Application Note

Interview: Transition from Osmometer A to the OsmoTECH® XT

This interview highlights Boston BioProducts' transition from a legacy osmometer (referred to as Osmometer A) to the Advanced Instruments OsmoTECH® XT. This conversation is between Ben Duckless, Field Application Scientist at Nova Biomedical, and Vinny Chan, Process Development Manager at Boston BioProducts.

Boston BioProducts

About the Interviewee

Vinny Chan is the Process Development Manager at Boston BioProducts, where he serves as the subject matter expert for osmolality testing and the method owner across process development and manufacturing workflows. With approximately five years at the company, Vinny has played a central role in scaling operations within a cGMP environment.

His responsibilities span hands-on instrument operation, method development, troubleshooting, and cross-functional collaboration with manufacturing, quality control, and process excellence teams. Through this work, he has been directly involved in evaluating legacy analytical systems and driving the transition to more robust, compliant, and scalable solutions.

Vinny's experience working with both the legacy osmometer (Osmometer A) and the OsmoTECH XT provides a practical and detailed perspective on the operational challenges and measurable benefits associated with this transition.

Q: Can you describe how osmolality fits into your workflow today?

A: Osmolality is a critical quality attribute across process development, manufacturing, and quality control. It supports in-process monitoring, lot release, and investigations. The results directly determine whether a product is released, quarantined, or rejected.

Q: What instrument were you using previously?

A: Prior to the transition, we were using a legacy freezing point osmometer, which we'll refer to here as Osmometer A. The instrument had been in place for several years and was effectively inherited as part of our operations.

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Q: What was the day-to-day experience like with Osmometer A?

A: The user experience was complex and highly manual. Only a small number of technicians were comfortable operating the instrument, and even fewer were capable of performing calibration. It wasn't something that could be easily scaled across teams.

Q: What made calibration particularly challenging?

A: Calibration was entirely manual and required adjusting physical settings and tuning values using a screwdriver. You had to time the instrument's readout as it approached the target value and make fine adjustments in real time. This process could take 30 to 60 minutes every single day.

Q: How did that impact your operations?

A: It created a significant bottleneck. Calibration alone consumed a meaningful portion of the day, and it required SME-level involvement. In total, we estimate losing approximately 1 to 1.5 hours per day due to calibration and reruns, which is roughly 10–15% of the workday.

Q: Were there issues beyond calibration?

A: Yes, we saw frequent inconsistencies in results. Some samples wouldn't freeze properly, and others required multiple reruns to get a stable result. Mechanical issues like the probe not seating correctly or inconsistent cooling would introduce variability between runs.

Q: How did this affect confidence in the data?

A: It introduced uncertainty. When results looked questionable, we had to ask whether it was the sample or the instrument. That led to repeated testing, additional troubleshooting, and increased investigation burden.

Q: Did support and service play a role?

A: Definitely. There was limited direct technical support available. If an instrument had issues, the recommendation was to ship it out for repair. That wasn't practical for a production environment, so we had to rely on backup instruments.

Q: What ultimately drove the decision to switch?

A: There were a few key drivers: the need to align with USP <785>, the need for higher throughput, and the need to increase confidence in our results. A major turning point was having multiple instruments down at the same time without a clear path to resolution.

Q: What were your key requirements for a replacement system?

A: Accuracy and precision were non-negotiable. We also needed ease of calibration, strong service support, compliance with recognized standards, and the ability for more operators to run the system reliably.

Q: How did you evaluate the OsmoTECH XT?

A: Evaluation focused on ease of use, consistency of results, and compliance with USP <785>. We conducted demos, reviewed performance across sample types, and ultimately validated the system through an IQ/OQ/PQ process with comparability testing.

Q: How quickly were operators able to adopt the new system?

A: Adoption was fast. Most operators were comfortable within about a month. The interface is intuitive, and the workflow is much simpler compared to what we were used to.

Q: What improvements did you see from support and service?

A: Calibration and verification became straightforward and no longer required SME involvement. Testing became faster, results were consistent, and the need to question data was essentially removed.

Q: Which specific problems were eliminated?

A: We no longer see freezing failures or mechanical inconsistencies. The need to rerun samples has dropped significantly, and we no longer have to cross-check results across multiple instruments just to build confidence.

Q: What impact did this have on throughput and efficiency?

A: Throughput improved significantly. We recovered the time previously lost to calibration and reruns, and testing is now a seamless part of the workflow rather than a bottleneck.

Q: How did confidence in the results change?

A: Confidence improved dramatically. Operators, QA, and process teams trust the results immediately. There's no longer a need to question whether the instrument itself is introducing variability.

Q: Did staffing flexibility change?

A: Yes. Tasks that were previously limited to a few experts—including calibration—can now be performed by any trained operator. That's a major shift operationally.

Q: How did this transition affect your compliance position?

A: Alignment with USP <785> was a major improvement. It strengthens our audit readiness and gives us confidence when communicating our capabilities to customers.

Q: If you had to describe the 'before and after' in one example, what would it be?

A: Before, the day started with a long, manual calibration process performed by an expert, and we often had to troubleshoot results throughout the day. After, calibration and verification are simple, quick tasks, and the workflow runs smoothly with consistent, trusted results.

Q: What would your headline message be to others considering a switch?

A: It's a high-throughput, easy-to-use system that delivers consistent, accurate results while supporting compliance with USP <785>. It removes a lot of the uncertainty and operational burden associated with older systems.

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MP00190 Rev 0