GMP / GACP Pre-Audit - GOOD AGRICULTURAL AND COLLECTION PRACTICES FOR MEDICINAL PLANTS

In the general context of quality assurance, the primary purpose of the WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants is to provide general technical guidance on obtaining good-quality medicinal plant materials for the sustainable production of herbal products classified as medicines. These guidelines cover the cultivation and collection of medicinal plants, including certain post-harvest operations. Medicinal plant raw materials must meet all applicable national or regional quality standards, so it may be necessary to adjust the guidelines to the situation in each country.

The objective of a GMP / GACP Pre-Audit is to obtain the appropriate system for eventual authorization from the AEMPS, establishing that 2 references apply in the medical cannabis industry:

- Good Agricultural and Collection Practices (WHO Guidelines on Good Agricultural and Collection Practices for Medicinal Plants)
- Good Manufacturing Practices (GMP PIC / S Guide for Medicines) We highlight Part 1 (Basic Requirements for Medicines) and Annex 7 (Manufacture of herbal medicines) that details the transition from GACP vs GMP as shown in the following table:

GACP vs GMP	GACP	GMP PART 1	GMP PART 2
Cultivation and collection of plants, algae, fungi and lichens and collection of exudates.	x		
Cutting and drying plants, algae, fungi, lichens and exudates.	x	x	x
Expression of the plant gene and distillation		x	x
Exudate processing, plant extraction, fractionation, purification, concentration or fermentation of herbal substances.		x	x
Additional processing in a dosage form that includes packaging as a medical product		x	

In addition to considering the different specific and legal policy considerations applicable:

SUBJECT	MINIMUM REQUIREMENTS (SIMPLIFIED)	
	GMP	GACP
PHARMACEUTICAL QUALITY SYSTEM	All relevant policies, standard operating procedures and support forms, registration books, records, etc. must be issued and controlled (usually by the Quality Department). Documents must reflect the actual processes that are carried out and cannot be used unless they are approved and active.	Recommendation of procedures and documented policies. Documents are not required to be controlled, although it is generally good practice to limit the ability of staff to edit master records only from the point of view of company security.

STAFF	Strict staff control, as well as specific training requirements for each work function. Staff must be properly trained (and each documented training instance) in critical activities before they are allowed to perform them unsupervised. This may include, but is not limited to: dressing, cleaning, waste disposal and other technical activities.	Recommendation to ensure that all staff receive adequate botanical and agricultural training before starting work. Staff should also be aware of safety and hygiene requirements.
FACILITIES AND TEAM	Extensive requirements for construction and maintenance: All critical equipment elements will require validation activities before being used in routine production.	It is recommended to choose, maintain and carefully clean the equipment and workspaces so that the plants do not accidentally contaminate during processing.
DOCUMENTATION	As detailed in the PQS section, all documentation must be checked and approved before being used as "active" references for the site. Any record generated must be properly reviewed and reconciled.	Records of cultivation processes should be kept, including any application of pesticides (if applicable). ODC's requirement to track quantities of material cataloged on site to final destination.
PRODUCTION	Normalized processes must exist. Batch records and forms must be used to document production processes. Only validated equipment should be used. Production processes may also require validation to verify that they are able to consistently generate	It is recommended to monitor and standardize critical production activities, such as harvesting, drying and trimming, so that a constant quality of the product can be achieved.

	products of the required quality.	
QUALITY CONTROL	Control of sampling, testing and release of materials (both raw materials and finished products) is required. This may also include verification that clean rooms are at the appropriate microbial environmental levels for production activities.	The starting plant material must be characterized prior to use and release, this includes: (A) Obtaining information on the initial seed or cutting material (B) Shipping of plant material to GMP authorized quality control testing laboratories for testing at TGO 93.
SUBCONTRACTED ACTIVITIES	Supplier warranty is a critical component of all GMP installations.	Recommendation to identify approved suppliers to stock critical materials.

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