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CASE STUDY

eBPCR

Electronic Batch Production & Control Records— From First Weighing to QA Release, Built on AWS

Executive summary

eBPCR is a cloud-native electronic Batch Production & Control Record platform built by Shri Sai Tech (SST) on Amazon Web Services (AWS). It replaces the paper Batch Manufacturing Record with a live, step-by-step electronic record capturing shop-floor data, in-process controls, equipment usage and multi-stage production & QA review — one closed, auditable loop between the plant floor and the quality office.

Regulated manufacturers know the problems: batch records on paper, review and release coordinated by hand, and data integrity that is hard to prove at audit. Built on PostgreSQL, FastAPI and Next.js, eBPCR unifies batch execution, in-process control, review, e-signed release and analytics — configurable to any product and process.

The Challenges

- **Challenge 1 – Paper-Bound Batch Records**
  The BMR lives on paper — hard to search, easy to mis-transcribe, and slow to move between production and quality.

- **Challenge 2 – Manual, Sequential Review & Release**
  Production review, QA review and final release are signed by hand across desks, delaying disposition and batch release.

- **Challenge 3 – Data-Integrity & Compliance Risk**
  Proving records are attributable, contemporaneous and unaltered (ALCOA+, 21 CFR Part 11) is difficult without a built-in audit trail and e-signatures.

- **Challenge 4 – No Real-Time View, Rigid Systems**
  No live view of batch status, results, equipment or deviations — and rigid, one-recipe tools can’t fit new products and workflows without costly change requests.

Smruthi Organics Limited

About Smruthi Organics

eBPCR is an electronic batch-record platform for organizations that manufacture regulated product — pharmaceuticals, APIs and specialty chemicals — bringing batch execution, in-process controls, review and release together in one live record.

Every product and process is configurable — tasks, data-capture rules, specifications and workflow — so the platform adapts across sites and product lines rather than being locked to one recipe. eBPCR is designed, built and delivered by Shri Sai Tech on AWS.

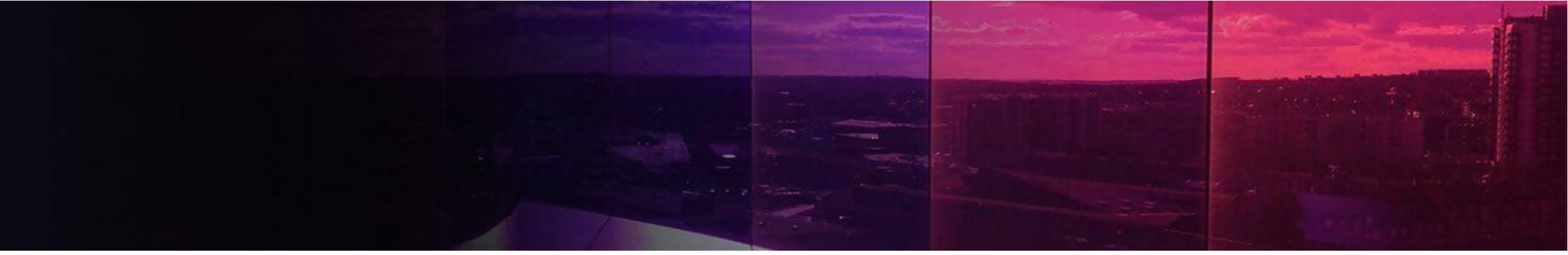
Swapnil Eaga

Joint MD & CFO

Swapnil Eaga is the Joint Managing Director & CFO of Smruthi Organics, responsible for Finance & Operations.

He holds a BSc (Chem) from the US and an MBA in Finance from Spain, with more than 8 years of professional experience in the API industry.

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Simplify Digital Transformation with AWS

Amazon Web Services (AWS) gives eBPCR a secure, scalable and cost-effective cloud foundation, avoiding the burden of building and running large-scale application and data infrastructure in-house.

Building on managed AWS services gives every client enterprise-grade identity, storage, database and monitoring that scale from a single site to an entire network of plants and product lines.

