

Mindteck offers analytical instrument qualification services to life sciences instrument manufacturers

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Mindteck, a global product engineering and IT solutions major, provides consultative services to chromatography instrument manufacturers to support development of qualification methods and automate them for use in pharmaceutical labs.

Analytical Instrument Qualification (AIQ) has four phases referred to as 4Q: design qualification (DQ), installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).

The company has its domain focus for analytical instruments industry and has two advanced Analytical Instrument Laboratories, to execute R&D assignments and conduct testing on a variety of instruments.

AIQ is required by many national and international regulations including quality standards: ISO 17025. Qualification of analytical instruments in the pharmaceutical industry is governed by GMP guidelines (EU GMP Guide, Annex 15 to EU GMP Guide, and FDA's Code of Federal Regulations, 21 CFR Part 211). Pharmaceutical industry uses a large number of complex analytical instruments and generates a huge amount of data. Various components of the pharmaceutical industry like R&D, manufacturing and quality control rely on the precision and accuracy of analytical instruments to obtain valid data. Regulations such as AIQ require the companies to establish procedures that will ensure the fitness of these instruments.

In 2006, the United States Pharmacopoeia (USP) published a new General Chapter--1058, Analytical Instrument Qualification, which has been adopted in the first supplement of USP 30 in 2008. Analytical instruments used in laboratories are required to be qualified and documented as suggested in these regulations.

"As part of our Life Sciences practice, we focus on regulatory compliance. The requisite knowledge and end-user perspectives are provided our chemists, instrument engineers, biotechnologists and biochemists. With proven experience in the domain we have built offerings to provide regulatory expertise in many areas of analytical instruments," Dr K V Krishnan, Practice Head, Life Sciences, Mindteck told Pharmabiz.

Instrument manufacturers engaged in automating the AIQ tool look for reliable partners since AIQ tools are strategy products. Unless convinced with the domain knowledge, they do not prefer to outsource such projects. "We have been able to amply showcase our knowledge of the client's product, process and technology and supplement it with our laboratory infrastructure and team skills that are required for execution of such critical projects.

Mindteck developed the methods that meet FDA specifications, provided samples and required documentation along with the product training to their field service engineers who will be actually carrying out the AIQ at their customer labs,” said Dr Krishnan.

Though analytical instrument qualification primarily originated with pharmaceutical industry as a value added activity, it is used today by petrochemical and environmental segments too. Since personnel with knowledge of analytical chemistry, regulatory requirements and analytical instrument testing are required, it is not simple to such resources, said Dr Krishnan.

Modern laboratories have a suite of instruments from simple to complex automated. Moreover, analytical instruments that are method specific and the conformity bounds are determined by their application require a full qualification process as suggested by FDA and EU. These instruments are HPLC, Mass spectrometers, GC, Atomic absorption spectrometers, Electron Microscope, Micro-plate readers, Thermogravimetric analysers, X-ray fluorescence spectrometers and Elemental analysers.

The latest trend is to use a single fully automated and harmonized system for qualification of all the primary lab instruments. This could lead to a paperless automated quality systems and cost savings apart from ensuring less instrument downtime.

There are many challenges like limited availability of qualified and experienced resources, regular and periodic introduction of multiple types of instruments with modern accessories, changing regulatory requirements and multiple regulations across continents.

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