



# Deeper Root Cause Analysis with Bigfinite



*Number of all new drug approvals by FDA in 2018 were personalized medicines*



*Reduction in average tenure of leading product per therapeutic area (2001-2018)*

# 10X

*Bio-process unit output increase in continuous processes, higher titers per Biogen presentation PDA AM (2018)*

Pharmaceutical manufacturers are under increasing pressure to perform. Almost half of the new drugs approved are now single-batch, personalized medicines. The average tenure for market-leading drugs has halved. New, intensified biotech processes, and smaller facilities, are driving dramatic changes to manufacturing capacity demand. Adding to the pressure, the pharmaceutical industry lags behind other industries when it comes to embracing technological advancements, often as a result of regulatory concerns. Taking advantage of emerging technologies to improve the efficiency of manufacturing operations is a key strategy for any company with market leadership aspirations.

Bigfinite's AI-powered, GxP-qualified platform offers a range of benefits to improve pharmaceutical manufacturing operations. The Bigfinite platform uses real-time data capture from disparate data sources and predictive models to optimize pharma manufacturing processes. The platform captures and stores data in a compliant manner, then provides capabilities to configure, explore and analyze predictive models to identify process improvements and deviation root causes.

## Bigfinite Root Cause Analysis (RCA) provides faster, smarter deviation analysis

Bigfinite's solution for Root Cause Analysis is faster and more powerful than traditional RCA solutions because Bigfinite's data sources are all connected and the platform ingests real-time, certified data. Combining multiple functionalities into a single tool also makes Bigfinite's platform a smarter way of handling Root Cause Analysis, helping to determine the main cause of abnormal events and provide immediate feedback and insights to resolve problems and adjust operations. Bigfinite monitors critical parameters across several unit operations and multiple data sources to enable a more holistic understanding of how processes are running and what is causing variations at any point in time.

# Solution Brief: Deeper Root Cause Analysis with Bigfinite

## Key advantages of Bigfinite's RCA solution

Bigfinite's RCA solution helps reduce time and resource costs by enabling faster responses to non-conformance events, faster time-to-market and shortened batch release time. It accelerates continuous process verification and improves corrective and preventive processes. Bigfinite's better root cause analysis also contributes to improving inspection readiness - having immediate access to trustworthy information from a GxP-compliant data storage to show regulators any requested information with confidence when being audited.

Bigfinite's RCA solution is a key way to gain in-depth visibility of manufacturing operations and provides valuable feedback on operational performance so companies can detect the risk of deviations before they occur.

## Solution Features

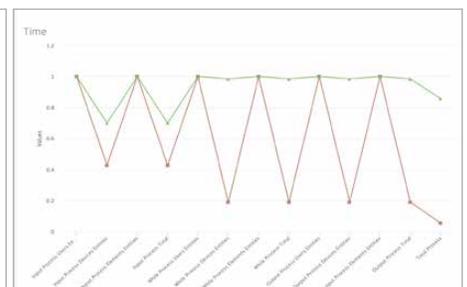
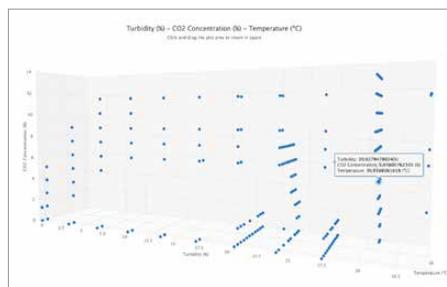
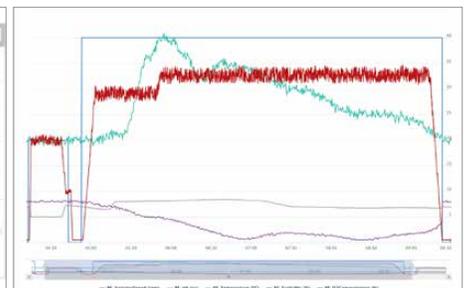
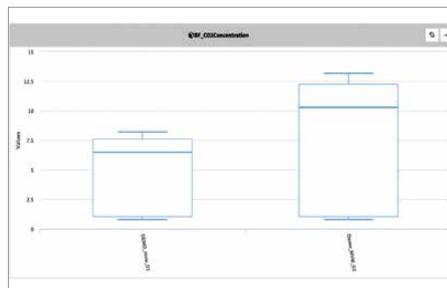
### Historical and Real-time Data

Use Bigfinite's data feeders and visualization tools to break data silos and gain a broader view of your process across various data sources with compliant data acquisition and discover and understand the cause of your previously unknown deviations.



