2020 Purified Water Monitoring Survey

American Pharmaceutical Review recently conducted a survey of our readers to determine their thoughts regarding pure water monitoring. Specifically, the survey asked questions regarding Total Organic Carbon (TOC) monitoring, sampling and analysis for purified water production. Please see the results of our survey below.

Please rank your concerns with grab sampling for TOC and conductivity.

(1 = Biggest concern, 4 = Least concern)

Rated: **1** - Biggest concern

Data and sample integrity *48.72%*

- *Time delay in releasing results*
- *Analyst time and resources*
- *Cost*

**COMBINED 51.28%*

Nearly half of respondents believed data integrity is as important as ever in an increasingly electronic industry. It's important to use instrumentation and software that can meet the rigors of data integrity guidance and 21 CFR Part 11 regulations.

Which of the following is most desirable about online TOC and conductivity analysis?

(1- Most desirable, 5-Least desirable)

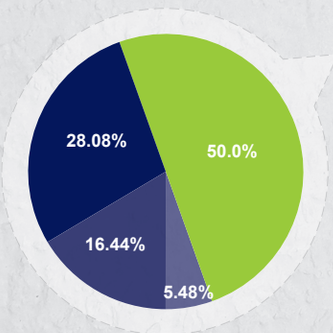
Rated: **1** - Most desirable

Data integrity and 21 CFR Part 11 compliance *45.11%*

- *Reducing or eliminating grab sampling*
- *Real-time data and real-time release*
- *Process control and efficiency gains*
- *Eliminating laboratory errors*

**COMBINED 54.89%*

How many cumulative hours per week are spent taking grab samples for TOC and/or conductivity monitoring?



Most GMP manufacturers are spending some amount of time on sampling and analysis. Online TOC monitoring for purified water and cleaning validation can eliminate or significantly reduce sampling.

1-4 Hours · 4-8 Hours · >8 Hours · None

Does your TOC instrument distinguish between inorganic carbon and total carbon?

YES 50.0%

NO/UNSURE **COMBINED* 50.0%

Half of respondents do not have appropriate equipment or are unsure if their instrument distinguishes inorganic carbon from total carbon as required by USP <643>. The other half are using equipment fit for purpose for measuring TOC in pharmaceutical grade water per USP <643>. Implementing instrumentation that distinguishes between inorganic carbon present in the sample and CO_2 generated from oxidation is important for compliance requirements and process understanding.

Do you monitor purified water systems in real time with online TOC and/or conductivity analysis?

Yes, the water systems are monitored online

YES 33.33% | 29.93%

Yes, with some grab samples for Point-of-Use

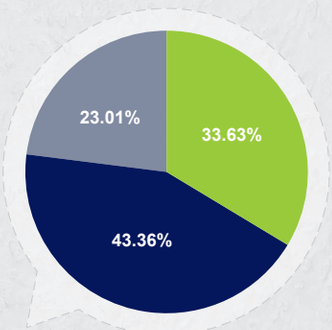
No, there are online analyzers on the water system, but it is for information only

NO 20.41% | 16.33%

No, we are exclusively taking grab samples

With the demand for efficiency and quality in CGMP facilities, over 63% of the industry has implemented some level of online analysis. Those who are not performing online monitoring may have equipment that is not fit for purpose and cannot be validated. When choosing online technology it's important to choose instrumentation that is quantitative and can be validated to the appropriate requirements.

How quickly are Out-of-Specification or Out-of-Trend results from your purified water system detected?



- In real time with online analysis
- Within hours of taking grab samples
- Within days of taking grab samples

66% of respondents experienced some delays, with 23% reporting delays up to several days. Furthermore, 80% had at least a moderate impact, with 40% having a high impact. Delays in detecting OOS/OOT results can impact batches, equipment, and leave the root cause unclear for a period. With online analysis, OOS/OOT results are detected in real time allowing for immediate remediation while limiting or eliminating impact to equipment and batches.