

Pharmaceutical Cannabis Facilities

EU cGMP standards

Roadmap for Finished Pharmaceutical Products (FPP)

Who is Axis Medical Construction?

Axis Medical is a consulting, planning and construction company, expert in the health care and laboratory construction, especially Operating Theatres, Intensive Care Units, EU GMP, and ISO 14644 Validated Clean Rooms.

Our high experienced and special educated in the healthcare & pharmaceutical design engineers and biologists, ensure high quality products and services at each stage of the project, from design to construction, ensuring at the same time an even and cost-efficient solution.

Our expertise on the design and materialization of certified / validated cleanrooms, with references successfully audited by the Greek NOM since 2015, put us in position to be one of the most reliable partners for the EU cGMP consulting in the rapidly evolving market of pharmaceutical cannabis facilities in the Greek and Balkan territory in general.



Consulting - Licenses

A to Z process

Installation Approval

This first stage includes the submission of the ministerial decision (no.27462/2022) Annex I questionnaire to the Directorate of Licensing of Businesses and the supporting documentation in digital and printed form. This file shall include all necessary certifications and approvals of the state entities. The Directorate of Licensing shall forward a copy of the file to the relevant authorities and the approval is granted following a Common Ministerial Decision (CMD).

Greenhouse Type Approval

Submission of study folder in compliance with the provisions of the ministerial decision. The approval is granted from the Directorate of cultivating systems and plant produce products - Ministry of Rural Development and Food.



Basic Design

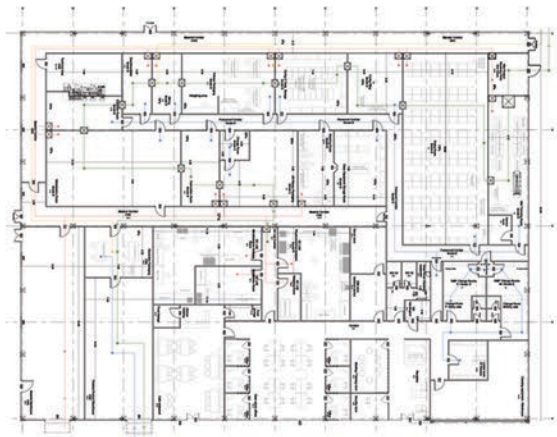
This part includes the Investment plan facility footprints that consists of the development of a plan layout (floor plan) for the facility in order to ensure compliance with EU cGMP requirements. Determination of areas as per cGMP and ISO 14644:2015 will also ensure full implementation of current and future manufacturing needs. The basic design depicts the business plan into drawings and areas sized according to the entrepreneurial calculations.

Post harvest equipment selection

The post-harvest equipment selection is a consultancy on the current and future trends in product development, conceptualization of the processing unit's operations and the optimal technologies based on the state-of-the-art Intellectual & Industrial Property (IP) and on GMP-compliance requirements.

Building Permit

Studies, technical reports, supporting documentation are submitted to the Information System "e-Permits" of the Technical Chamber of Greece for the issuance of a Building Permit to carry out construction works. The Building Permit File includes the Pre-Approval, the Architectural Council Approval, and the Building Permit itself.



Building Application Study

Includes the final architectural and electromechanical study as well, designed with the construction details on a scale 1:20, including all facilities and equipment. There is also a complete series of studies, plans, issues and specifications. The Deliverables include fully detailed drawings for the Contractor as well as an Issue of Obligations and pre-measurements which will be used by the project owner in order to set a Private Tender procedure and receive realistic and complete offers from the tendering companies.



Studies for Building Permit File

The **Architectural study** includes the preparation of all architectural plans such as floorplans, elevations, sections, coverage and topographic diagram etc. that are necessary for the issuance of the Building Permit, in accordance with Greek Legislation.

The **Electromechanical study** includes the design of electromechanical installations, as heating, ventilation, and air conditioning (HVAC), electrical system, water / sewerage, fire systems, etc. according to the Greek legislation, as well.

The Structural design is the elaboration of a **Static study** for the building to be included in the Building Permit, with calculation of all loads, construction details, calculation of weight and cost of metal shell.

