VEEDA EDGE

Change in Regulators Outlook towards Indian CROs

In the process of India aiming to become Pharmacy of the World, the Indian Pharmaceutical & CRO Industry is posed with the challenge of maintaining adherence to the requirements of various Regulatory Authorities like USFDA, EMA, UK-MHRA, WHO, ANVISA etc.To stay in tune with the changing regulatory requirements, it is imperative for Indian Industry to grasp the ever-changing Regulatory expectations; perennially evolving Regulatory Inspection methodologies and Regulators outlook in spirit.

With the evolution of Indian CRO industry, various Regulatory authorities kept changing their Inspection methodologies in line with changing requirements and also the experience they had duringlocal Inspections. Initially the inspections were primarily based on Traceability aspects for over a decade to evaluate whether a study / product development can be reconstructed at the site of Inspection, based on the submitted dossier. The Inspection scenario in general for Pharmaceutical Industry and Clinical Research fraternity emerged into evaluation and identificationof Research Misconduct and Fraud by adapting a risk based approach in the last few years. Risk based approach included extrapolation and Investigation based on observed issues.

The most recent trend is evaluation of Data Integrity by delving into scientific aspects of study conduct in addition to Compliance assessment. This type of evaluation by Regulatory Inspectors aims at evaluating whether systems are designed to maintain accuracy and consistency of data over its entire life cycle or not. This becomes a highly reliable qualitative indicator of process performance in an organization.

In such an evolving scenario of stringent evaluations by Regulatory authorities, Veeda CR underwent 14 USFDA Inspections since Jan-2015. Apart from evaluating Compliance and Traceability aspects, the Inspectors also focused on evaluating if any research misconduct and Fraud took place or not. Veeda CR underwent 2 Data Integrity Inspections from USFDA (Feb-2016& Mar-2017). 13 out of 14 Inspections ended without any FDA 483s and one Inspection got closed with a 483 under no action required category. 11 Inspections were for Patient-PK studies at clinical trial sites and 3 were for Healthy volunteer BA/BE studies. Veeda CR faced an ANVISA Inspection in 2015 and a UK-MHRA Inspection in Dec-2016 with positive outcome.

Sr. No	Year	Scope	No. Of Inspection	Outcome
1	2015	Healthy volunteer BE studies	1	No 483s
2	2015	Patient PK Studies	1	No 483s
3	2016	Healthy volunteer BE studies	1	No 483s
4	2016	Patient PK Studies 5 Inspections	5	No 483s
5	2016	Patient PK Studies 1 Inspection	1	483s No action required.
6	2017	Healthy volunteer BE studies	1	No 483s
7	2017	Patient PK Studies 4 Inspections	4	No 483s
		Total	14	

Veeda CR thus underwent rigorous evaluations from USFDA and other authorities in the last decade from the perspective(s) of:

- Traceability
- Regulatory Requirements Compliance
- Systems and process adequacy along with risk assessment
- Data Integrity

With organizational belief in Integrity and all-time readiness driven approach towards achieving higher compliance and maintaining high quality standards, Veeda Clinical Research Pvt. Ltd., has completed dosing of approximately 30,000 healthy subjects and500 patients;bio analysisof 1.4 mil samples during the last 5 years.We at Veeda are committed to strictly adhere to the Regulatory expectations and shall keep adapting our systems for staying compliant.

Pride is concerned with who is right Humility is concerned with what is right

Ezra Teft Benson

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