

Qualify suppliers of raw materials, packaging materials and services has always been considered an essential activity for the proper functioning of the system as a pharmaceutical.

The inspection activities, historically introduced as a method to reduce the controls on the finished product, it became mandatory for both GxP and ISO systems.

Supplier qualification methods were left to pharmaceutical companies depending on the type of product supplied, the simple evaluation of data from an information questionnaire, examination of the historical supply, until such audits to ascertain the level of existing quality and compliance with certain requirements.

With the transposition of EU Directives 2001/83/EC and 2003/94/EC is obliged to European companies consented to the production of drugs used in the manufacture of medicinal products only active ingredients (API), and in future some of the ingredients, from approved manufacturers that comply with Good Manufacturing Practice and the manufacturer has a particular and thorough knowledge. This "evidence" through the availability of GMP Certificate issued by a European health authorities following a formal review (audit) per the manufacturer's website and / or distributor, both in Europe outside of Europe.

But not enough, it is always the holder pharmaceutical workshop also carry or have carried out on its behalf by third parties, such inspections to the sites of manufacturers of APIs to ensure that beyond what authorities stressed in the first audit, requirements defined for the Quality System are also respected for the process / product. The burden that the implementation of this legislation means for pharmaceutical manufacturers is certainly evident and clear to all the corporate function responsible, usually the QA, must devote more time to inspections and undertook to travel longer or shorter as a function of 'importance of supplier and distance control with a number of human resources and increasing costs.

In this context, retrieving and pooling expertise and experience established over more than a decade of work by the Group Quality Project ", born in 'area of the Italian Quality Control (AICQ), has recently formed the" Group Inspections Suppliers " (GIF).

In this new guise the Group, joined at about 50 qualified professionals through their primary business is pharmaceutical / cosmetic manufacturers of APIs and excipients, it is proposed to conduct joint audits, all in analogy to what is in place in Germany and Spain, where in fact for many years active associations and groups that carry out inspections of suppliers and then putting together the findings: the VFA (Verband Forschender Arzneimittelhersteller - Association of Research-based Pharmaceutical Companies) in Germany comprises about 40 pharmaceutical companies and pharmaceutical chemistry and Spain Forum Auditorias.

Obviously one of the first activity which the GIF had to deal with itself as a credible partner, reliable and free from potential conflicts of interest was the creation of a well organized, with strict rules and procedures that can protect needs of member companies and the companies inspected, particularly with regard to retention and the right to decide on who may become aware of the findings of the inspection through a strictly controlled management reports.

To ensure maximum objectivity, because the inspections are conducted by teams consisting of at least two inspectors from different companies, qualified and experienced and professional knowledge.

History of GIF

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The benefits brought by GIF, both member companies and suppliers inspected, resulting in savings of time, human and economic resources and training of auditors in compliance with regulatory requirements. In fact, participate in shared audit results in professional growth for young inspectors who, by participating in audits conducted by senior colleagues, they see the field increased their understanding of issues relating to the qualification of suppliers.