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Good Distribution Practice (GDP) of Medicines and APIs For Human Use, Focused on Transport

"Useful Training for you and your company"

Objetives

Participants have the opportunity to access a description and detailed explanation of Good Distribution Practices (hereinafter GDP) of medicines for human use, and to understand in depth all aspects related to quality in the transport of medicines and active principle ingredients (APIs), and the increasing demands of laboratories, distribution warehouses, etc.

The objectives of this training have been established based on the same level of abstraction of the regulations, based on the EU Guidelines of November 5, 2013 on correct practices for the distribution of medicines for human use, and the EU Guidelines of March 2015 on Good Distribution Practice of active substances for medicinal products for human use, of the European Commission and further MHRA guidelines as equivalent to USA FDA GDPs which are included in the cGMP.

The objectives have been identified in the framework and scope of application of these guidelines in all aspects, so that the student obtains a global vision of these regulations, and can identify the interrelation between the entities and personnel that intervene in the distribution of medicines.

These general objectives lead to specific objectives when focusing this training towards workers or employees of laboratories, manufacturers, distribution departments, logistics departments, and drug stores, to highlight the knowledge, skills and attitudes in this type of activity that must be adopted and maintained.

Also derived from the general objectives and content of the regulations, it is necessary to contemplate and convey to the student a series of operational objectives in terms of procedures, processes and conditions, during the storage of medicines as well as in the entry and exit of medicines from the warehouse.

Contents

The contents are the proper GDPs described in the Guidelines, developed to convey the real practice to the student, so the participant can get a deep understanding of them.

The training is organized into 9 modules plus an additional module on customer and transport audit, whose units are the structure and organization of the guidelines themselves, and whose contents are the requirements and tasks or functions at the level of nomenclature or reference.

Methodology and extras

Training in GDPs constitutes, like other quality reference systems or frameworks, a field of concepts and abstract content, which turning into the real world must be developed in each case and company in which they are applied. This course combines explanations and illustrations that clarify and allow ideas and concepts to be visualized.

For this reason, the platform also provides a messaging tool to contact the course teacher for further explanations or clarifications, which enlivens the monitoring and sequence in the training content as well as its similarity with the dynamics of the business or distribution processes.

Assessment and Certificates

There is an assessment at the end of the course. Each participant getting 75% of qualification will get a certificate of attendance and achievement, and to get at least the attendance certificate each person has to go over 75% of contents.

Participant Profile

The contents are adjusted to the needs of any personnel of logistics operators, distribution and transport entities, carriers, and the personnel of pharmaceutical laboratories that manage or are in relation to logistics, transport or warehouses by contract, distribution, etc., of medicines.

Tutor:

Isabel Cartas: Pharmaceutical Graduate, and Master in Pharmaceutical Industry, with a long career as Technical Director and Responsible Person in Medicines Distribution Entities.

Dynamizer:

Javier Aseguinolaza: Chartered Engineer (UK Engineering Council), Master in Industrial Environment Management, consultant with extensive knowledge and experience in Quality, Innovation, Organization, Lean Six Sigma, etc.

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Registrations:

Please get in touch with ATEC+ID at javier@atecid.com if you have any question.

The Price is 300 € per person and can be paid by different methods, just follow our online shop or get in touch with us for further guidance.

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