

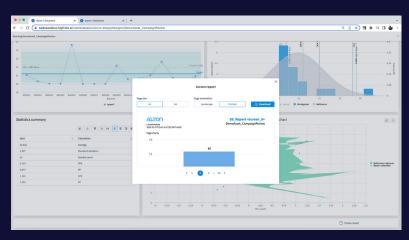
SOLUTION BRIEF AIZON UNIFY



Automatic Product Quality Review

Product Quality Review (PQR) reports are complex and time consuming due to the complexity of the data and the time Quality department spends compiling the information necessary to produce a complete report. In order to create a PQR, organizations are spending significant effort on gathering data from several different sources like Batch Records, Historians, QMS, ERP, CMMS, LIMS, MES, and others. Once the data is collected, additional effort is required to structure the report in the necessary format to follow regulatory requirements and internal SOPs. Manual processes not only cost time, but also increase the possibility of data integrity risks and subsequent audit findings.

Aizon's digital solution is easily configurable and tailored to customer procedures to enable an effortless Automatic PQR. Aizon's platform seamlessly integrates unlimited sources of structured and unstructured data to deliver actionable dashboards with all the information you need in one screen. The ability to aggregate, structure, and analyze data, in real time, from all systems, in a fully compliant GxP manner, allows for the visibility of a full campaign summary in one click.



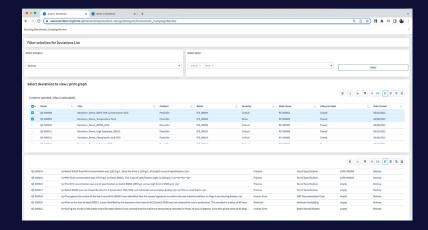
Features:

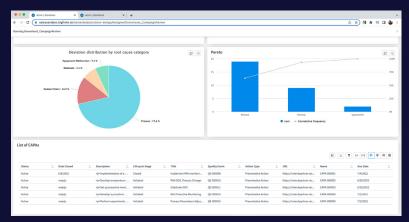
Aizon's platforms enables comprehensive reporting due to its data contextualization features. The report includes the following sections:

- → Summary of Campaigns and Batch Information
- → QC Testing & Product Quality Results
- → Critical Process Parameters Review
- → Deviations & CAPAs
- → Change Controls
- → Process Equipment
- → Process Data & Trend Analysis
- → Process Validation

Comply with all PQRs regulatory requirements and internal SOPs through compliant and complete data collection, and lifecycle management.

Ensure audit readiness, standardized reporting, and complete information by automatically delivering PQRs at the end of a production campaign configured to specific needs.





Aizon Automatic Product Quality Review: Functionality

Aizon's Data Comparison and Statistical Analysis tools are the easiest way to perform batch comparisons and generate trending detail. They are customized to present exactly what you require for the PQR. Because Aizon also connects historians, BMS, and FMS with CMMS data, and is able to contextualize that data with equipment requirements, you can assess the qualification status of all systems without having to gather data manually, eliminating all risks of data integrity.

With Aizon's solution, you can reduce time and effort while securing data integrity with PQR generation through automated, dynamic, and standardized reporting capabilities.

Collect report specific data from different systems in real time. Perform automatic statistical analysis.

GxP Compliance:

The platform allows you to maintain full GxP compliance via robust security features and data validation processes that are specifically and expertly designed to adhere to fluid pharmaceutical regulatory requirements. Aizon complies with industry standards to provide GxP compliance you can trust:

- → Quality: ISO 9001
- → Information Security: ISO 27001
- → Cloud Security: ISO 27017
- → All data collection complies with ALCOA+ principles

Aizon's Platform

Aizon's solutions enable life sciences manufacturers to improve decision making and outcomes by aggregating data and deploying compliant AI across the manufacturing ecosystem.



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