Are You Running Your Equipment or is Your Equipment Running You?

The Difference is Often a Matter of Predictive Maintenance

A White Paper by Lucas Vann, Nirav Shah, and James Moyne

Abstract

Applied Materials, the innovator of the SmartFactory Rx suite of software products, is taking the lead on leveraging Industry 4.0 principles and technologies, such as Industrial Internet of Things (IIoT) and advanced analytics, to optimize manufacturing process performance, asset utilization, and supply chain. SmartFactory Rx Analytics & Control (A&C) collects real-time data from interconnected sensors and learns equipment behavioral patterns using machine learning techniques, connecting physical objects to a digital world. With such a cyber-physical system, process and condition monitoring can be fully integrated on one platform for operators to monitor process performance and for maintenance users to analyze equipment health. This integrated analytics and maintenance system enables maintenance to be accurately predicted and prescribed to prevent unexpected machine breakdowns, improve asset utilization, and reduce costs.

The Current State of Maintenance in Pharma

In the highly regulated pharmaceutical industry, the ability to maintain equipment in a validated state makes up a large part of the overall compliance effort.[1] In this environment, the calendar-based preventive maintenance (PM) approach is still the most widely accepted. This maintenance approach often leads to either reactive maintenance, performed after the unexpected failure and shutdown occurs, or unnecessary maintenance, which creates more work than necessary to increase equipment reliability without providing additional benefits. In fact, these types of programs often tighten maintenance schedules in response to unplanned events and deviations, which can result in inadvertently introducing even more premature failures.[2] Besides complying with regulatory requirements, many in the industry struggle to strike the right balance between over and under-maintaining equipment. Overly vigorous maintenance schedules are also costly and can have a negative impact on cost-benefit, reliability, and compliance.

The pharmaceutical industry is asset-intensive and continues to move to a 24/7 schedule. One of the primary operational risks to the business is the unexpected failure of assets and downtime, resulting in lost productivity.

The Shift Towards Predictive Maintenance

To ensure high overall equipment effectiveness (OEE) and equipment availability for production, pharmaceutical companies have gradually adopted a predictive maintenance (PdM) approach, especially for their critical assets.[3] This field has been studied for decades, however, PdM has gained wider acceptance as regulatory agencies become more supportive of science and risk-based maintenance techniques.

COMPONENTS OF PREDICTIVE MAINTENANCE

PdM consists of a set of modern technologies that effectively monitor equipment performance and schedule necessary maintenance interventions in a timely manner. In contrast to reactive and preventive maintenance, PdM offers a predictive, condition-based approach that detects potential failures well in advance and plans appropriate actions accordingly. This approach eliminates the need to shut down equipment, resulting in increased equipment uptime.

Condition monitoring, a major component of PdM, is a methodology of monitoring equipment conditions and identifying potential faults in advance of failures. This methodology uses techniques such as vibration, acoustic emission, ultrasound, infrared thermography, and oil analysis. These techniques are normally implemented on critical assets, either in real-time or offline in an isolated fashion. With condition monitoring, experienced maintenance users play a crucial role in interpreting data and determining what is contributing to potential failures. It should also be noted that because prediction is the foundation of PdM, it is critical that the correct methods are employed to obtain future probabilities of failures.[4]

Figure 1 shows the evolution of maintenance—from reactive maintenance to prescriptive maintenance. Building on predictive maintenance, prescriptive maintenance provides the capability to advise on cause and effect relationships and prescribes timely maintenance actions.

