Turning Data into Knowledge

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It takes on average 12 years to bring a new pharmaceutical product to market at a cost in excess of $1 Billion. While this is without doubt a staggering figure it looks set to increase as new treatments become more complex and focused in nature This has lead to products which require greater development resources and treat a smaller range of symptoms. Rigorous quality procedures, designed to protect patient health, have to date demanded a quality by lab test approach to production which leads to inefficient processing, delays in product release and large amounts of documentation.

Recent initiatives by the Food and Drugs Administration and the industry itself have asserted that the solution is to change from a quality by 'lab test' to a quality by design approach to development and manufacturing. The use of Process Analytical Technology (PAT) is seen as key to better understand the complex nature of new products, current manufacturing processes and offers a mechanism by which processes can be controlled to maintain quality rather than final product testing.

One major barrier has been the lack of integrated solutions and a data standard to pull together the many different facets required to provide a PAT solution (A common platform to integrate multiple analytical instruments, data synchronization, storage of data in a common format and the ability to pass or extract data to third party platforms.)

So what is being done to move things forward?