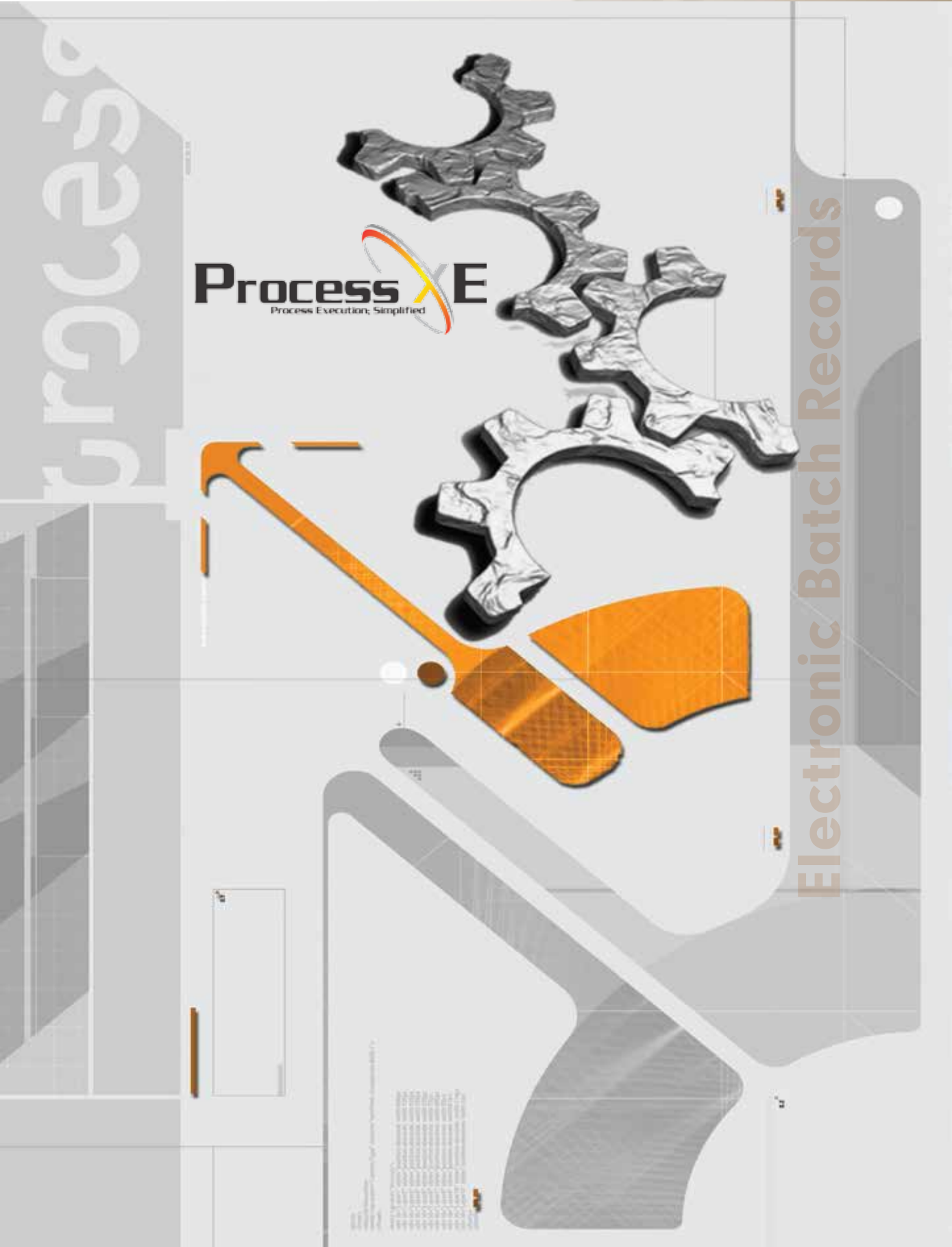
Process XE
Process Execution; Simplified
Electronic Batch Records

Interface with

- Equipments
- ERP
- EQMS
- ETMS
- EDMS
- LIMS
- more...