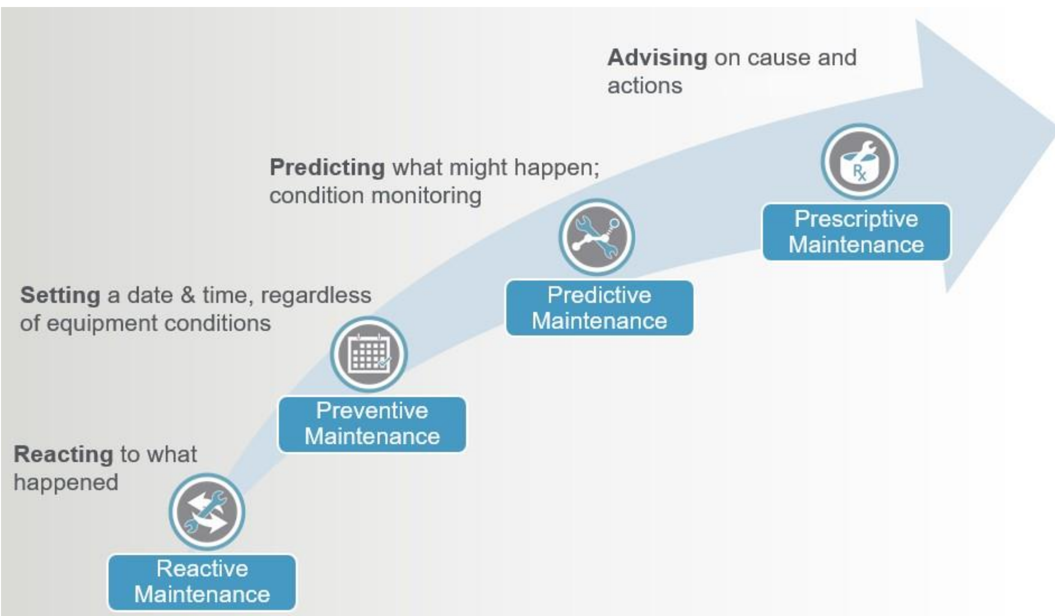

Figure 1. Evolution of Maintenance

New Era of Maintenance

In recent years, several initiatives with the same purpose have been proposed to promote the use of advanced technologies to revolutionize the manufacturing sector—for example, Smart Manufacturing (USA), Industry 4.0 (Germany), and Made in China 2025 (China). The key enabling technologies of these initiatives, for instance Industrial Internet of Things (IIoT), Augmented Reality (AR), Virtual Reality (VR), machine learning, and big data analytics, have already started to impact many areas of the pharma industry, including R&D, manufacturing, and supply chain. Although implementing these emerging technologies is still in its infancy, many pharma companies have started creating strategies and roadmaps to develop enterprise solutions for digital transformation to drive productivity, quality, and compliance.

As innovative technologies are applied to maintenance, early adopters are capitalizing on the massive amount of equipment data and interconnected cyber-physical systems for monitoring, diagnostics, and prognostics. Integrating IIoT and analytics with maintenance represents a huge opportunity for manufacturers to revolutionize how maintenance can be performed more intelligently to avoid costly and catastrophic machine failures.

Advanced Analytics and Maintenance

Based on research from Gartner and McKinsey, a large portion of the data (both structured and unstructured) collected from manufacturing is unused due to the complexities of the sensors and systems involved. For the data that has been examined, the information is mostly used to detect and diagnose anomalies not for prediction and optimization. This is typically due to a lack of expertise in predictive and prescriptive analytics and a missing strategy for advanced maintenance.

As mentioned previously, commonly used PdM techniques on critical assets, such as condition monitoring, are most often based on a limited number of sensor attributes, such as vibration or load, that normally occur in silos. The data generated is usually not shared with other applications or systems; therefore, these approaches do not provide a sufficient understanding of an asset's propensity to fail.[5] As such, to implement an effective solution, the effort must not only overcome data integration challenges but also enable the correct analytics to be performed in order to transform big data into useful insights.

