

Datamining and Smart Services @ Bosch Packaging

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PURPOSE

Regarding state of control of its quality, today's pharmaceutical industry is still behind the automotive, the aerospace or the semiconductors industry. Although, guidelines such as ICH Q 8/9/10, PAT, QbD and CPV aim for a better control of the current manufacturing processes only few successful advanced controlled strategies are known today (1). In case of an out of specification result (OOS) the necessary root cause analysis (RCA) takes only a few selected critical process parameters (CPPs) into account. Interactions or slight variations of apparently insignificant variables are hard to detect by currently used methods (2). The following study investigated the use of datamining tools for detecting correlations between process variables and end product quality of pharmaceutical products.

METHODS

Historic process data from lab scale fluidbed granulators (Solidlab 2, Hüttlin GmbH, Germany) and from production scale fluid bed coaters (HDGC, Hüttlin, Germany) were analysed. For data pre-treatment, data mining and sensitivity analysis, a self-developed software tool kit was applied.

RESULTS

Process data were arranged, cleaned and pre-treated for noise reduction. In the following, process models were built and investigated via sensitivity analysis. By the established method various events caused by the condition of the equipment (e.g. spray system, filter) the environment (air handling) and the operator (manual intervention) were detected.

CONCLUSION

In the current study it could be shown that the proposed data mining method is able to quickly detect sources of variability. Nevertheless, the efficient development of such process models is dependent on reliable and clean data. Therefore, the equipment needs to be prepared on a hardware as well on a software level. That means, sufficient sensors have to be in place. Processes need to be accurate and simple to control. Finally, a proper data warehousing has to allow further data

processing. The know-how availability of data scientists, process specialists and engineers determines the degree of success in process model development.

ACKNOWLEDGEMENTS

The authors would like to thank the Bosch divisions of Corporate Research (CR) in Renningen & Palo Alto, and Packaging Connected Industry (PA/CI) for their support.

REFERENCES

(1) Kurtyka, B, FDA, AAPS annual meeting, 2012

(2) Meneghetti N, International Journal of Pharmaceutics (505), 2016