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QbD approach applied to PAT screening

Process Analytical Technologies (PAT) are spreading in different business area of the company and this abstract is a specific example of how the Quality by Design approach is also used to cover this PAT implementation. Currently, a component of a GSK adjuvant is quantified by dry cell weight and the value obtained is needed to pursue the production process. Thus, to improve the performance of the process by decreasing lead time, different PAT were screened. To do so, Quality by Design was used as a framework to perform a Proof of Concept coupled with a method screening.

First the Analytical Target Profile was used to define the expected performance of the different analytical parameters, including the range to be covered and the specificity of the method. Then the Business Drivers were used to define the constraints.

A theoretical and experimental method screening was performed considering different PAT :
- Raman (Kaiser)
- Raman (Tornado)
- FTIR (ReactIR)
- UV-Vis (Asuryan)
- NIR (Hyternity)

The experimental screening was used to optimize the parameters of the different PAT. It was performed offline with manufacturing samples. The aim was to see if at least one of the tested technologies was able to follow the compound of interest. For each technology, chemometric models were built.

After the experimental screening, an a posteriori method screening was performed considering the results of the chemometric models for each technology. This screening was successful and the most suitable technology was determined based on ATP and business drivers requirements.

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