INTELLIGENT PROCESS AND CONDITION MONITORING

SmartFactory Rx Analytics & Control (A&C) seamlessly interoperates with existing sensors, equipment, process analytical technology (PAT) analyzers, lab instrumentation, process control systems, MES, and computerized maintenance management systems (CMMS). A&C collects data from various disparate sources, and then aggregates, contextualizes, and analyzes the data, enabling intelligent process and condition monitoring for predictive and prescriptive maintenance. A&C provides users with an array of advanced analytics, such as machine learning, to effectively monitor equipment health, analyze behavior patterns, detect anomalies, issue alarms, and fix problems before they occur. More importantly, machine learning techniques enable the condition monitoring system to evolve and get smarter over time, identifying abnormal vs normal operating conditions and learning new equipment behavior.

Figure 2 illustrates a maintenance strategy that integrates A&C with PdM. Data from multiple sources, such as operations, maintenance, and inspection, can be aggregated and contextualized into a unified data platform. Advanced analytics are then applied to extract information from the data (for example, sensor, repair, and service reports) and transform that data to machine intelligence, enabling data-driven prescriptive maintenance.

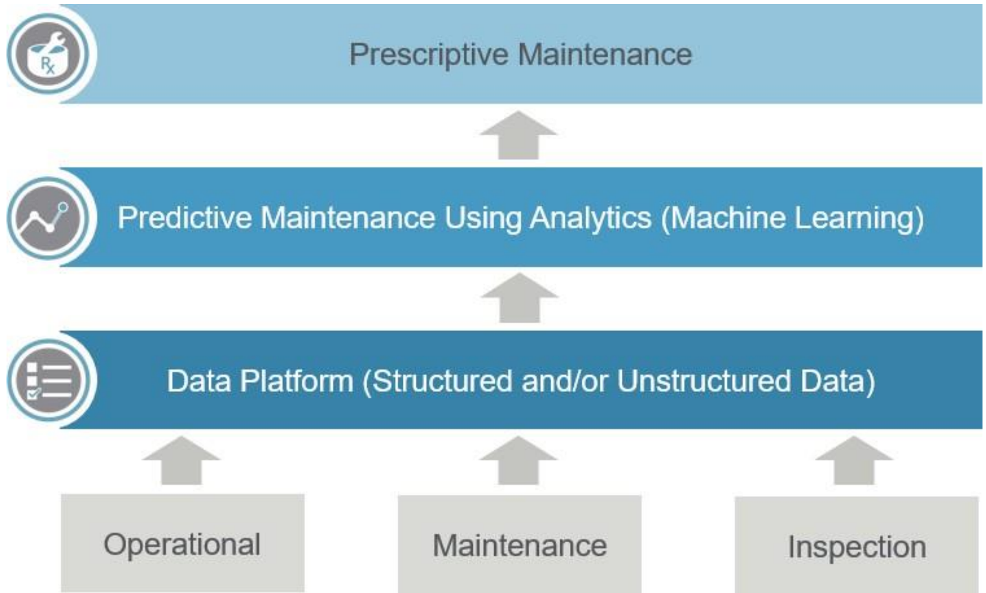

Figure 2. Analytics-driven Maintenance Strategy

WHAT PDM ANALYTICS PREDICTS & AVAILABLE MODELING APPROACHES

The purpose of PdM analytics is to predict anomalies and failures at different points in the lifecycle of equipment. Specifically, PdM analytics predicts the following:

- Whether a machine condition is normal
- When a potential failure may occur (or the initial point where a machine fails)
- When a functional failure may occur (or the point where a machine breaks down)
- The remaining useful life (RUL) of a machine

In general, three types of advanced analytics approaches exist with PdM:

1. **First-Principle or Mechanistic Modeling**. This is the best and most robust approach if the physics of the equipment is well understood and a first-principle equation is available to describe the equipment health or life. However, first-principle modeling for equipment is seldom available.
2. **Empirical Modeling**. This is the most commonly used approach as equipment data is readily available. Using machine learning algorithms, a model can be trained and validated based on historical data to predict potential failures. The model can be retrained periodically by learning the equipment behavior as new data becomes available.
3. **Hybrid Modeling**. This approach combines first-principle and empirical modeling, and therefore it possesses the merits of both techniques.

