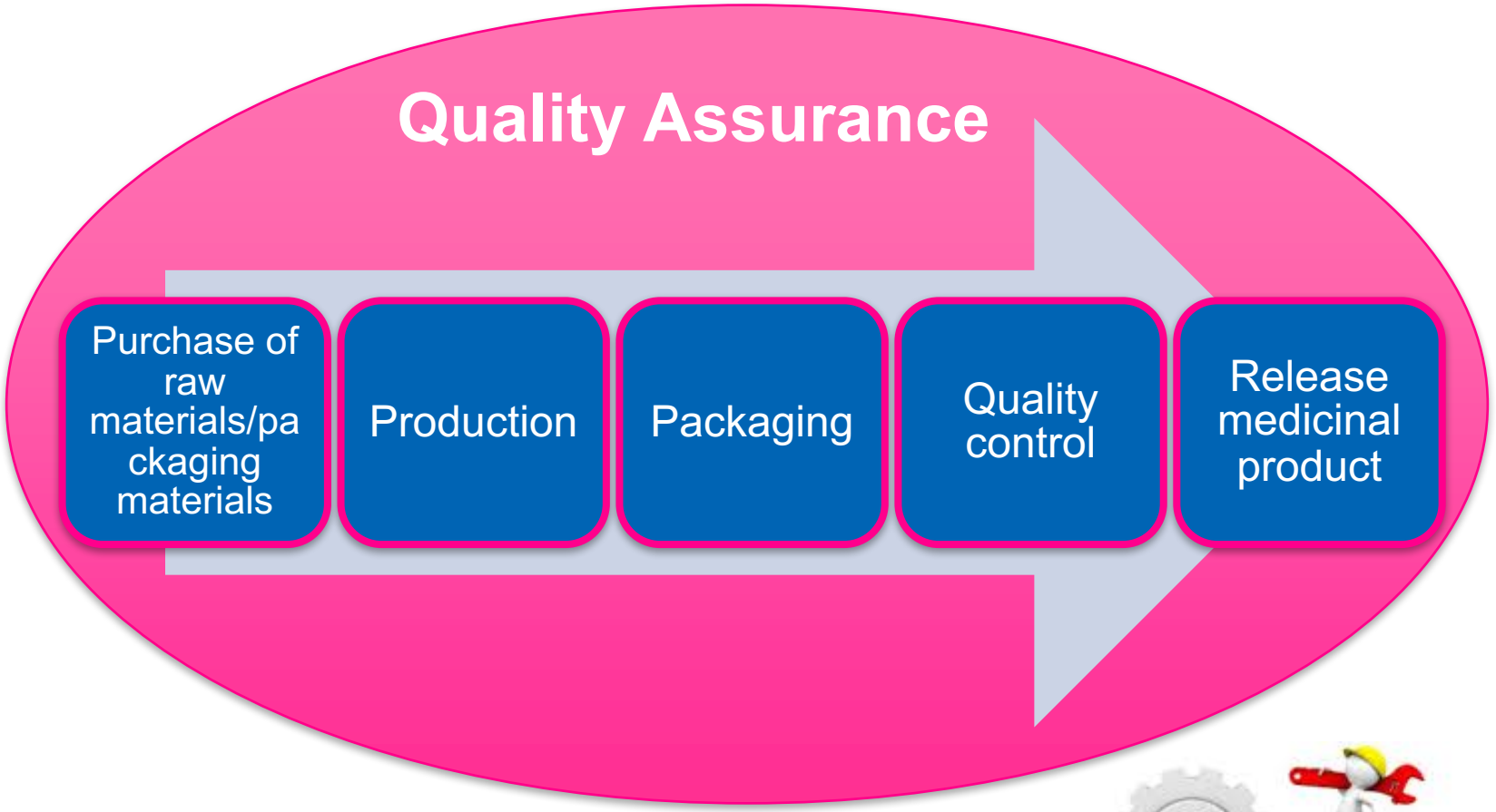
Los lotes de medicamentos controlados en un Estado miembro, a los que se refieren las letras a) y b), quedarán exceptuados de los citados controles cuando se comercialicen en España, si bien deberán ir acompañados de las actas de control firmadas por el director técnico.

c) En el caso de medicamentos importados desde terceros países con los que la Unión Europea hubiere adoptado disposiciones adecuadas que garanticen que el fabricante del medicamento aplica normas de correcta fabricación, por lo menos equivalentes a las establecidas por la Unión Europea, el director técnico del importador se asegurará que se han efectuado en el país exportador los controles mencionados en la letra b), quedando dispensado de realizarlos.

2. En todos los casos, y en particular antes de la liberación al mercado de los medicamentos, el director técnico deberá certificar que cada lote de fabricación responde a las disposiciones del presente artículo, en un registro o documento equivalente previsto a este respecto; dicho registro o documento equivalente deberá tenerse al día, a medida que se vayan efectuando las operaciones, y estar a disposición de la autoridad sanitaria competente durante un período de cinco años, como mínimo.

3. El director técnico deberá auxiliar a las autoridades inspectoras en el ejercicio de sus funciones y será el interlocutor, por parte del laboratorio, ante las autoridades sanitarias competentes para los aspectos recogidos en este real decreto.

3. Importance of the department inside the pharmaceutical industry



4. Career Development

5. Personal skills

- Attention to detail
- Communication skills - verbal and written
- Leadership
- Process approach
- Data collection, management and analysis
- Problem analysis and problem solving
- Planning and organizing
- Judgment
- Decision-making
- Continual imporvement
- Customer service orientation
- Teamwork

Questions??

Thank you!