CASE STUDY | CSL Behring

A New Approach for Product Quality Reviews

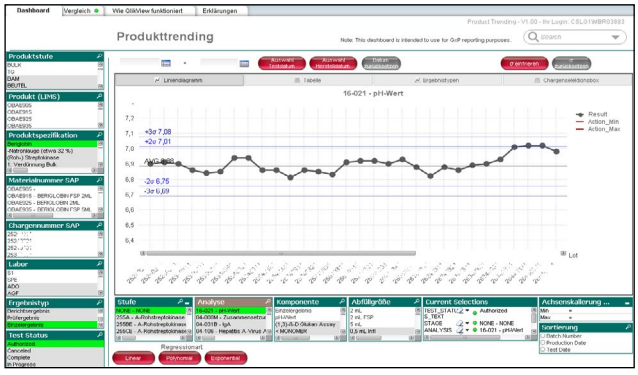
Annual Product Quality Reviews (APQRs) stipulated by approval authorities are obligatory for pharmaceutical and medical technology companies. The effort involved is considerable and they must be completed within a tight timeframe. Several company departments are burdened by manual, error-prone research. The Manufacturing Intelligence approach used by pharmaceutical company CSL Behring shows that there is another way.

CSL Behring has an extensive, diverse range of products for the treatment of coagulation disorders, immune deficiencies, tissue repair, and for use in intensive care situations. The company must create 29 different APQRs of up to 500 pages every year. As part of the research process, data from various different source systems in different departments is compiled, output, formatted, and presented in a uniform layout. The variety of processes, products, and areas means that in parts there are only a few similarities.

Complex manual processes

»We have to create APQRs for every product once a year. We are under tremendous pressure to complete time-consuming research across several company departments. The employees involved are always challenged anew to take account of the special features of the product in question. This is another potential source of error that we have to eliminate using additional test methods. All in all, the effort involved is very high,« says Helmut Rector, Quality Assurance Manager eSystems at CSL Behring, describing the requirements.

For each product, it is necessary to compile data on raw materials, batches, deviations, supplied countries, and



»We work with a wide range of IT systems in the GMP department. QlikView really stands out from the other applications. It's simple and intuitive to process even complex research,« says Helmut Rector, Quality Assurance Manager eSystems at CSL Behring.

CSL Behring

Biotherapies for Life™

With 11,000 employees, CSL Behring is one of world's leading manufacturers of plasma derivatives. The company is committed to saving lives and improving the quality of life for people with rare and serious diseases worldwide. CSL Behring is a global producer and distributor of a range of plasma-based and recombinant therapies for the treatment of coagulation disorders, immune deficiencies, tissue repair, and for use in intensive care situations.

much more and include various departments such as the laboratory, bottling plants, logistics, change management, or the department for pharmaceutical/technical complaints. It is necessary in many cases to first determine basic data from the manufacturing plant on the batches produced before it is possible to request information on the associated packaging. The often multi-level information chains are very time-consuming and take up a large amount of the processing period. It means that there is little time for detailed overall evaluation of the report at the end of the processing period.

In the past, the manual effort was also very high because the different IT systems – from the commercial SAP system right through to the LIMS laboratory system – lacked standardized interfaces. »We looked for a consistent solution that would help us ensure constant data quality for regulatory requirements,« says the QA manager.

»The innovative Manufacturing Intelligence solution enables cross-department big data analyses while avoiding the need to implement costly data warehouse concepts. We are transferring the analytical function away from the IT office and putting it back to the individual departments,« says Dirk Bode, CEO of fme AG.

One system for all data sources

The IT department initially had reservations about introducing a further BI solution. Because of this, a hands-on workshop was organized to clarify the possibilities of the fme approach. A useable dashboard based on the BI system QlikView was developed within just three days. It features its own interface based on real company data from two databases and was created in accordance with the individual requirements of the GMP department. The IT department was immediately won over by how simply, intuitively, and quickly the solution could be implemented along with the reduced IT burden and very short development cycles for add-ons and enhancements.

»The new application acts like a vacuum cleaner in that it brings together previously isolated data islands of the operational IT systems. It is now possible to automatically query the different source systems from SAP right through to LIMS at the push of a button. It is no longer necessary to deliver information manually,« explains Helmut Rector.

Major savings alongside high quality

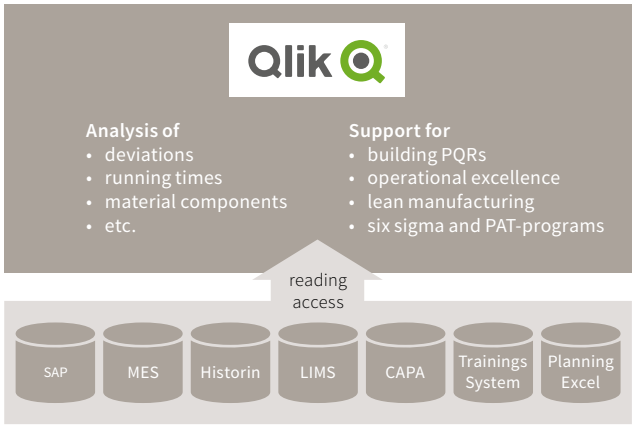
At CSL Behring, increasingly more data is being collected in a central business warehouse. In the background, the QlikView system collects data from the different relational databases and consolidates the content in a large, multi-dimensional database, which is then kept in the main memory. Data operations now run at top performance thanks to in-memory technology.

»We work with a wide range of IT systems in the GMP department. QlikView really stands out from the other applications. It's simple and intuitive to process even complex research,« says Helmut Rector, praising the new system. Because many laborious manual activities now run in an automated, rule-based procedure, the level of effort has been reduced and the evaluation quality has increased. Previously when creating APQRs, numerous individuals had to leave their actual work due to many more or less short activities. This is no longer necessary. The QA manager estimates the time savings for the entire location to be the equivalent of two full-time employees.

In addition to these savings and the more valid data basis, he believes the main benefit to be the new analysis options, for example, the deviation analyses.

Completely new analysis options

Previously, it was not always possible to clearly determine which products were affected by which deviations using standard reports. For example, it required a high level of additional research effort in order to determine whether



»Information at the push of a button is now feasible. We now have a self-service process where we can track typical questions regarding the reasons for deteriorating KPIs or whether different deviations have the same causes,« reports Helmut Rector.

a deviation that arose over a year ago could still affect a current product. »The problem was the extensive batch trees. It meant that several employees had to monitor thousands of messages. QlikView allows us to track these kinds of connections at the push of a button,« says the QA manager.

One basic difference between QlikView and other BI systems is QlikView's associative analysis instead of rigid reports. While many questions had to remain open for earlier standard reports, ad-hoc evaluations have now become standard procedure. »It always requires a lot of effort when it is necessary to match data from multiple systems such as our quality management system and SAP. The interfaces lacked the ability to retrospectively compare production orders and batches from an earlier stage of manufacturing with deviations. Now we have the option to link quality notifications in SAP with any deviation number and track batches and materials across the entire batch tree,« explains Helmut Rector.

The move toward self-service BI

It is now possible to better deal with other issues at CSL Behring. Here, the QA manager cites the creation of KPIs and batch tracking. Audit lists in the preparation of inspections for the regulation authorities have become much simpler, too. »Information at the push of a button is now feasible. We now have a kind of self-service process where we can track typical questions regarding the reasons for deteriorating KPIs or whether different deviations have the same causes,« reports Helmut Rector.

After the Quality and Production departments had positive experience with the new analysis tool, further departments such as R&D are set to implement it, too. Other locations are also recognizing the benefits and want to implement the solution.