Process Monitoring in Pharmaceutical Manufacturing Units using Data Based Model

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Motivation

In process industries, performance monitoring and apriori detection of faults are important for quality control and process safety. These process parameters are measured at different time intervals; for example, measurements for pressure and temperature are often available every second, whereas concentrations are available only hourly.

Since most pharma products are manufactured in batch mode, any upset in process parameters from their specified limits not only results in the entire batch being unusable but also results in additional costs towards disposal. So a clear need exists for an early warning system to detect faults in either the process or its equipment.

Problem

Portable Continuous Miniature Machines (PCMM) manufactures drugs in bulk quantities while reducing manufacturing costs significantly. In PCMM, there exist several stages of operation which are executed sequentially, each stage being characterized by its own set of parameters. Any deviations among these process parameters at any time instant, can lead to product 'failure' which in turn will lead to an additional operational cost through loss of raw-materials and additional operational resources for transforming the failed product into an environmental-friendly 'disposable product'.

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Due to the proprietary nature of the PCMM, no knowledge of the underlying processes was made available. The challenge was then to develop a fault detection system using only the process parameter data. Complicating matters further, the nature of the relationships between these variables i.e. linear or non-linear was not known apriori.

Solution

Over thiry different parameters and their timestamped measurements were made available as part of the PCMM. As first step, these process parameters were categorized into parameters which had a direct influence on the process and those which had an indirect influence on the process.

The models were developed for two scenarios:

1. Considering all parameters together, leading to implicit models
2. Regressing only parameters which had an indirect influence on those which had a direct influence leading to explicit input-output models

Using the given process data, models were developed using Principal Component Analysis (PCA) [1],[2] and kernel Principal Component Analysis (kPCA) [3] to identify linear and non-linear relationships respectively.

Using the developed regression models, a metric was developed to identify abnormal operation of the PCMM through K-fold cross validation results. This metric was then used to benchmark the various modeling strategies and best-model was subsequently employed in process monitoring.

The developed solution was demonstrated to the client as a feasible approach for the PCMM monitoring application. This resulted in deep technical and domain related discussions with the client to improve the process.

References

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