Why Shri Sai Tech?

Engineering depth in regulated manufacturing:

- GxP domain modelling — batches, tasks, in-process controls, review & release
- Data integrity by design — audit trail, e-signatures, ALCOA+ controls
- AWS cloud-native architecture — RDS, Cognito, S3 and managed services
- Configurable, multi-tenant platform with role-based access control
- Agile, full-stack SaaS delivery — web console and shop-floor screens, from rapid iterative prototyping to production

The Solution

SST designed, built and delivered the entire batch record — end to end and electronic — on AWS.

Electronic Batch Record

Every step captured in sequence on screen — weights, liquid charges, temperature/vacuum monitoring and in-process tests — replacing the paper BMR.

Role-Based Execution & Multi-Stage Release

Operator, chemist, production reviewer, production manager, QC/QA reviewer and QA approver each see only their stage — Production Review → QA Review → QA Release, with per-block sign-off, queries and rectification.

Electronic Signatures, Deviations & Audit Trail

PIN-based sign-off binds signer, record, meaning and timestamp at every gate (21 CFR Part 11); deviations are raised against the exact step, and every action is written to an append-only audit trail.

IPC Requisition & Out-of-Spec Flagging

Production raises an IPC requisition; QC returns the AR number, result and remark under PIN authorization — results auto-checked and flagged against min/max specifications.

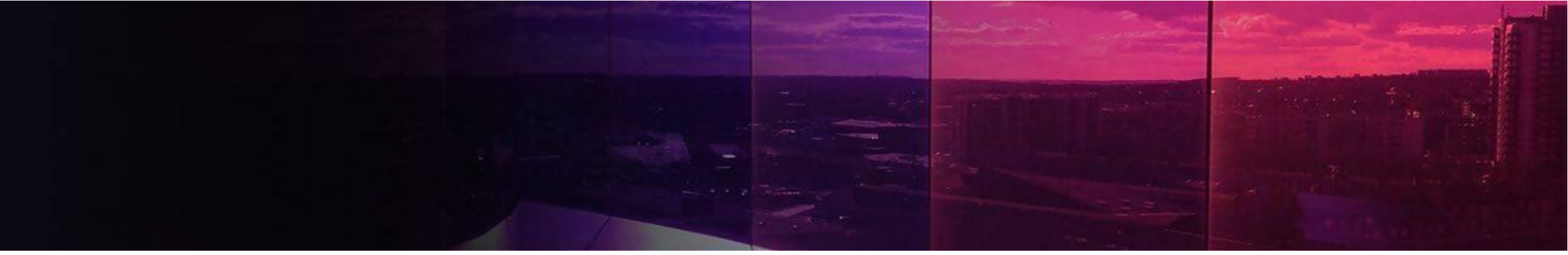
Equipment & Cleaning Control

Equipment usage is logged per batch, and cleaning — batch-to-batch, major and product-changeover — locks equipment until completed and recorded.

Configurable Master BPCR, Scheduling & Live Visibility

Products, tasks, data-capture rules, specifications and parallel steps are configured — not coded — with schedules, planned-vs-actual timing and live dashboards across blocks.

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Technology & AWS Services Used

Platform Foundations

Application & Delivery	Data & Storage
Next.js · FastAPI · Docker • Next.js / React web application — shop-floor and office screens • FastAPI (async) REST service layer • Docker containers with Amazon CloudWatch monitoring	Amazon RDS · Amazon S3 • PostgreSQL on Amazon RDS — batches, tasks, reviews, signatures, audit • Amazon S3 — batch-record PDFs and attachments (versioned / WORM) • Append-only audit trail and retention
Identity & Security	**Compliance Foundations**
Amazon Cognito — SSO / MFA • Authentication and identity for every role • Role-based access, scoped per site and area • Encryption of data in transit and at rest	21 CFR Part 11 · ALCOA+ · GAMP 5 • Electronic signatures and tamper-evident audit trail (21 CFR Part 11) • Data integrity — ALCOA+ enforced by mechanism