Personnel Requirements

The personnel needs and hiring periods for each sector of the staff is defined during this stage (agronomists, office employees, GMP qualified staff, security, workers etc.). Axis Medical can facilitate in the preparation of a list of necessary personnel in accordance with the layout, the scale of the investment and the anticipated production capacity of the facility.

Greenhouse Application Study

Includes the pre-measurements of earthworks and concrete for the base of the greenhouse and the materials, as well as quality characteristics specifications and the necessary plans. Deliverables, also: Studies of individual systems such as HVAC, air recirculation, dehumidification, irrigation systems, electric and plumbing installations with all the theoretical calculation of the systems based on the climatic data of the area and the requirements of the crop.



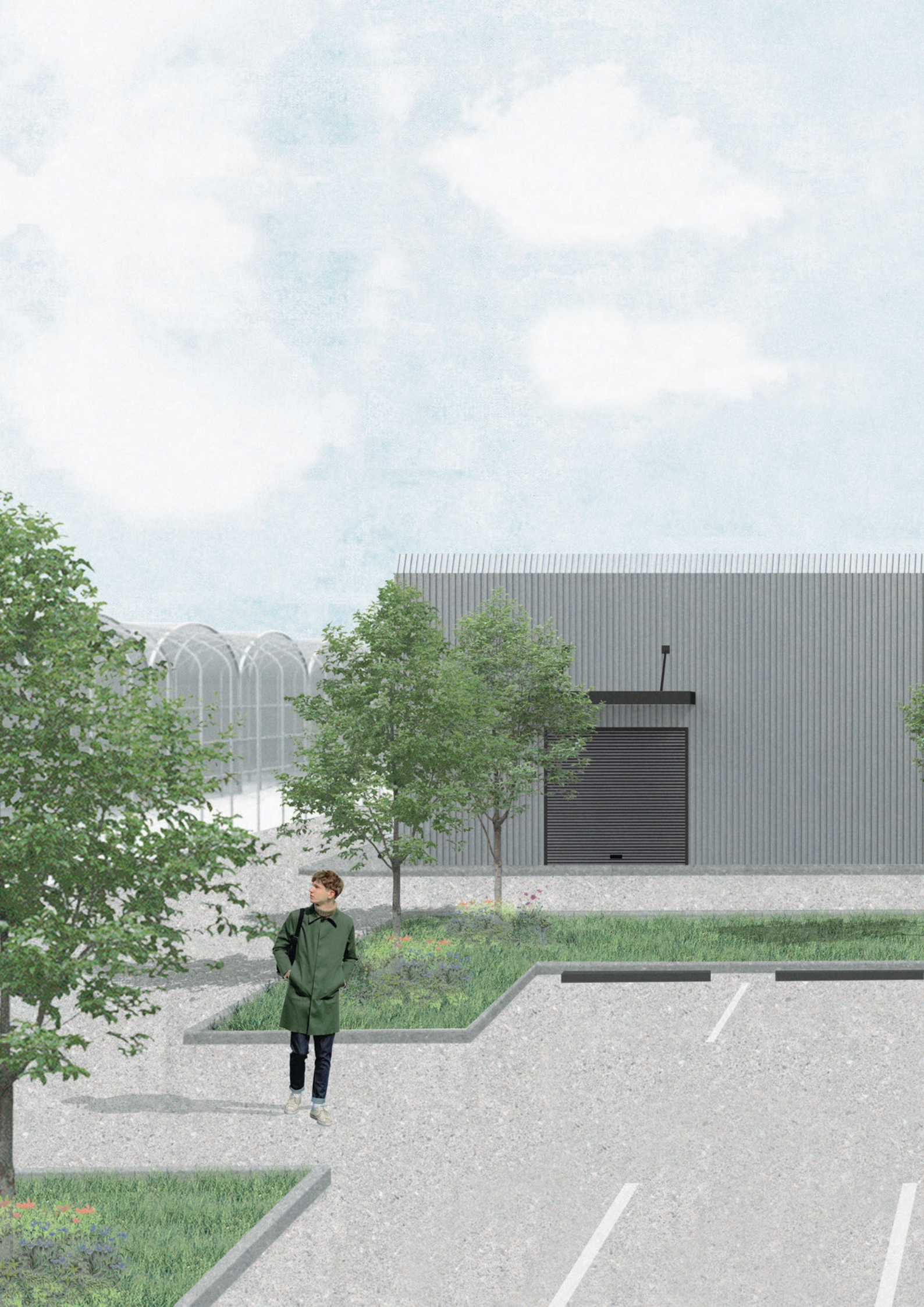
Operational License and Production License

