Qlik® for Life Sciences: regulatory compliance, drug safety and pharmacovigilance

Consistent and transparent mitigation of risk

Challenge

Many companies in the life science industry treat each compliance requirement as a separate management program. Whether it's clinical trial reporting, manufacturing lot tracking, pharmacovigilance, or any other requirements from a wide array of possibilities, these programs tend to proliferate. What's more, each program often develops its own approach to gathering data and reporting to regulatory authorities. This increases the cost of compliance as well as the potential for mistakes. A better approach is to standardize compliance by building it into your business processes. This is where Qlik can help.

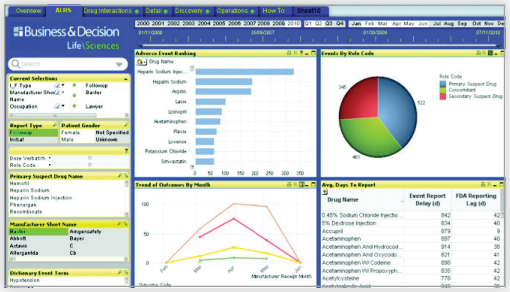
Solution

High-performance, self-service BI apps built for Qlik with Qlik partners address and demonstrate capabilities related to compliance in the life science industry. Using Qlik, you can implement an enterprise compliance architecture for collecting, organizing, and analyzing large volumes of compliance data and reporting to the appropriate regulatory authorities in a standardize manner. You'll be able to:

- Improve regulatory oversight for a streamlined product approval process
- Optimize your pharmacovigilance with improved data analysis
- Leverage the Qlik associative data model to intuitively analyze adverse reactions
- Monitor critical KPIs such as serious flags, proportional reporting ratios, and timeline for report to FDA (including the number of late reports and reasons why)
- Track and audit your standing across multiple compliance programs to avoid oversights and improve overall compliance effectiveness
- Use trending and what-if analysis to gain insight into your compliance efforts and make continuous improvements over time
- Streamline legal reporting and project management
- Benchmark drug safety measures

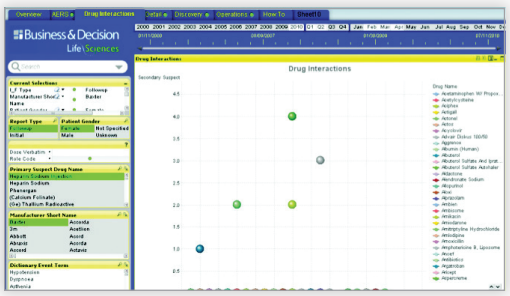
Customer examples

- To ensure post-market drug safety, the pharmacovigilance business unit at Genzyme uses Qlik to monitor adverse event reports that come from various channels across the UK – including healthcare professionals and patients. With automated monitoring, Genzyme has vastly improved follow up reports. Employees use the application to better manage their workloads and maintain compliance with the company's standard operating procedures for adverse event follow up. Using the application, Genzyme can glean more precise information about adverse events, such as the number of events reported against individual products, and whether they are in clinical trials. The application also shows which hospitals or healthcare providers have reported adverse events.
- Lundbeck uses Qlik in clinical settings to optimize reporting and data consolidation for trials and regulatory reporting. With Qlik, the company can more rapidly analyze and report on information from many different sources. The many new analytical capabilities assist in clarifying interrelationships, which would otherwise be difficult to discover in a timely manner.



Example: Pharmacovigilance – Monitoring app contributed by partner Business & Decision

> "In order to be competitive, it is important for any business concern to meet the user's needs as quickly as possible, which a flexible system like Qlik allows for. For Lundbeck it is at the same time indispensable to be able to monitor the quality of data as well as provide an overview of the many study results coming in continuously. We therefore need to make information accessible to users, so that they have the best possible basis for making decisions."
>
> — Jack Jakobsen, Application Manager Specialist, Lundbeck



Example: Drug Interactions, Safety Data – App contributed by partner Business & Decision

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