AWS Cloud Services

• Amazon RDS (PostgreSQL) — batches, tasks, reviews, signatures and audit • Amazon S3 — versioned / WORM storage for batch-record PDFs and attachments	• Amazon Cognito — authentication and identity with SSO / MFA • Amazon CloudWatch — monitoring across the containerised platform

Delivery & Governance

- Multi-tenant SaaS delivery with role-based access control, scoped per site and area
- Risk-based validation lifecycle (GAMP 5) and change control
- Agile delivery — rapid, iterative prototyping to production, adapting to any product and process through configuration rather than code

Results — paperless, connected, audit-ready

With eBPCR in place, the batch record becomes paperless, connected and audit-ready — one system of record for how every batch is made and released:

A single source of truth

A single electronic source of truth for every batch record.

A closed review-and-release loop

Production and quality connected in one closed review-and-release loop.

Spec-checked at the point of work

n-process results captured and checked against specification at the point of work.

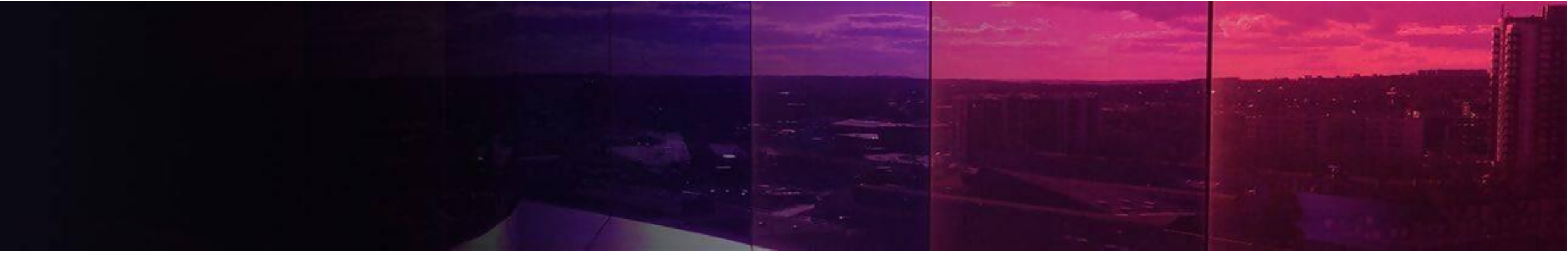
Signed at every gate

Every action electronically signed, binding signer, record, meaning and timestamp.

Audit-trailed for inspection

An append-only audit trail of who did what, when, on which batch — inspection-ready.

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Benefits

- **Faster batch review and release —**
  No re-keying and no lost paperwork between production and quality.
- **Data integrity by design —**
  Data integrity and e-signatures designed around 21 CFR Part 11 and ALCOA+.
- **Real-time visibility —**
  A live view of batches, deviations and equipment as they happen.
- **Configurable to any workflow —**
  Adapts to any product, recipe and workflow without code changes.
- **Secure and multi-tenant —**
  Role-based access with encryption of data in transit and at rest.
- **Cloud-native on AWS —**
  A scalable, cost-effective architecture built on managed AWS services.

Next steps

- Digitise a first product’s master BPCR and run a pilot batch
- Enable SSO / MFA and per-tenant validation environments
- Integrate with LIMS, ERP and QMS across the plant
- Roll out across additional products, blocks and sites — adding analytics, cleaning scheduling and release forecasting

About Shri Sai Tech LLC DBA SST

SST is an AWS Partner specializing in AI-driven, cloud-native architecture and secure, compliant solutions across a wide range of industries — including healthcare, finance, education, retail, manufacturing, logistics, energy, government and public sector, telecommunications, and media and entertainment. Partnering closely with our clients, SST rapidly designs and deploys production-ready AI platforms on AWS, bringing AI-powered capabilities to market with speed and confidence.

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Network Competency

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