After the successful trials and personnel training on the cultivation and production parts, the Project Owner shall submit the necessary documentation to the Directorate of Licensing of Businesses, General Secretariat for Industry and apply to National Organization for Medicines (NOM) and/ or to the MoH for the Operational license and FPP circulation.

EU cGMP and GACP quality systems for pharmaceutical cannabis facilities

The GMP and GACP quality system applies from the begging of the consulting and the studying process and its application continues until the end of the installation process. It includes the development of the GACP Management System according to the applicable EMEA Guideline and the development of the EU cGMP Pharmaceutical Quality System (Site Master File, Basic SOPs, Standards, etc.) according to the EU cGMP requirements for the respective product classification and the dosage forms.





Construction

Installation of the facility

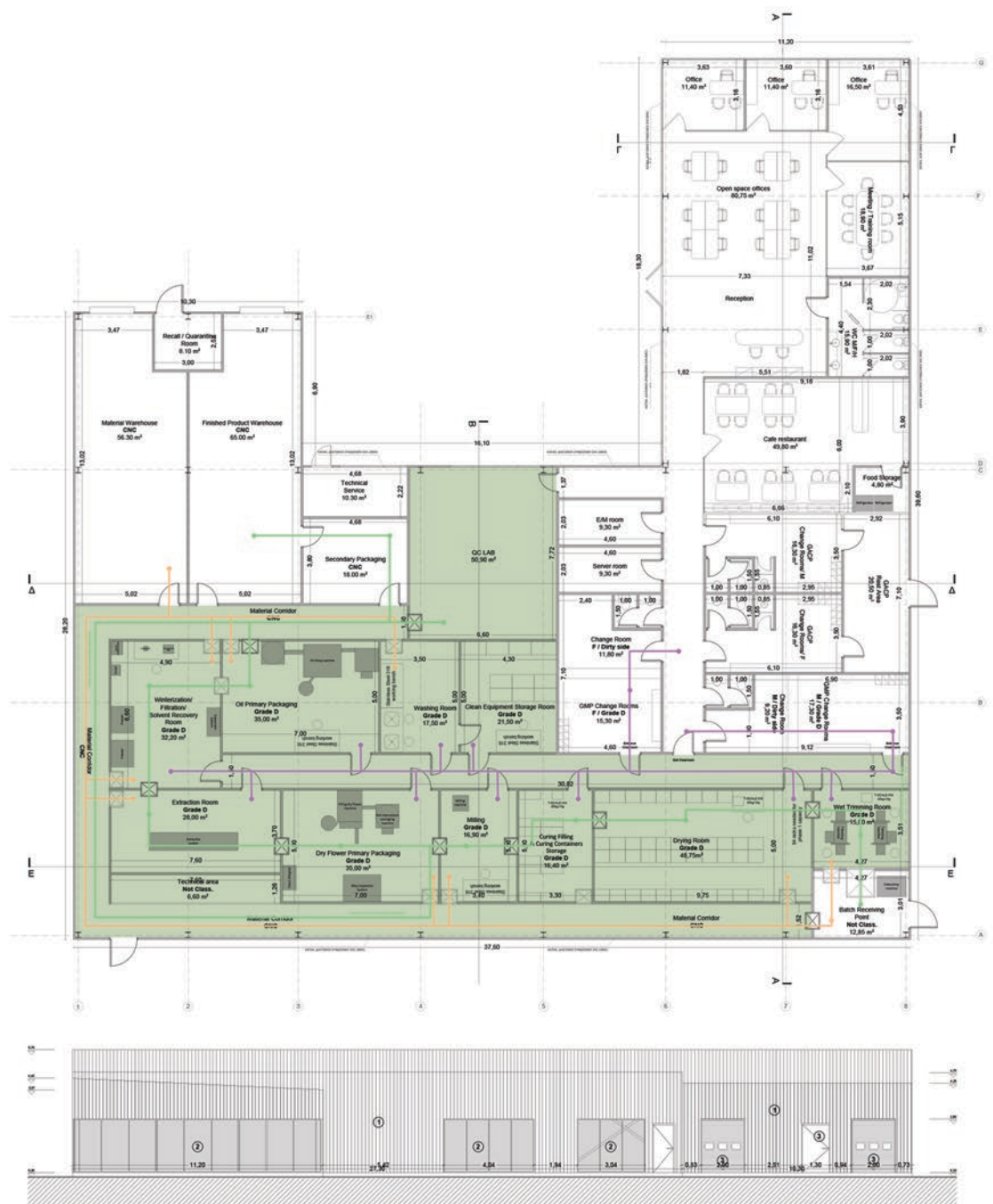
Axis Medical, always following the GMP and GACP quality systems and the studies that have been done, undertakes the construction of such pharmaceutical cannabis facilities, a sector that is now growing rapidly in Greece.