SmartFactory Rx applications in the pharma manufacturing industry have demonstrated the ease of implementing such hybrid models along with their usefulness in predicting failures with sufficient time for planning and action. Mechanistic models based on fundamental equipment operation principles (such as thermodynamics and known causal relationships) have been easily integrated into empirical multivariate principle component analysis models to generate hybrid models with increased robustness and predictability.[6]

CATEGORIES OF MACHINE LEARNING ALGORITHMS

Condition monitoring, or rules in SmartFactory Rx Analytics & Control, can be developed based on any of the above modeling approaches. A set of machine learning algorithms are available for building the models for PdM. Note, however, that the data for maintenance in this context usually comes from multiple sensors, sensors that provide multiple values simultaneously, or both (for example, spectroscopic analysis techniques). In general, two main categories of machine learning algorithms are available:

1. **Unsupervised Learning**. This category is used for exploratory analysis of the dataset and consists of the inputs but no labeled responses (or outputs). It identifies hidden patterns, groupings, and similarities and dissimilarities in data. An unsupervised algorithm learns by itself with no direct human intervention or supervision necessary. The unsupervised learning problems can be grouped into clustering and association problems. Cluster analysis, Principal Component Analysis (PCA), Apriori algorithm, and Neural Network are among the most commonly used unsupervised learning algorithms. It is always useful to start with an exploratory analysis of the historical data from equipment before developing a model for classifying an anomaly or predicting a failure. The exploratory analysis helps find equipment operating patterns (for example, normal conditions, anomalies, degradation trends, and failure modes). This information, in combination with domain knowledge about the equipment, can be used to define output response labeling for supervised learning (the next step).
2. **Supervised Learning**. This is the process for inferring a model from labeled training data. Each sample (normally a vector or a matrix) in the training data set is assigned a required output value (also called the supervisory signal). The supervisory signal could be numerical or a categorical value representing a normal, anomaly, or failure mode.
   - **Classification** is designed to classify normal vs. failure events and addresses whether the equipment might fail within certain time frames or operation cycles. Logistic regression, Software Independent Modelling by Class Analogy (SIMCA), Principle Components Analysis (PCA), Partial Least Squares-Discriminant Analysis (PLS-DA), Decision Tree, Random Forest, Support Vector Machines, and Neural Network are available in A&C.
     - **Binary classification** deals with two class problems (either normal or anomaly).
     - **Multi-class classification** differs from binary classification in classifying multiple normal and failure groups and determining whether the equipment may fail within multiple time frames or operation cycles.
   - Regression **models** are used to predict the number of operation cycles remaining and remaining useful life (RUL) as well as how long the in-service equipment may last before it fails. The algorithms that are available in A&C are Simple/Multiple Linear Regression, Logistic Regression, Partial Least Squares (PLS), and Neural Network.

Note that deep learning is a class of machine learning. It is a non-linear method, computation intensive, and one of the hottest Artificial Intelligence (AI) technologies today. It usually refers to Artificial Neural Network (ANN), or Deep nets. “Deep” indicates many layers in ANN. SmartFactory Rx A&C can deploy deep learning or neural network for developing maintenance models.

Regarding workflow, A&C provides users with a graphical (drag and drop) strategy development environment to create workflows that train, validate, and deploy models for PdM. A&C also supports integrating third-party analytics tools for condition monitoring.

A typical workflow in analytics for PdM, illustrated in Figure 3, includes the following steps:

1. **Data Preparation**. Data from sensors and maintenance records is aggregated, contextualized, and structured. It is important that data should indicate an aging pattern to predict RUL or to predict failures within a time frame. For a common 2-D dataset, the row usually represents samples and observations, machine ID, run-time points, and the column sensor measurements and labeling. Appropriate data labeling is assigned to label rows as normal vs. anomaly, a developing fault or failure in multi

time frames, or RUL. More complex data (3 dimensional or more) could be handled through appropriate data arrangements and advanced techniques.

