Helixer

whitepaper

FROM PAPER LOGS TO REAL TIME CONTROL

A Sintering Succes Story at CAM Bioceramics

Whitepaper Summary

"Helixer has become a trusted part of our core operations. The automation of sintering validation significantly improved data quality and process efficiency, while reducing manual effort and risk"

CAM Bioceramics faced the demanding task of manually validating critical sintering data. This was an essential but intricate process with zero tolerance for deviation, where precision and compliance are non-negotiable.

By introducing Helixer OS, the company automated quality checks, enabled high-resolution furnace data in real time, and created a digital, audit-ready record of every batch.

The project eliminated hours of manual QA work, improved data precision tenfold, and cut the review and release cycle by 75 percent. Setting a new benchmark for quality, efficiency, and regulatory confidence in medical grade ceramic manufacturing.

Hans van Donge

CEO CAM Bioceramics

Background

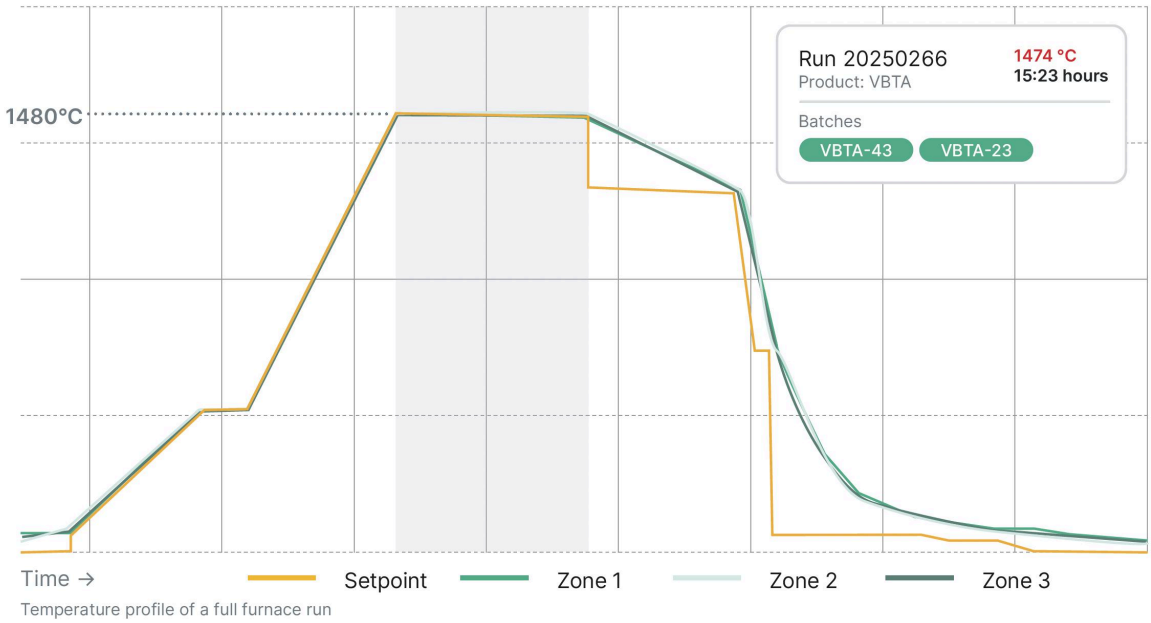
Why Precision in Sintering Matters

In the bioceramics industry serving the medical device sector, **sintering** is recognized as a critical high-temperature process that transforms ceramic particles into a dense, crystalline structure. For orthobiologic materials such as hydroxyapatite (HA) and β-tricalcium phosphate (β-TCP), precise temperature control during sintering plays a vital role in defining key product characteristics, including density, porosity, and crystal form that ultimately determine the biological properties of the bioceramic.

Even a few degrees of variation can change how a ceramic behaves in the body, affecting how well an implant bonds to bone or how predictably a graft dissolves. Reliable sintering means reliable products, and ultimately patient safety.