### Automatic Data Alignment

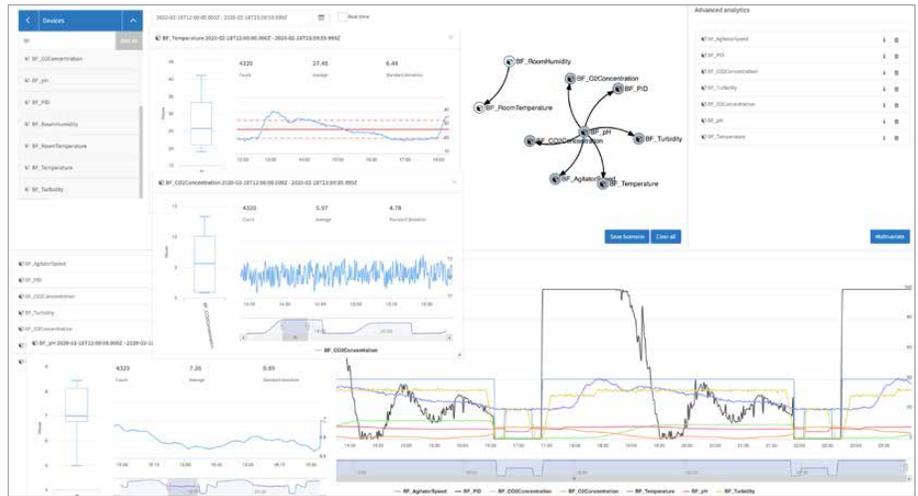
80% of data scientists' time is wasted aligning the data points of their processes to specific timestamps and normalizing them for their AI models to properly function. In Bigfinite, this process is done automatically by default. Furthermore, if you want to customize the way it is done there are also several easy-to-use tools for the alignment and propagation of the data available at any time in the platform.



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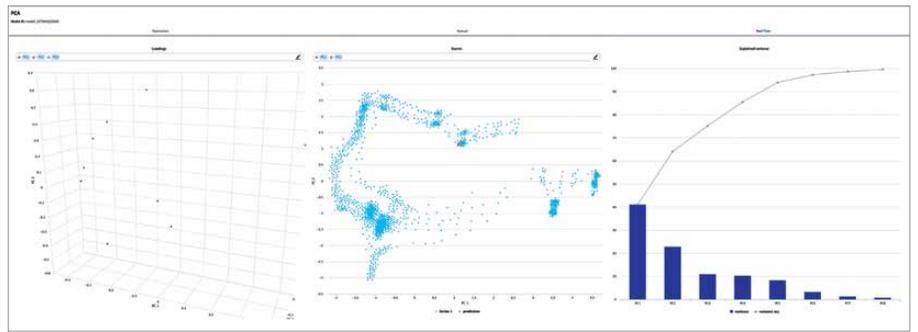
## Structured and Unstructured Data

Store all kinds of data into Bigfinite's GxP unstructured cloud data lake. From numbers to videos, from single values to complex aggregates. At Bigfinite, the nature and origin of your data is not only irrelevant, but also presents no limits.



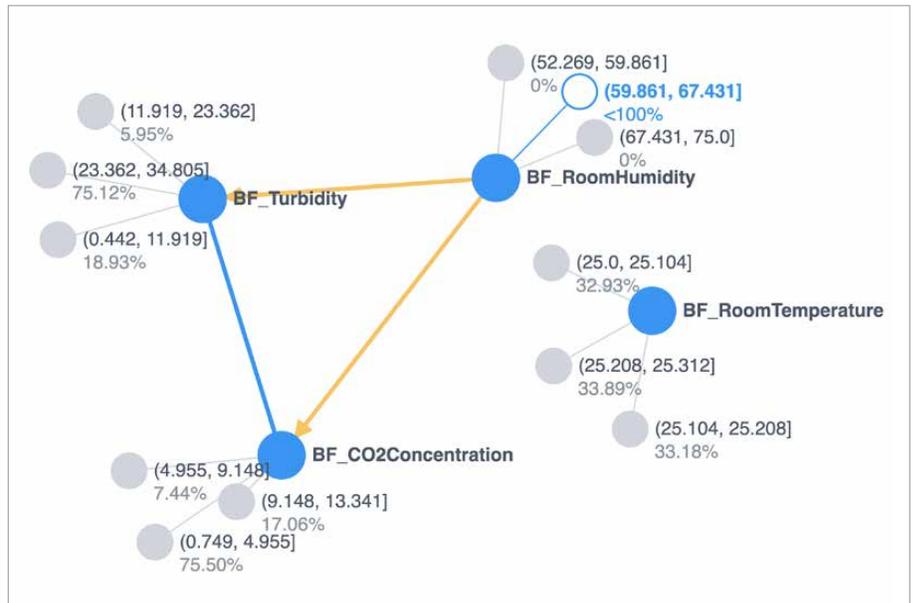
## Continuous Principal Component Analysis (PCA)

Discover and analyze the relationship between your most relevant process variables to reduce complexity and continuously control for any potential deviations and its causes, even when inside the specification limits. Use the batch fingerprint to calculate, in real-time, potential multivariate deviations.



## AI Causality Detection

Unlock the power of Machine Learning to visualize the causality between your variables and find hidden insights in a sea of data, something impossible to perceive by the human eye alone. Conclusions derived from the dependence tests and the cause-effect widgets to the anomaly detection algorithm provides clarity about the factors affecting the variation of your process.



## About Bigfinite

Bigfinite is a software provider that transforms manufacturing operations with the use of IoT, cloud, advanced analytics, artificial intelligence, and pharma 4.0 technologies focused on optimizing pharmaceutical and biotech companies. The Bigfinite analytics platform seamlessly integrates unlimited sources of structured and unstructured data to deliver actionable insights across all manufacturing sites. Bigfinite offers an intuitive way to gain meaningful operational intelligence with data by enabling real-time visibility and predictive insights in a GxP compliant manner with end-to-end data integrity. Founded in 2014, the company is based in San Francisco, California and also has a European office in Barcelona, Spain.



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