IX. GOOD MANUFACTURING PRACTICE (cGMP)

A GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

GMP covers all aspects of production from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

The purpose is to enable you to establish and implement an effective tailored cGMP system in line with requirements:

- ☐ **Quality Systems**
- ☐ **Documentation**
- ☐ **Good Documentation Practices**
- ☐ **Personnel**
- ☐ **Premises and Equipment**
- ☐ **Facilities and Equipment Systems**
- ☐ **Materials Systems**
- ☐ **Production Systems**
- ☐ **Packaging and Labeling Systems**
- ☐ **Laboratory Control Systems**
- ☐ **Complaints and Recalls**

Our services include:

Upon completion of this course, trainees will:

E. **be able to understand the basics of Good Manufacturing Practice for medicinal products for human use and the current legal regulations and guidelines;**
F. **have the confidence to outline the main GMP requirements;**
G. **get familiar with the principles of the GMP quality system and quality control and the important procedures when dealing with complaints and recalls.**
H. **Implementation Consulting and maintenance**

Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up, support certification

References

21 CFR Part 210 & 211: Pharmaceutical

EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines