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 for Medicinal Products
- Part III: GMP related documents
- Annexes

Europa (Eudralex):

Spain (AEMPS):
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 Product 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 Article 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.
3. Importance of the department inside the pharmaceutical industry

Quality Assurance

- Purchase of raw materials/packaging materials
- Production
- Packaging
- Quality control
- Release medicinal product
4. Career Development

- Technician
- Inspector/Auditor
- Qualified Person
- Manager
- Director
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 improvement
- Customer service orientation
- Teamwork
Questions??
Thank you!