2. **Data Transformation or Feature Engineering**. This step pretreats raw data and creates features that provide additional predictive power to the learning algorithm. For example, normalization can be performed to apply equal weights to measurements in different units. Fast Fourier Transform (FFT) can be applied to transform a raw acoustic waveform to frequency components that have more information-rich features.
3. **Model Training and Validation.** After data has been properly prepared, a machine learning algorithm can be applied to train a model. Validation, such as cross validation, is then performed to evaluate the model predictability.
4. **Model Update and Maintenance.** Due to few or no failure events in the beginning of equipment usage, models developed with limited data may not be accurate. As the equipment continues to be used in its lifecycle, a model typically needs to be updated by including the new data that has become available. Automatic retraining can be developed to enable the model to learn new behavior patterns by itself, which is self-service machine learning.

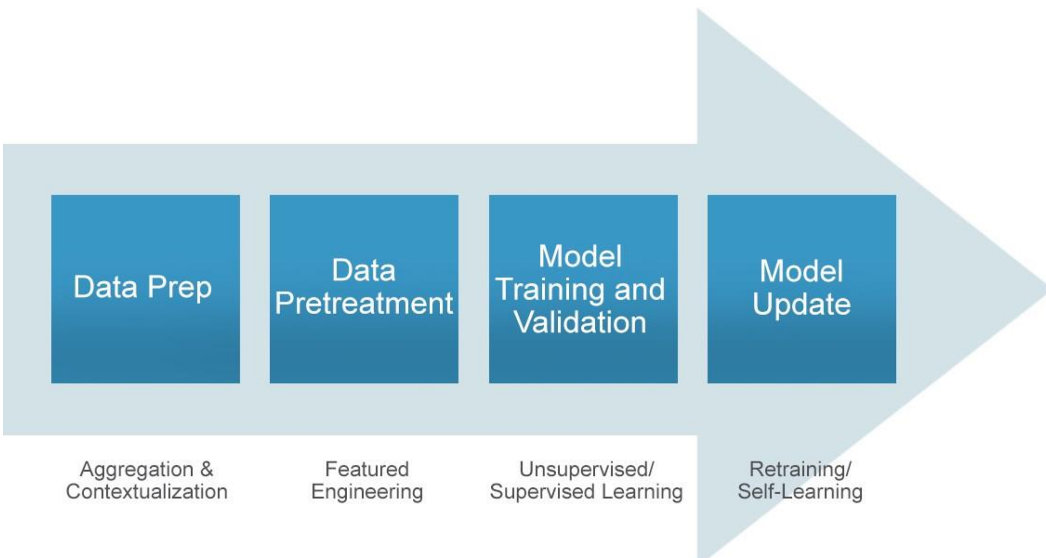

Figure 3. Machine Learning Analytics for PdM Workflow

Integrated Platform for Collaborative Production & Maintenance Operations

Analytic toolsets, such as univariate and multivariate statistical process control (SPC and MSPC) methods, have been widely used in process industries for fault detection and diagnosis, enabling predictive actions in conjunction with a control system. The methodology provides a real-time health check for production process performance by predicting a critical quality attribute, a process health index, or a maturity against a specific operating condition in a steady state or dynamic process. Any process deviation from the defined process trajectory can be detected, and alarms and alerts are generated when the process goes out of predefined static or dynamic control limits. Usually, such a deviation results from a sensor failure, equipment component degradation, malfunction, or other failure. Process and equipment are inseparable in production. Therefore, a rationale exists to combine process data with equipment condition information for more effective process monitoring and equipment maintenance.