For CAM Bioceramics, a Netherlands-based CDMO that supplies advanced calcium phosphate components worldwide, sintering is therefore mission-critical. Meeting ISO 13485, FDA, and EU MDR requirements means every furnace run must be reproducible and fully traceable.

In short, reliable sintering = reliable products.



Temperature profile of a full furnace run

Legacy approach 1/2

Paper Logs and Manual Checks

Until 2023 CAM Bioceramics validated each sintering batch with a paper print out of the oven profile. Operators annotated the chart, typed key points manually into the quality assurance system, and filed the paperwork for QA review. The method had three built in weaknesses:

- Labor intensive: Roughly 30 minutes of operator time followed by 30 minutes of QA review per batch.
- Low resolution: Data points captured at 10 minute intervals masked short term excursions that could affect material properties.
- Human error leads to waste: Handwritten notes and transcription mistakes sometimes caused discrepancies that required rework or even batch rejection.

The process was disciplined but fragile. The repetitive paperwork was seen as "strafwerk", a tedious task that added no real value. Removing it not only reduced human error but also improved job satisfaction and focus on meaningful work.

At the same time, manually entering furnace programs carried its own risk. A single incorrect parameter could lead to an invalid cycle and destroy an entire batch, wasting both time and material.

With growing order volumes and an expanding furnace fleet, the paper-based process had become both a bottleneck and a liability.

Industry Pressures Raising the Stakes

Across the medical device industry, regulatory expectations and market dynamics are rapidly evolving. New EU MDR requirements and updated FDA guidance demand more granular, instantly retrievable production data.

At the same time, competitors are adopting Industry 4.0 platforms for real-time monitoring and "zero defect" initiatives, raising the bar for data integrity and process control.

Labor shortages add further pressure. Experienced furnace operators are retiring faster than replacements can be trained, making automation essential to capture expertise and reduce workload.

Finally, any mistake in furnace programming or unnoticed deviation during a run can destroy an entire batch, directly impacting margins and delivery schedules.

Legacy approach 2/2

Strategic Imperative for CAM

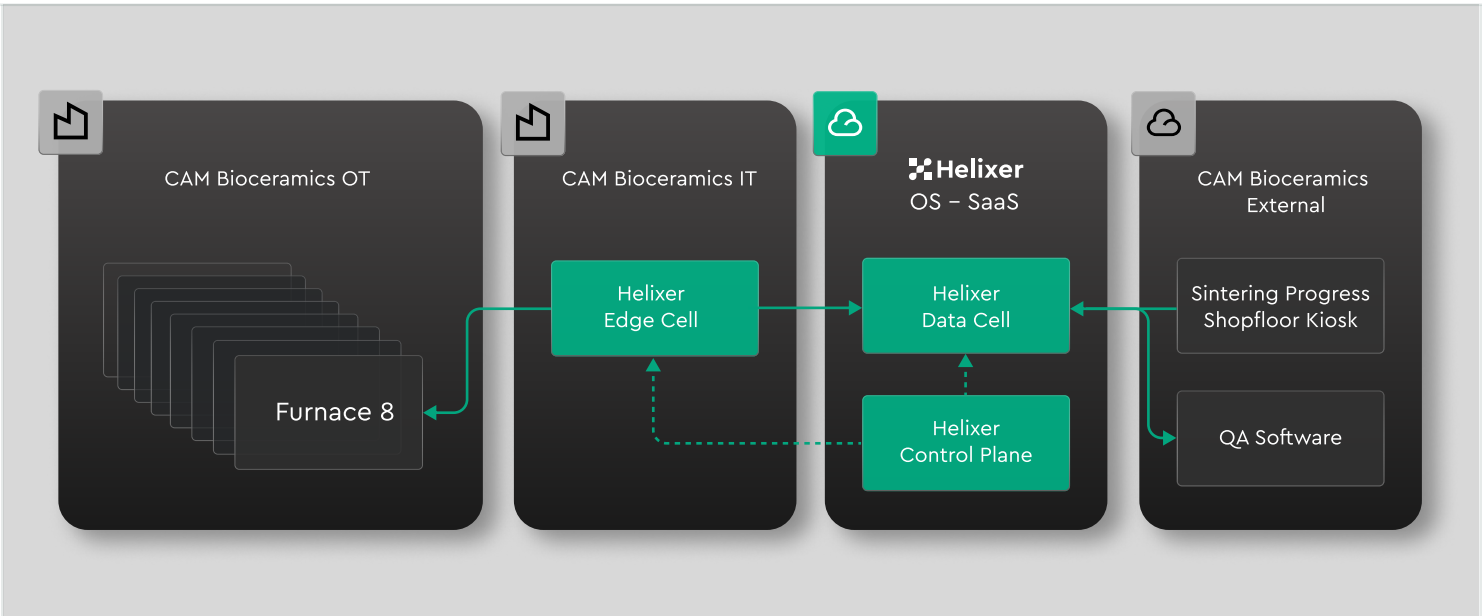
To maintain its reputation as the partner of choice for leading orthopedic and dental OEMs, CAM needed to:

- Eliminate manual data handling and the risk of transcription errors.
- Capture high-resolution temperature profiles for every run.
- Ensure the correct parameters were loaded automatically according to the production schema.
- Create an audit-ready digital trail that QA could trust instantly.

The answer was a targeted, low-disruption digital transformation, starting with one furnace and scaling across the sintering department.

"Helixer OS connects directly to CAM's furnaces, monitors every sintering cycle in real time, and validates that each run meets strict quality requirements. Without any manual paperwork."

How Helixer OS Powers Digital Sintering Control



Helixer OS connects securely to CAM-bioceramic's OT domain as well as to the SaaS data cell, ensuring safety, reliability and third-party integrations.

Connect
Interfaces directly with CAM's industrial furnaces over Modbus to capture seven temperature channels and various other parameters per furnace in real time.

Helixer OS also verifies that the correct parameters are loaded for each production batch, based on the defined production schema.

Visualize
Live dashboards display temperature curves, set points, and run status across all ovens, giving operators and QA full, live visibility into every process step

Unify
Combines real-time furnace data with existing QA system records to create a single, coherent source of truth.

Helixer OS stores sub-second time series data for every sinter run alongside production and validation metadata, providing a unified view for traceability, audits, and long-term trend analysis.

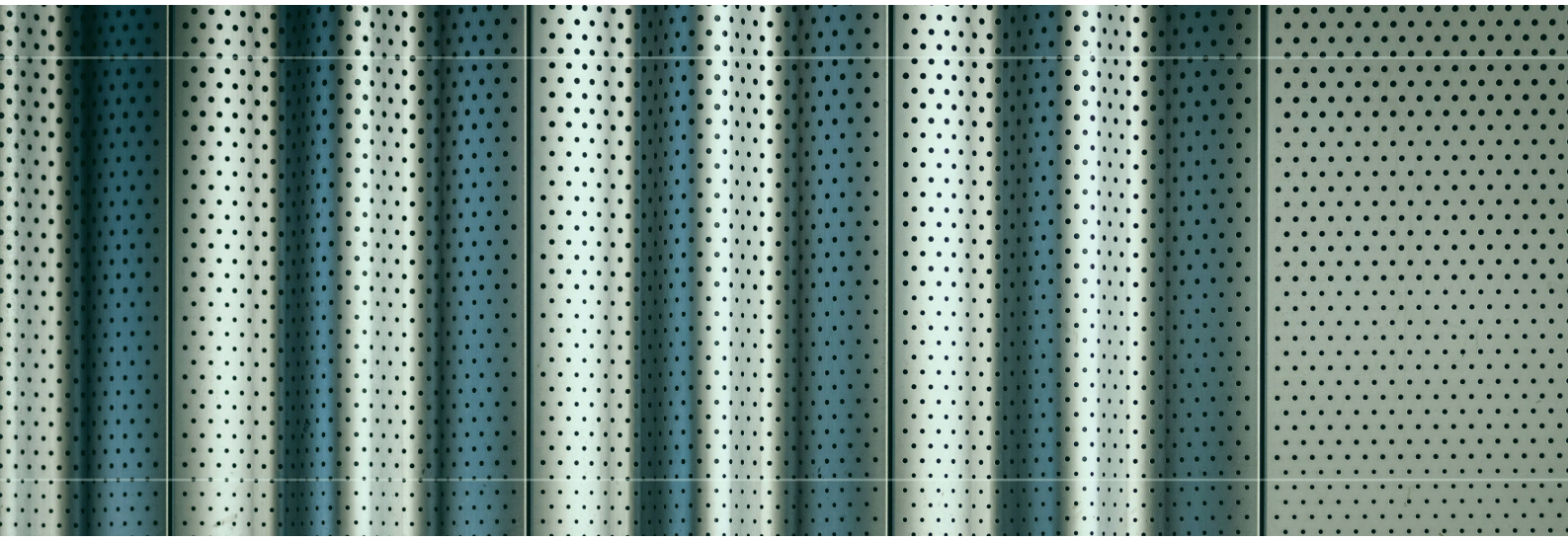
Extend
A custom App Engine algorithm validates each run against specific specs and writes the results to the QA system, fully automating the workflow.

