KNOWLEDGENET

www.knowledgenet.in

## The dilemma!

Meet real-time challenges in an ever evolving, dynamic regulatory environment...

New directives and regulations make it increasingly tricky for companies to effectively navigate the complex submissions!

With shorter timelines to meet regulatory approvals, while efficiently managing multiple formats, documents, and dossiers throughout the submission lifecycle can severely stress company's resources, budgets, and the overall submission process!

## Why go Electronic?

Having data in a common electronic environment will allow the regulatories to regulate product documents quickly, eliminating difficulties with accessing, searching through and finding data in paper forms;

Ultimately, regulatories want to create an electronic information exchange network to share with the public, so that information can be traded between different agencies, investigators, healthcare professionals and patients.

While electronic submissions help the agency speed reviews and share information.

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.

It is ready with pre-loaded checklists and template structures for US, EU, Gulf (GCC), Africa, Australia, Asia, CIS and Latam regions that can make dossier compilation process >60% faster.

## Features

- Dossier project tracking and life cycle management
- Dynamic template structure management
- Published document formatting
- Reusability of documents (upload once and use in multiple dossiers)
- Project status dashboard and MIS
- Set default working project
- Autocorrect of PDF property as per guidelines
- Real-time alerts and notifications to corresponding users
- Document transformation, i.e., word to pdf
- Project level attributes such as submission, MA grant and approval date

## Benefits

- Eliminate risk of non-compliance
- Improvement with submission effectiveness
- Eliminate delays due to queries
- Reduce user dependency
- Reduce dossier preparation time
- In-built document search engine
- Post submission query management
- User skills on multiple formatting tools not required
- One solution for all submission types (PDF, HTML and XML publishing)
- Single solution to manage global publishing

# Electronic submissions

## KnowledgeNET - eCTD/NeeS ePublishing

KnowledgeNET is a complete epublishing software for the creation, validation, publishing, viewing and reporting of regulatory documentation for electronic submissions by pharmaceutical companies to regulatory authorities.

## NeeS/vNeeS

- EU human version 4.0 and validation criteria v4.1
- Gulf countries v1.2, v1.5 and validation criteria v1.2, v1.4
- AU/NZ version 1.0 and validation criteria v3.0
- EU veterinary medicinal product, v2.5

## eCTD

- US eCTD v2.01, v2.3 and validation criteria v3.1, v3.5.1
- EU eCTD v3.0.2 and validation criteria v6.1
- Gulf countries eCTD v1.2, v1.5 and validation criteria v1.2, v1.4
- South Africa eCTD v1.0, v2.0 and validation criteria v1.0, v2.1
- Australia eCTD v3.0 and validation criteria 3.0
- Thailand eCTD draft v0.92, v1.0 and validation criteria v0.92, v1.0
- Switzerland eCTD v1.3 and validation criteria v1.3
- Canada eCTD v2.2 and validation criteria v4.2

## Electronic submissions: Features

- Paper/CTD to eCTD switching
- Dossier created using other software, can be continued with KnowledgeNET
- Submission procedure compatibility
- Project recompilation to avoid checksum warnings
- Add/Edit hyperlinks within the system

# KnowledgeNET – CTD/ACTD/Paper submission

## Features

- Automatic TOC generation with hyperlinks
- Bookmarks, header, footer and title page generation for each and every section
- Fit scanned files as per requirement
- Copy documents from one project to another
- Assign user for specific project with timeline with specific rights
- Dossier document summary report in tree and table view

## Submission regions

- ASEAN region – Malaysia, Singapore, Vietnam, Cambodia, Myanmar, etc.
- African region – Nigeria, Kenya, Zimbabwe, Tanzania, Ethiopia, etc.
- CIS region – Russia, Ukraine, Georgia, Kazakhstan, Uzbekistan, Moldova, etc.
- Latam region – Mexico, Panama, Venezuela, Chile, Costa Rica, Dominican Republic, etc.

# KnowledgeNET - Add ons

## Query management system

- Post-submission query tracking, eliminate delays due to queries
- Helps in compiling dossier effortlessly with immaculate precision
- Assign query to responsible person with timelines
- Regulatory agency's query response along with its compilation and review
- Real-time alerts and notifications to corresponding users
- Helps company to get faster approval of one product in different country

## eCTD viewer

- An engine which can manage uploaded dossier sequences, when loading for review
- Quick review of single/multiple sequences
- Compatible with any eCTD publishing solution
- With complete dossier submission history

## Dossier project tracking

- Assign project to responsible person with timeline
- Dates to manage re-submission/renewal for multiple products
- Manage other dates

# Are you running late for submission deadline?

## Regulatory services offered...

- eCTD, NeeS, CTD submission for IND, NDA, ANDA, DMF, ASMF, CEP
- Dossier document creation
- Electronic submission SPL (ER, NDC, GDUFA, Drug listing)
- Electronic submission for PADER/PAER
- ESG account setup
- EVPRM/xEVMPD and eCTD training
- US agent service
- Software validation according to regulatory guidelines
- Label and carton contents

## 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**

### FForce - Field Sales Excellence Platform

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

**fforce.sarjen.com**

### ProcEdge - Business Process Automation

- Processes automation
- Workflow automation
- Document management

**procedge.sarjen.com**

### QEdge - Enterprise Quality Management System

- Quality processes automation (CRF, Deviation, Investigation, CAPA, etc.)
- Document control (SOP, BMR, etc.)
- Training records keeping and management

**qedge.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**

### PvEdge - Drug Safety Database

$360^0$ 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**

## 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

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