cGMP Compliance

- *What does the FDA ecpect about cGMP compliance in relation to processing environment in pharmaceutical industry ?*

  It has been clarified by the FDA that cGMP compliance relates not only to the raw materials and their quality but also to the environmental conditions during the processing of the drugs.

- *Why is cGMP compliance most critical from humidification or dehumidification point of view?*

  Both humidification and dehumidification involve moisture transfer. If condensate is not treated and drained correctly stagnant water in the AHU (Air Handling Unit) can lead to microbial growth with associated high risk of product contamination.

- *What is the present practice being followed in India ?*

  Presently the equipment manufacturers provide a complete package – the processing equipment as well as the AHU (Air Handling Unit)
  While they have the expertise in manufacturing of the processing equipment the same cannot be said to be in the case of Air Handling Equipment.

  Humidification and dehumidification are highly specialized subjects and require product and process as well as location specific design – one size doesn't fit all.

  An internal inspection of the air handling systems installed for API processing is likely to lead to some surprising results in most cases.

- *How can we help ?*

  We have the the know-how and support of most experienced design engineers as well as specialized equipment from Europe which can ensure the air handling equipment remains contamination free, reducing risks for you.

  We will always provide you with a correct technical solution which complies with the cGMP standards and in case it is not possible to do so due to equipment or space limitations we will not offer our equipment.

  We are here to help you reduce risks and increase productivity.