



Quality Processes . Doc Control . Training Records



# Enterprise Quality Management

**AI enabled smart Enterprise Quality Management software solution;**

**\* helps develop enterprise wide culture of quality**

**\* for continued strong data integrity**

**\* maintaining overall compliance**

QEdge helps organisations manage their Quality Processes, Document Control and Employee training records on a single solution across multiple sites.

- Part 11 (21 CFR Part 11, Annex 11) compliant
  - AI enabled eQMS
    - Enterprise wide implementation
      - GxP audited – MHRA, US FDA, Health Canada, Others

## Processes & Control

**Configurable processes**

**Dynamic workflows**

**Process versioning**

Increased efficiency by 60%

## Training

**eLearning**

**Training rooms**

**Employee dossiers**

Reduced paper cost by 50%

Enhances productivity

## Integration

**SAP/ERPs, SharePoint**

**O365 plugin**

Increased audit readiness by 40%

## Features

**Dashboard**

**Record/Field -level audit trails**

**MIS reports**

**Independent/Dependent processes**

Easy adaptability



Fully validated



Cloud ready



Brings Audit  
readiness



Ready-to-use configured quality processes

## Other GxP compliant solutions

### KnowledgeNET - Dossier Publishing & Management

- eCTD Publishing and Lifecycle viewer
- CTD/Paper Submission
- SPL
- ISO IDMP
- SPOR Database
- Establishment Registration

[knowledgegenet.sarjen.com](http://knowledgegenet.sarjen.com)

### ProcEdge RIMS - Regulatory information management

- Track Label changes
- Manage Submissions 'n Timelines
- Manage Approvals
- Manage Query/s
- Manage Product Licenses
- A step towards ISO IDMP...

[rims.sarjen.com](http://rims.sarjen.com)

### PvEdge - Drug Safety Database

- Human PV Safety Database
- Product Enquiry Trail and Response
- Veterinary Vigilance
- Multisource Case Inbox
- EV Triage and Inbox
- PV Training

[pvedge.sarjen.com](http://pvedge.sarjen.com)

### BizNET CTM - Clinical Research platform

- eCRF, EDC and Clinical Data Management
- IWRS and Pharmacy Management
- Medical Imaging Trials
- Clinical Laboratory Management
- Bioanalytical Laboratory Automation
- eTMF

[biznet.sarjen.com](http://biznet.sarjen.com)

### Process XE - Smart Manufacturing

- Electronic Batch Records; eBMRs
- eLogbooks
- eLabNote books
- Dispensing management
- Manufacturing Execution (MES)

[process-xe.sarjen.com](http://process-xe.sarjen.com)

### StackTrack - File Tracking System

- Digitize physical file storage
- E-repository for digital documents
- Manage physical binders & digital media
- Configurable workflows & barcodes/RFIDs
- 3D view of archival space

[stacktrack.sarjen.com](http://stacktrack.sarjen.com)

## About Sarjen

- Journey of IT consulting for business and technology since 1998
- Domain expertise in Pharmaceutical, Life Science and other domains
- Subject Expertise in SCM, CRM, SAP, QMS, PV, Clinical, eCTD and MES
- Client presence in 50+ countries
- Partnerships with Microsoft, Apple, Amazon, Azure
- Members of, Nasscom, Gesia, Pharmexcil
- Proprietary Technology Stack
- Proficient in cGxP, Part 11, GDPR compliance
- In-depth knowledge of Computer System Validations (CSV)



Business Solutions with Technology Edge

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