Tracking

- Incomplete and mismatch data
- Batches with non-conformance and associated CAPA
- Pending tasks
- Graphs and reports to track batch progress

Key Operations

- MPCR* preparation
- MPCR approval
- BPCR** request
- BPCR issuance
- BPCR execution
- BPCR approval
- BPCR archiving

Trends; Analyses

- Quality Issues
- Critical in-process controls like hardness, dissolution, disintegration, etc.
- Rejections

* MPCR - Master Production Control Records

** BPCR - Batch Production Control Records

Overview

Process XE is;

- Compliant with 21 CFR part 11 and Annex 11 requirements
- Risk based validation approach as per GAMP5
- Covers entire cycle starting from MPCR preparation to approved BPCR archiving

features

- Videos and Photos for operator instructions
- Auto-calculations
- Real-time tolerance checking
- Compliance flags indicating non-conforming data values
- Managing SOPs, ensures the utilization of current procedures, which ultimately reduce manufacturing of non-quality batches
- Manages equipments' validation and calibration status for assisting the operators to utilize validated equipments for manufacturing the batch
- Generation and re-printing of label for containers that hold dispensed material
- Operation to validate the batch for completeness before closing
- Indicators to batch executors for activities like validation and stability
- Compatible with devices and OS – helps in utilizing Process XE on shop floor
- Interface with Equipments, ERP, eQMS, eDMS, eTMS, LIMS, others

Benefits

Marked reduction in…

- Document creation/revision time with improved productivity
- Number of documents with improved accuracy and consistency
- Pages with reduced operating costs
- Entries with increased compliance
- Documentation error with increased and improved decision making
- Review cycle time with increased efficiency and competence
- Product release time
- Manufacturing time
- Investigation time
- Training time
- Recipe preparation time

Other Products

PharmaNET - Sales and Distribution

Sales and distribution solution with Demand, Warehouse, Financial, Purchase & Material Management…
Also, tracks Primary and Secondary sales channels to provide a consolidated picture of dispersed and complicated analysis.

pharmanet.sarjen.com

PvEdge - Drug Safety Database

360⁰ pharmacovigilance solution which covers Post marketing, Clinical, Medical devices, Vaccine, Veterinary Pharmacovigliance. Enabled with Literature automation and Signal detection modules, Ethics committee functioning and SAE management, xEVMPD and Product License management.

pvedge.sarjen.com

BizNET CTM - Clinical Trial Management

Complete Clinical Trial management for CROs with Project tracking and monitoring, eCRF/EDC, Biometric volunteer registration, Medical screening, Medical coding, Clinical LIMS, BA LIMS…

biznet.sarjen.com

FForce - Field Sales Excellence Platform

- Distribution Management System
- Electronic Order Management System
- Sales Force Automation System
- eDetailing
- Field Sales Information System

fforce.sarjen.com

KnowledgeNET - Dossier Publishing Solution

KnowledgeNET is a robust, featured-packed, well established dossier submission and life cycle management solution. It has great adaptability of compiling dossiers with various global regulatory standards in distinct publishing formats like CTD, eCTD, NeeS, ACTD, GTD, vNeeS and the regional formats.

knowledgenet.sarjen.com

QEdge - Enterprise Quality Management System

- Quality processes automation (CRF,Deviation, Investigation, CAPA, OOS, OOT, Audit, etc.)
- Document control (SOP, Specification management, Other documents etc.)
- Training records keeping and management

qedge.sarjen.com

ProcEdge - Business Process Automation

- Processes automation
- Workflow automation
- Document management

procedge.sarjen.com

About Sarjen

- Over 19 years' journey of IT consulting for business and technology
- Domain expertise in Pharmaceutical, Life Science and other domains
- Expertise in SCM, CRM, QMS, PV and Dossier Publishing solutions
- Client presence in 40+ countries; mainly in UK and rest of Europe
- Partnerships with Microsoft, Apple, HP, IBM
- Solutions built with own IP; adoptable to meet business challenges
- Solutions compliant with 21 CFR part 11, Annex 11 and GxP
- In-depth knowledge of Computer System Validations (CSV)

Sarjen Systems
ISO 9001:2015 certified company

6th Floor, Arista, Anandnagar road, Ahmedabad 380015, India
+91-79-66214899 +44-208-432-6393 +1-847-307-5937
www.sarjen.com sarjen@sarjen.com