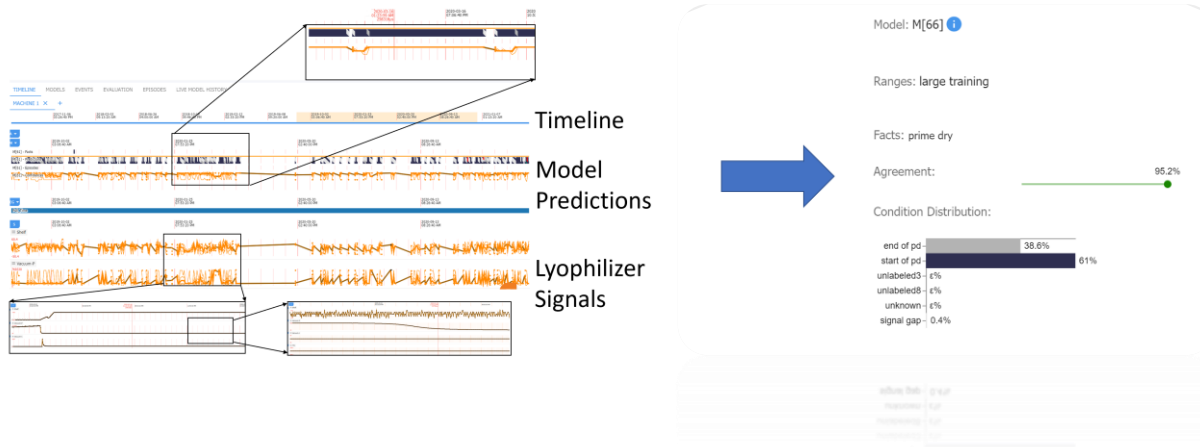


## Machine Learning for Prediction and Optimization of Lyophilizer Equipment Performance Collaboration with Falkonry

The machine learning (ML) algorithms can be applied to the lyophilization process and be used to predict and quantify different phenomena in the lyophilizer during all stages of freeze-drying: freezing, primary drying, and secondary drying. The information can be further applied for cycle optimization and reduction of operational costs. Notably, the machine learning algorithms' potential "on-the-fly" usage for equipment failure detection is demonstrated. An example of big data analysis is shown based on the lyophilization cycle data recorded during the several-year period.

Falkonry machine learning system is used to perform the data analysis, and its effectiveness is demonstrated on the lab-scale freeze-dryers using the output data recorded during four years of operation. The ML algorithms allowed to deeply analyze the data and extract various metrics used to estimate the performance of the equipment. Specifically, the system successfully detected all the phases of lyophilization: freezing, primary drying, and secondary drying. Eventually, the duration of each phase was calculated, and the efficiency of equipment usage was inferred. In addition, the ML system was trained to determine the excipient being dried and to detect the equipment failure due to the issue with shelf temperature control. It was shown how the obtained information could be potentially used to increase the efficiency of the lyophilization cycles.



**Figure 1: Falkonry ML interface: events detection during the operation of lyophilizer**

Effective ML-based models for predicting and optimizing lyophilization cycles can correctly identify specific lyophilization events and differentiate between solutions used in freeze-drying cycles. The developed models will be adapted for identifying and alerting the lyophilizer users of issues in real-time ("on-the-fly"), which paves the way to more time-and cost-effective freeze-drying cycles.