The same methodology used to create a process monitoring system may also be used for a condition monitoring system to provide real-time equipment health information with additional equipment specific sensors (for example, vibration, thermography, or ultrasound) if available. With

SmartFactory Rx A&C, process and condition monitoring can be fully integrated on to one platform for operators to monitor process performance and for maintenance users to analyze equipment health. Figure 4 shows an example of a bioreactor health model during sterilization (SIP) over 11 runs. The relationship between jacket and bioreactor temperature and the rate of increase weight over the SIP is related to possible clean steam condensate bleeding through the mechanical seals on the agitator shaft. This mechanistic model helps identify abnormal operation and can be relayed to maintenance engineers to implement repairs before complete seal failure.

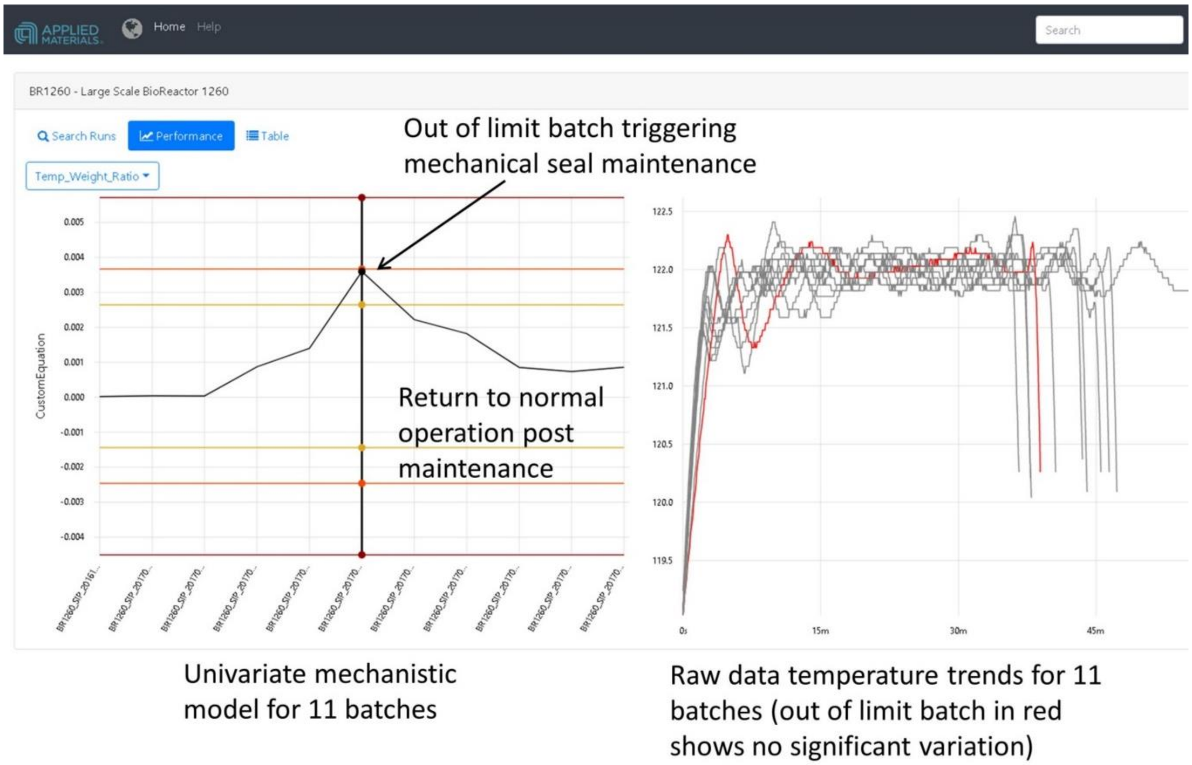

Figure 4. SmartFactory Rx Solution – Custom univariate models help identify abnormalities where raw data alone is insufficient

As illustrated in Figure 4, the predictive model, developed based on mechanistic understanding of equipment operation, exposes abnormalities that are not evident when looking at univariate raw data trends alone (such as the temperature trends shown on the right).

The integrated analytics and maintenance system identifies cause and effect relationships, ensuring appropriate support staff are notified and timely actions are taken. An overview and the execution of this relationship is demonstrated in Figures 5 to 7.

