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DANGER ZONES IN PHARMACEUTICAL INDUSTRIES

Production processes in companies that produce pharmaceutical products through mixing, emulsifying and chemical reaction of organic compounds, may generate environmental conditions that create potentially explosive atmospheres. Substances in liquid state are very often used during manufacturing process. They can reach temperature which emit flammable vapors or temperatures above the flash point.

In addition to industrial installations with production process, research and development chemical laboratories may use liquids, gases or combustible dusts in quantities that could cause a hazard of explosion. These dangerous substances are usually contained in closed containers in storage areas before being put into production.

Therefore, quantifying the risk of explosion, we've to consider these possibilities:

1. potentially explosive atmosphere due to the manufacturing process for the presence of: gas, vapors of flammable liquids in process at temperatures above the flash point, combustible dust;
2. potentially explosive atmosphere due to installations at the service of the production process, such as fuel systems of methane gas;
3. potentially explosive atmospheres in chemical laboratories where there's a study and research activity with the use of flammable substances in the form of gases, vapors or mists and dusts, in the presence of potential sources of ignition.

As always, in order to proceed with the area classification, the first step will be to verify the characteristics of all substances in the production process, make a detailed list and map the area in which these substances are used or stored. This is an activity that must be carried out with the help of the managers of the various processes. For each hazardous substance, must be prepared a card with all the chemical and physical properties necessary for the classification (flash point, ignition temperature, UEL, LEL, etc...).

Reference Standards

The classification of dangerous areas is made in accordance with:

- EN 60079-10-1 standard for the part of the plant with presence of gas, vapor or mist:
- EN 60079-1-2 standard for the part of the plant with presence of combustible dust in cloud and/or in layer. The EN 60079-1-2 standard allows carrying out the classification considering all the hazards due to the presence of dust, taking into account also the type of machining performed.

Emission sources of a pharmaceutical plant

Now let's see what should be the emission sources of an industrial pharmaceuticals plant.

The following emission sources must be considered of continuous degree (if there is air in the system):

- tanks;
- closed chemical reactors;
- conveyor systems;
- containment of flammable substances in general.

Depending on the operating procedures, the following emission sources must be considered of continuous degree or of first degree:

- open containers containing substances in processing;
- containers in free air used for the preparation of compounds for manual or automatic mixing and / or in which are appended additions to the liquid solution in processing;
- sample points for sampling;
- loading and unloading in free air.

Flanges, joints, valves and, in general, the discontinuity, containment and conveyor points of a production plant, must be considered emission sources of second degree. In case of presence of combustible dust in the process, such as, for example, lactose that is used as an adjuvant, will be appropriate to assess if dusts layers may form and if there's the risk that these layers can rise up in clouds becoming emission sources.

Classification for gases

The classification result depends on:

- operating conditions;
- plant parameters;
- volume of the environment;
- the ventilation;
- coefficient of effectiveness of ventilation

In general, as far as concern the gas, we could have:

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- Zone 0, within containment systems and within open containers;
- Zone 1, around mixing, sampling points, loading, unloading operations etc.
- Zone 2, originated from the Emission sources of discontinuity points in the plant.

The extension of the dangerous zone can be determined by the distance "dz" starting from the source of emission (ES) in the direction depending on the type of gas.

Classification for dusts

In case of presence of dust in the process, we could have:

- Zone 20, in containment systems, hoppers, etc.
- Zone 21, originated from the emission source due to the operations of loading and unloading, etc;
- Zone 22, arising from the points of discontinuity of the containment systems, from the closed charging doors and from the possible outline of Zone 21.