

CASE STUDY

Driving Pharma Compliance & ROI Through Intelligent Building Automation

Project	Provider	Industry	Platform
Bafna Phase-2 Optimisation	EnSmart Controls	Pharmaceutical Mfg.	SmartNova

1. Executive Summary

In an industry where data integrity is as critical as production quality, Bafna Phase-2 required a partner capable of bridging the gap between complex HVAC operational demands and stringent USFDA regulatory standards.

EnSmart deployed a custom-engineered automation solution centred on the Smart Nova Controller — integrating AI-driven predictive maintenance to ensure continuous audit readiness while delivering measurable energy efficiency gains.

The result: full 21 CFR Part 11 compliance, annualised energy savings of ₹3,226,243, and a transition from reactive to predictive maintenance — achieved through a single, open-protocol platform with no vendor lock-in.

2. The Challenge

The Bafna Phase-2 pharmaceutical production environment presented three core pain points that demanded a multifaceted, purpose-built solution:

- Regulatory Rigor**
100% adherence to 21 CFR Part 11 was non-negotiable — specifically unalterable electronic audit trails, secure user authentication, and cryptographically timestamped records ready for USFDA inspection.
- Operational Inefficiency**
Manual monitoring failed to capture granular energy data, resulting in inflated operational costs, blind spots in batch quality assurance, and reactive — rather than predictive — maintenance cycles.

System Fragmentation



The facility required a cohesive, unified control architecture capable of preventing unauthorised access while delivering deep real-time analytics across all HVAC systems and critical environment parameters.

3. The EnSmart Solution: SmartNova as the Central Nervous System

EnSmart rejected off-the-shelf compromises. Instead, a proprietary, custom-built open-framework solution was implemented — positioning the Smart Nova Controller as the intelligence hub of the entire facility.

Audit-Ready Architecture

A closed-loop system generates tamper-proof, immutable logs for every operational event. Every setpoint change, alarm trigger, and system override is timestamped and cryptographically secured — delivering seamless audit readiness without manual data reconciliation.

AI-Powered HVAC Optimisation

The proprietary AI analytics engine continuously monitors all environmental variables, predicting load requirements rather than reacting to them. This maintains the precise climate control — temperature, humidity, differential pressure — critical for pharmaceutical product stability and batch integrity.

In-House Engineering & Data Ownership

Built on custom software architecture rather than third-party platform limitations, the system provides EnSmart clients with complete data ownership. The BMS evolves with the facility's specific manufacturing needs — no vendor dependency, no hidden migration costs.

Industrial Protocol Integration

Native BACnet/IP and Modbus integration ensures seamless connectivity with all HVAC plant, chillers, AHUs, and BMS field devices — future-proofing the facility against equipment changes and expansions.

4. Key Performance Metrics — Bafna Impact

The deployment of EnSmart BMS AI Analytics at the Bafna Pharma Phase-2 site yielded immediate, independently verifiable results:

Annualised Energy Savings	₹3,226,243
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Compliance Standard Achieved	21 CFR Part 11 — Audit Ready
Maintenance Model	Predictive (Proactive vs. Reactive)
CO ₂ Footprint Impact	Significant reduction achieved
Audit Trail Integrity	100% tamper-proof, cryptographic
Regulatory Readiness	USFDA inspection ready

5. SmartNova Platform — Verified Pharma Capabilities

The SmartNova Platform delivers a compliance backbone that eliminates manual data reconciliation and positions pharma facilities for USFDA and global regulatory demands:

- **Unalterable audit trails: Every log entry is timestamped, user-attributed, and cryptographically sealed**
- Centralised compliance reporting for temperature, humidity, pressure, and all critical environment parameters
- Automated report generation eliminates human error in regulatory logging
- Secure electronic signatures compliant with 21 CFR Part 11 Sub-Part C requirements
- On-premise AI deployment — no pharma data leaves the facility boundary
- Multi-site, web-based dashboard accessible from any browser without additional client software
- BEE / ECBC 2017 compliant energy reporting and ISO 50001-aligned analytics
- CE/RoHS certified hardware with PICS-prepared BACnet conformance documentation

6. Pharma & Industrial Deployment Track Record

The Smart Nova platform has been deployed across India's leading pharmaceutical and chemical manufacturing organisations — demonstrating a consistent, scalable standard for 21 CFR Part 11 compliance at enterprise scale:

- ◆ Aurobindo Pharma
- ◆ Zydus Lifesciences
- ◆ Aspiro Pharma
- ◆ Tata Chemicals
- ◆ Sun Pharma
- ◆ One Source
- ◆ Natco Pharma
- ◆ Johnson & Johnson

These deployments span cleanroom HVAC validation, sterile environment monitoring, multi-site centralised BMS, and energy management — underscoring the platform's adaptability across varying production environment requirements.

7. Why EnSmart — The Strategic Differentiators

23+ Years Domain Expertise	Deep pharma, hospital, IT park, and industrial BMS knowledge built into every deployment.
200+ Buildings Transformed	Proven scale across India's most demanding regulatory environments.
Open Protocol — No Lock-In	BACnet/IP and Modbus ensure freedom to integrate, expand, and upgrade independently.
18–27 Days Engineering Saved	Automated IO-list to wiring-drawing workflow eliminates project delays.
Made in India Hardware	CE/RoHS certified DDC controllers with ARM A53 — designed for industrial reliability.
FDA Registered Platform	Compliance certificates available for download; PICS-prepared documentation on request.

8. Conclusion

The success at Bafna Pharma Phase-2 underscores a fundamental shift in how pharmaceutical facilities view building automation: not as a utility overhead, but as a strategic compliance and financial asset.

By integrating 23 years of domain expertise in industrial protocols with custom-coded AI analytics, EnSmart delivers more than control — we deliver operational transparency, regulatory peace of mind, and significant, quantifiable financial returns from day one of deployment.

The SmartNova Platform is not bolted-on compliance. It is pharma-grade automation, built from the ground up for GxP environments — and deployed at scale across India's most regulated manufacturing facilities.

Ready to Transform Your Pharma Facility?

Tell us your facility type — we will walk you through the 21 CFR validation process.

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