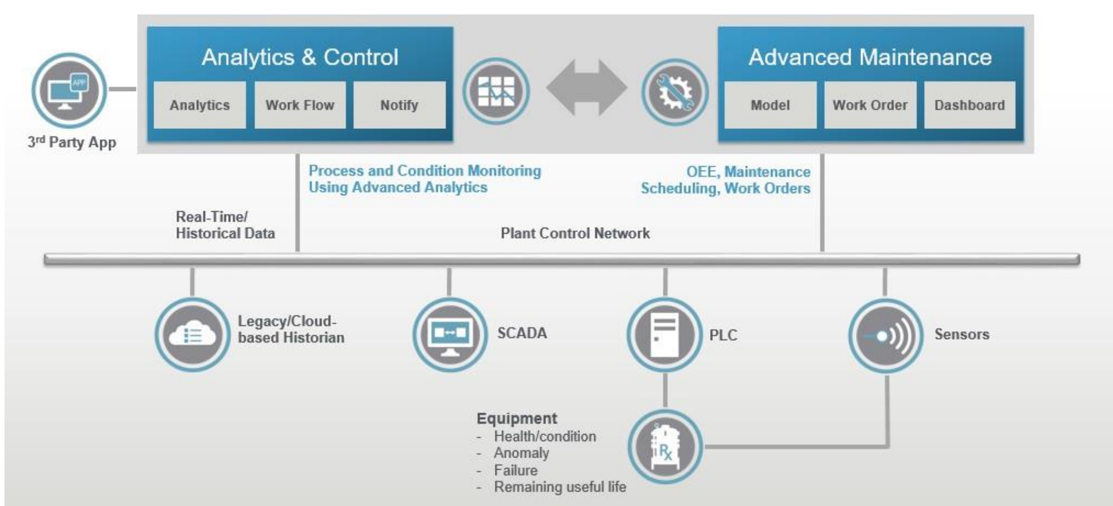

Figure 5. SmartFactory Rx Solution – Integrated Predictive Analytics and Maintenance Platform

Figure 6 illustrates the maintenance strategy for SmartFactory Rx Analytics and Control. This includes (1) Process Health Monitor and Dashboard, (2) Analytics Launcher, (3) Graphical Strategy Editor, (3a) Prediction Block, (3b) Notification Block, (3c) Work Order Block.

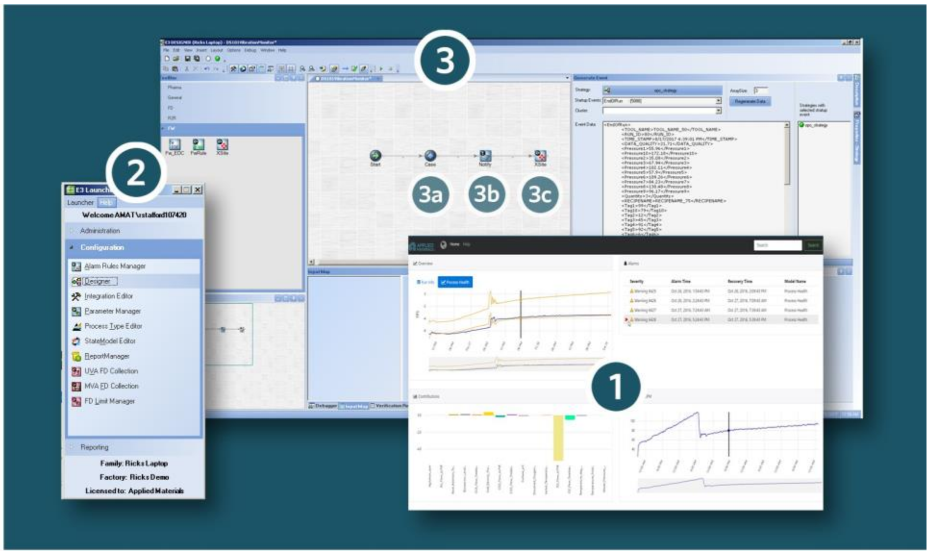

Figure 6. SmartFactory Rx Analytics & Control

Figure 7 illustrates the maintenance strategy for SmartFactory Rx Advanced Maintenance. This includes KPI Reporting (showing Maintenance, Drug Substance, Buffer).

