QEdge

Quality Processes . Doc Control . Training Records

*E*nterprise
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

Training Records

Change Request

Deviation

Specification

CAPA

SOP

Investigation

Audit & Tracking

Market Complaint

APQR

OOT

OOS

Edge
Quality Processes . Doc Control . Training Records

Enterprise Quality Management

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

knowledgenet.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

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

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

Process XE - Smart Manufacturing

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

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

About Sarjen

- Over 21 years' journey of IT consulting for business and technology
- 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)

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