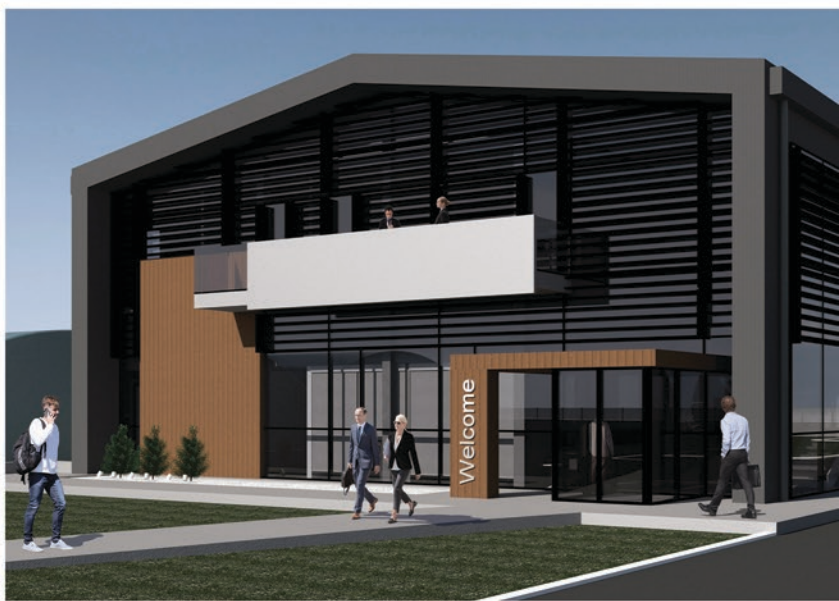
Our company uses only the highest-quality materials ensuring that everything included in the classified areas will be according to GMP standards and no contamination will be present. However, this doesn't only apply to the materials that are used but also the process of construction.

It is very important to underline the fact that during this process, all the necessary tests are taken to ensure that the process of the construction as well as the result of it will follow all the GMP protocols.



In addition, we provide a complete solution for the electromechanical needs of the pharmaceutical cannabis facilities such as electrical and plumbing systems but emphasizing on the HVAC System. Its method of installation and the equipment that is necessary shall be such as to ensure proper operation of the premises according to the specifications of required purity levels of GMP & ISO 14644-1.







Related Projects

Laboratory Facilities

_King field - Study, GMP validation, Cleanroom Construction – finished (NMK)

_Pharmacann – Constructional part (subcontracting cleanroom elements) (NMK)

_NGP - Study, GMP validation, Cleanroom Construction – finished (NMK)

_Patra project – Study, building license – in process (license issued)

_Korinthos project - Study, Building licenses, GMP validation, Whole building Construction – in process 95%

_Trikala project – Study, building license, full consulting and business planning – in process

_Volos project – lowest bidder/ project winner (construction phase)





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