Solution Overview 2/2

Helixer OS integrates deeply with existing QA processes and machine controls, while remaining non-disruptive to daily operations.

The system delivers:

- High-resolution data capture for full traceability.
- Automatic validation of each run against defined specifications.
- Rule-based parameter control suited for regulated environments.
- Audit-ready digital records that meet ISO and FDA scrutiny.
- Happier operators who spend less time on paperwork and more on process improvement.
- Unified view combining real-time furnace data with existing QA system records.



Spotlight CAM Bioceramics

Founded as a Leiden University spin off in the 1980s, CAM Bioceramics has grown into a global CDMO supplying medical grade hydroxyapatite and β TCP components to leading orthopedic, dental, and regenerative medicine OEMs in more than 30 countries. With ISO 13485 certification and class 7 cleanroom production, CAM is recognised for pioneering plasma sprayed HA coatings and for tailoring calcium phosphate materials to exacting device requirements.

Q3 2023 Pilot
Connected a single furnace to Helixer OS and validated data capture plus QA-system integration.

Q1 2024 Roll-out
Expanded to all furnaces, enabled real time dashboards, and closed loop QA reporting.

30
minutes saved per batch

75
percent cycle time reduced

100
percent elimination of manual QA entry

ROI Highlights

- **Labor savings:** Eliminating manual QA checks saves roughly 30 minutes per batch, equivalent to more than one full-time employee across thousands of batches each year.
- **Rapid time to value:** Measurable improvements appeared within two weeks of rollout, with minimal production disruption.
- **Operator satisfaction:** By removing repetitive paperwork, Helixer OS eliminated what operators called "strafwerk." The system improved focus, reduced stress, and made their work more meaningful.

Challenges

- Manual, paper based validation of sintering runs.
- Up to 30 minutes operator time + 30 minutes QA review per batch.
- Data granularity limited to ±10 minutes; prone to transcription errors.
- Risk of missing or inconsistent records jeopardising ISO/FDA compliance.
- Repetitive administrative workload lowered morale

Results

- 100 % elimination of manual QA data entry.
- Review and release cycle time cut by 75%.
- Data precision improved from 10 minute to sub second resolution.
- Zero missing records or non conformances since launch.
- Operators report higher satisfaction and ownership of the process

Building on a Reliable Foundation

Connecting quality, insight, and the people behind the process

CAM Bioceramics' digital sintering process shows how automating one critical step can deliver outsized gains in quality, efficiency, and compliance. Real-time validation and audit-ready data have set a new benchmark for reliability in medical ceramic manufacturing. Beyond performance, the project improved the daily experience of operators and gave the QA team complete confidence in every batch.

Looking ahead, CAM Bioceramics plans to extend Helixer OS to additional process steps and harness AI-driven analytics to deepen insight, cut manual effort, and further future-proof operations.

Ready to digitise and optimize your critical manufacturing processes?

Book a demo or request a process assessment at helixer.io or via info@helixer.io

Let's build the foundation for smarter, more reliable manufacturing together.