**Title: GOOD MANUFACTURING PRACTICE: THE HOSPITAL LABORATORY**

**Unit 1- introduction to Good manufacturing practice (GMP)**

* Quality system Key concepts and principles
* Certification and Accreditation
* Basic requirements for medicinal products
* [Pharmaceutical Quality System](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/vol4-chap1_2013-01_en.pdf)
* personnel
* Premise and Equipment
* Documentation
* Quality control
* Outsourced activity
* Complaint and product recall
* Self inspections

**Unit 2. Regulation for research and Advanced Therapy Medicinal Products (ATMPs)**

* Good laboratory practice (GLP)
* Good clinical practice (GCP)
* Good manufacturing practice (GMP)
* Clinical trial phases
* Authorization Institutions (AIFA/ISS and EMA)

**Unit 3. Implementation of a GMP system**

* Personnel, training, documents
* Production
* Quality control
* Risk analysis
* Qualification and validation
* Raw materials
* **GMP related documents**
* [Site Master File](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2011_site_master_file_en.pdf)
* [Quality Risk Management](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002873.pdf)
* Validation master plan

**Unit 4. ATMP production: from the raw materials to the patient**

* Example di ATMP production: from raw materials to clinical application
* Mediafill
* Production Process Validation
* Stability program
* Transport validation
* Certificate release

**Visit to the GMP quality control laboratory and cell therapy laboratory (group work)**