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A Holistic Approach to Quality in the Pharmaceutical QC Laboratory

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Abstract:

The primary goal of an effective quality system is to get product to a patient and to assure an uninterrupted supply of that product. In ICH Q10 terminology, this is called product realization. In return, the company makes a legitimate profit, a substantial part of which is placed back into the R&D program to produce additional life-saving and enhancing products.

The Quality Control (QC) Laboratory together with analytical Research and Development (R&D), probably represents more than half of the resources needed to get and keep a product into the market place. In the past few years, with data integrity taking front stage in inspections, the laboratory has once again come under close scrutiny. The outcomes in many cases have ranged from unsatisfactory, to discovery of outright fraud.

This article looks at analytical data governance and quality through the prism of the Analytical Procedure Lifecycle. It considers current drivers (continuous manufacturing, real time release testing, process vs product control); developing guidance (ICH Q12, 13, 14, Data Integrity final and draft versions) and data governance. The author's intention is that through understanding the drivers of the current situation and by analyzing past errors, to have a model for a holistic approach to Quality in the pharmaceutical Quality Control Laboratory.

Introduction

Earlier this year, FDA released a draft guidance on continuous manufacturing. FDA's vision encompasses Process Analytical Technology (PAT) , Real Time Release Testing (RTRT) and modern analytical technologies. During the past 30 years, there has been a move from product control (finished product sampling and testing) to process control (critical process parameters are adjusted within a defined range to ensure critical quality attributes are achieved) using modern in-line, online or at line analytical techniques such as NIR, Raman, NMR, MS.