

Aspen Pharmacare Relies on Swan's Online TOC Measurement

Securing your pharmaceutical water loops with online measurement is a major quality monitoring challenge. This can be guaranteed by using continuous analyzers, which must combine efficiency, robustness, ease of use, and smooth operation. One of the key parameters in pharmaceutical water loops is Total Organic Compounds (TOC).



The AMI LineTOC Monitor measures TOC continuously and reliably.

What parameters do you measure continuously in your purified water (PW) and water for injection (WFI) loops?

How do you validate TOC, ozone, and conductivity measurements?

How do you validate the absence of ozone in PW?

How much time do you spend on the maintenance of your analyzers?

How many nonconformities do you encounter in one year?

You are responsible for your raw water. How do you control the quality of water entering your plant?

How do you secure the draw-off points?

This use case is the result of a collaboration with Aspen France where the easy operation, the low maintenance and high reliability of Swan's AMI LineTOC monitors resulted in several installations.

Below is a Q&A with Mr. Gonidec, utilities manager at Aspen Pharma's Notre Dame de Bonneville site.

Swan: "What problems were you experiencing with your equipment on site?"

Aspen: "The analyzer wasn't able to analyze samples with very low TOC levels (in the range 0 to 5 ppb). Analysis errors were generated by the analyzer, because the difference in conductivity readings before/after going through the UV lamp was too small, so the analyzer misinterpreted these results. The analyzer would generate an error message and, as a result of this fault, the water for injection (WFI) or purified water (PW) was prevented from being drawn off.

In addition, the sampling time between each analysis was too long (around 5 to 15 minutes).

The calibration method was too burdensome because it involved bringing the analyzer to the lab and a long calibration time (a day of immobilization for the analyzer). Therefore, no analysis was possible during the entire calibration period."

Swan: "Who was affected by these problems? (The maintenance manager? The quality manager? The production manager? Production itself?)"

Aspen: "The metrology technician was fully occupied for a day."

Swan: "How were these problems managed?"

Aspen: "A quality deviation was recorded each time the analyzer indicated a malfunction, when in fact the values were simply too low and couldn't be analyzed. In addition, the analyzer had to be recalibrated each time this event occurred."

Swan: "How long did that take?"

Aspen: "A day for the calibration."

Swan: "Was the financial side of things ultimately impacted?"

Aspen: "The blocking of the draw-off points when the alarms were triggered had a production impact and thus a financial impact, too. The intervention of quality and metrology personnel was required during these incidents."

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Swan: "Why did you trust Swan?"

Aspen: "The reputation of their equipment and after-sales service."

Swan: "How did you justify this change?"

Aspen: "Resolution of the problems relating to low values. No more error messages for low values. Simplification and reduction of time for the calibration procedure."

Swan: "How did you proceed and who was involved?"

Aspen: "By change control and drawing up a qualification protocol to enhance the Swan qualification protocol."

Swan: "Was this hard work?"

Aspen: "It took time, but no major difficulties were encountered."

Swan: "Are you satisfied?"

Aspen: "For the moment, yes. I'm very satisfied because the calibration time has been greatly reduced. Maintenance of the analyzers has been simplified and we've eliminated the unintentional errors."

Swan: "In your opinion, were the efforts involved in this change justified?"

Aspen: "Yes!"

Swan: "Would you recommend our equipment to your colleagues?"

Aspen: "Yes!"

Swan: "Will Swan be among your suppliers for other parameters, such as ozone and conductivity measurement?"

Aspen: "Right now, the question hasn't arisen for our other equipment, as a standard is already established at our site."

Swan: "How could we do better?"

Aspen: "For now, I have no suggestions to give you. Your teams are attentive and helpful."

Swan: "What do you think is our best argument for winning over new customers?"

Aspen: "The emphasis should be placed on simplicity of operation and the easy-to-use drop-down menu. The same applies to maintenance. The appearance of the analyzer should be downplayed. At first glance, you get the impression that you have a "factory" to run, because the footprint of your analyzers is larger than your competitors'."

Like Mr. Gonidec, you can trust Swan's equipment and expertise.

Swan Analytical Instruments,
ASPEC member and trainer.

*Aspen Pharmacare

After a major deal with GSK (notably including the Bad Oldesloe plant in Germany), Aspen Pharmacare decided to enter the European market in 2009. However, it was not until 2014 that Aspen truly extended its European presence and became one of the fastest-growing pharmaceutical companies on the continent. Aspen France was founded during this expansion in 2014, quickly becoming a new force in thrombosis and, since 2017, in anesthesia, with a wide range of anesthetic products from AstraZeneca and GSK.

**Swan

Founded on January 1, 1991 by a group of experienced engineers (chemists, physicists, electronic engineers), Swan specializes in developing and manufacturing process analytical instruments for water quality monitoring. The company focuses its activities on the electricity production market (monitoring of the water-steam cycle) and semiconductor industries. Drawing on its expertise in measuring very low concentrations, in 2010 Swan expanded its offerings to include a range of instruments for water for pharmaceutical use. With a permanent inventory of analyzers, spare parts, and local after-sales service teams, Swan can guarantee the continuity of your water production processes.

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