PHARMSOL NEWS

GMP AUDIT—MAKING COMPLIANCE YOUR HABIT

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Let the company beware!

The companies take the responsibility for the condition of the items or quality of the products that they purchase. Prior to the current consumer protection laws, buyers had no warranties for the products that they purchased. Today, most states require products to be of "merchantable or sellable quality." As this condition is often next to impossible to define and enforce, buyers are advised to embrace the principle of “let the company beware” to "signing on the dotted line."

While being conscious of the products purchased is good practice for consumers and most businesses, it is a regulatory requirement for pharmaceutical manufacturers. For these organizations, the decisions where to purchase raw materials, components, manufacturing and testing equipment, need to be well informed. The results of poor purchasing can lead to situations that impact product quality, regulatory compliance, company profits, and even the reputation of the company.

Who can commission the audit?

Although the EMA has given an unequivocal statement on the question, there still exist API manufacturers who commission an audit themselves. Audit reports which have been issued by the API manufacturer are not valid i.e. not recognized by the inspection authorities.

It should have a confirmation that the audit was ordered by one or several manufacturers of medicinal products who purchase one of the products from the API manufacturer in question. The audit cannot be independent when the API manufacturer is the ordering party. Third Party Audits accepted are based on a comprehensive regulations’ framework. These Audit Schemes are particularly important when used by several companies (Shared Audits).

PharmSol

How does a company qualify a vendor?

What approach will give the company the best probability of an accurate vendor assessment, meet current regulatory expectations, and still remain practical?

One of the phases in the vendor qualification process is a site audit of the potential vendor's facility.

Vendor Qualification is more than auditing. Vendor qualification can be seen as a risk assessment tool. It should provide an appropriate level of confidence that suppliers and contractors are able to supply consistent quality of materials, components in compliance with regulatory requirements.

PharmSol conducts qualification of the manufacturing sites in accordance with ICH Q7, EudraLex Volume 4; Code of Federal Regulations 21 CFR Part 11; PIC/s Guide to Good Manufacturing Practice for Medicinal Products, January 2017; and Good Manufacturing Practice for Drugs 2010 Revision (MOH Decree No. 79) and provides detailed and comprehensive GMP audit reports. We reduce the number of audits and expenses while providing the highest quality of audit reports. PharmSol has in-house team of Auditors who are accredited with various certifications including APIC/CEFIC/ASQ CQA/IRCA. PharmSol has successfully conducted over 900 GMP audits across the globe till the date.

We are thrilled to officially announce the launch of PharmSol`s newly designed multilingual website:www.pharm-sol.com. Our new website provides a clear message about who we are, what we stand for and about our solutions. The website also boasts a clean design and intuitive and consistent site-wide navigation system with improved menu functionalities that direct you to the most relevant information for your needs.

For your convenience we have extended our solutions by sharing the Audit reports. Please check our GMP Audit Reports page where you can choose available reports of products for further purchase https://pharm-sol.com/gmp-qp-audits/