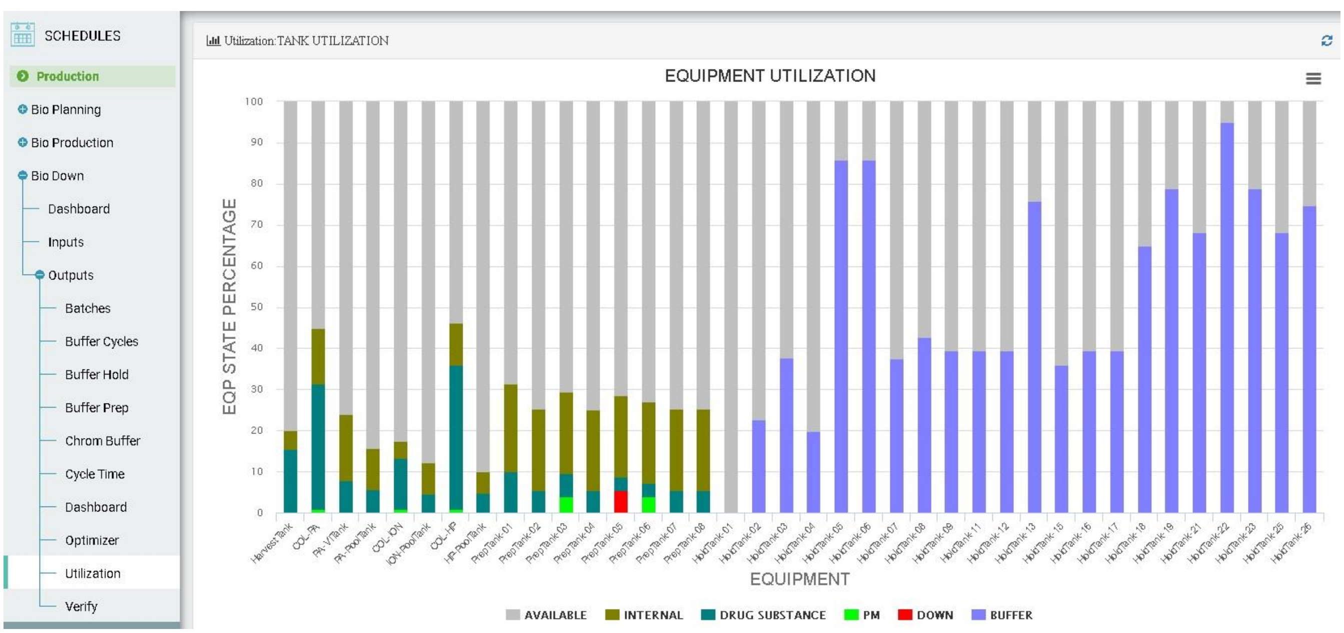

Figure 7. SmartFactory Rx Advanced Maintenance

Conclusion

Achieving a high level of productivity requires maximal equipment availability while meeting regulatory requirements. Unplanned downtimes, shutdowns, equipment failures, and reactive maintenance all must be minimized. The SmartFactory Rx Analytics & Control and Advanced Maintenance suite offers a unique and integrated approach to collaborative production and maintenance operations, revolutionizing how users perform maintenance. IIoT enables users to assess equipment remotely, and machine learning provides the ability to continually improve model prediction accuracy to optimize operations. SmartFactory Rx Analytics & Control is a powerful platform that implements PdM strategies and maximizes equipment availability and OEE. Applied Materials looks forward to working with your organization to uncover the full potential that these technologies can bring to your manufacturing operations.

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