Pharmaceutical Regulatory Compliance Management System

Process Automation & Digitalisation

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In most Pharmaceutical Companies the management of Compliance with rules, policies, guidelines, practices, and standards is largely done through a manual and labor-intensive process

Document versioning, signed hard copies, distribution and archiving can become complex and time consuming.

Things are getting tougher when **unpredictable events** happen, at the manufacturing process, and must be tracked and reported following a specific protocol.

Organizations must act very quickly and **adapt their business processes**, introducing **changes** that will fix problems, boost productivity and maintain high quality.

How can you manage this critical & complicated business flow without introducing expensive software or hiring expert resources **?**

Intelligent Regulatory Compliance Management System

✔ **Regulatory Documents Workflow**

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✔ **Quality Compliance**

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✔ **Manufacturing Process C.A.P.A.**

- **Deviation Incidents**
- **Change Requests Management**

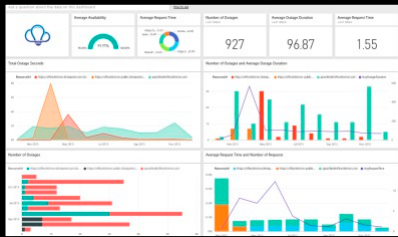**Based on the solid ground of**

S> SharePoint

Modular approach with powerful build-in search service

Interfaces with existing systems & applications

User friendly and easy end-to-end process execution

Scalable

Fully customizable

DOCUMENT MANAGEMENT

REVIEWERS

APPROVERS

DEADLINES

Q/A

ACKNOWLEDGERS

UP-TO-DATE REGULATION DOCUMENTS

SharePoint
WORKFLOW ENGIINE

DEVIATIONS

CHANGE REQUESTS

DEVIATION LOGGING

MANUFACTURING

ALERT

C.A.P.A. PROCESSING

CORRECTIVE ACTIONS

DELEGATION OF DUTIES

DEADLINES

MANUFACTURING

CHANGE REQUESTS

TASKS

C.A.P.A. MANUFACTURING PROCESS
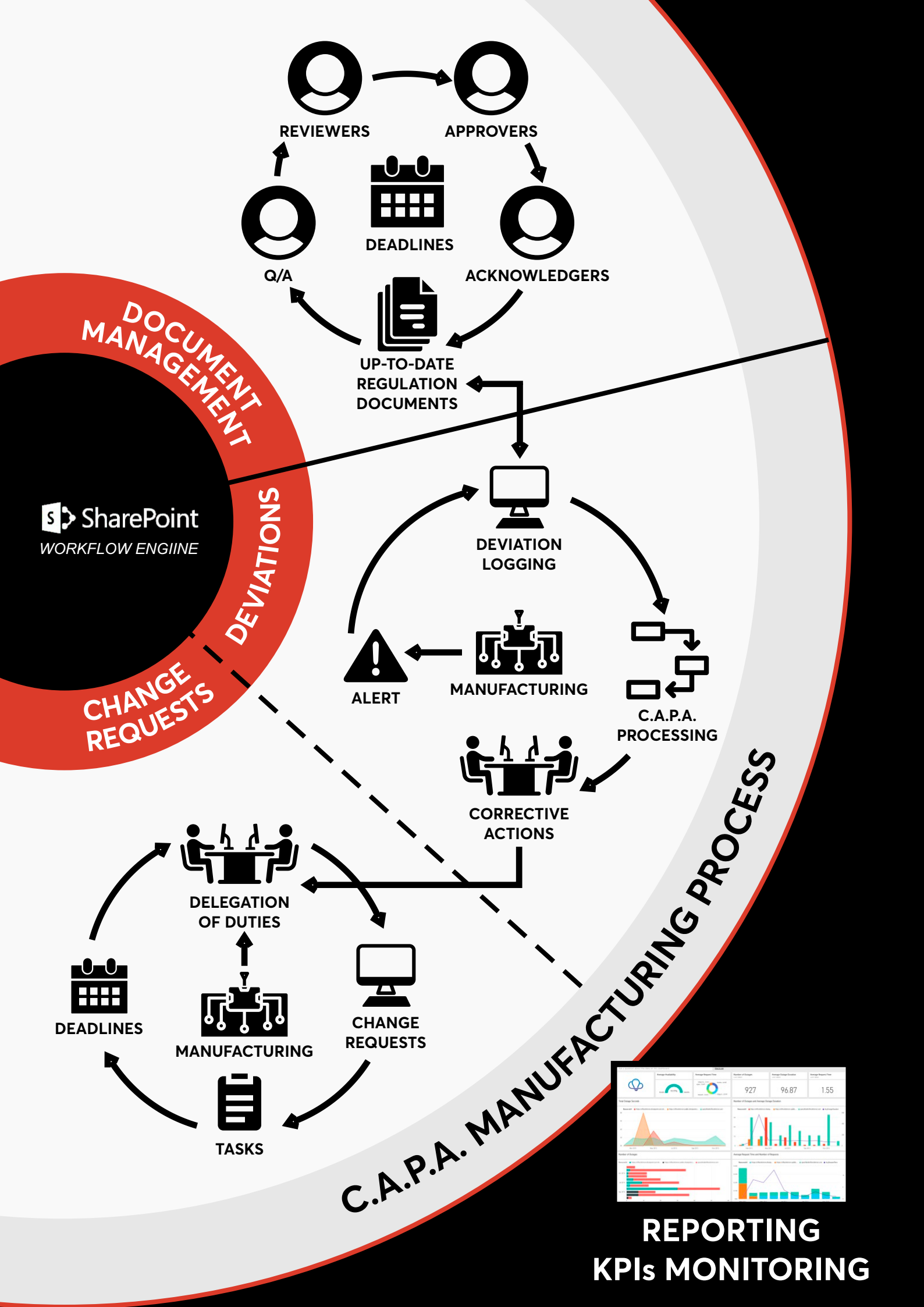
REPORTING KPIs MONITORING

Intelligent
Regulatory Compliance Management System

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Regulatory Documents Workflow

- Full Document Management
- Revision / Review Workflow
- Pending Tasks per User
- Deadlines Calendar
- Recurring Tasks
- Custom Document versioning
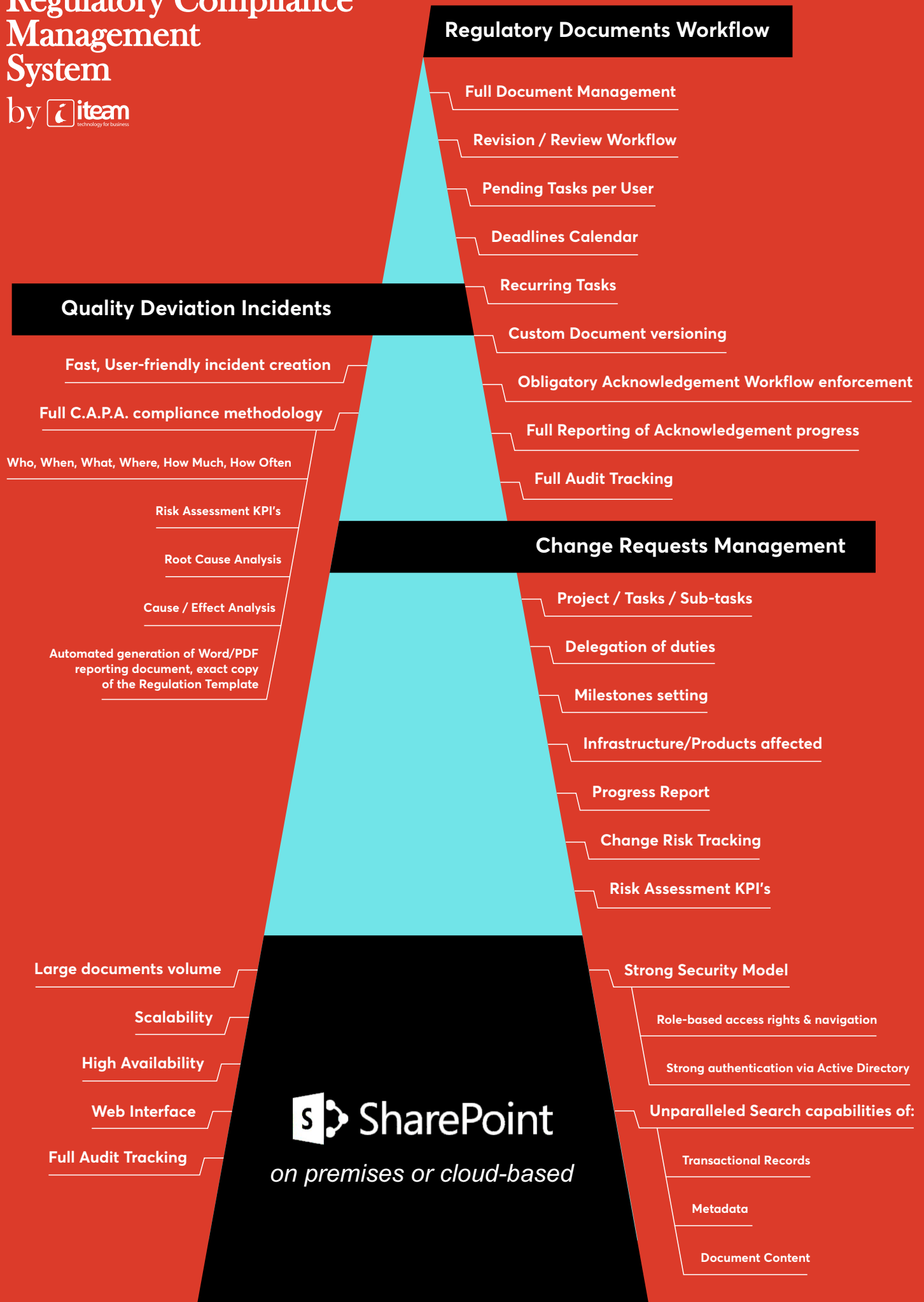- Obligatory Acknowledgement Workflow enforcement
- Full Reporting of Acknowledgement progress
- Full Audit Tracking

Quality Deviation Incidents

- Fast, User-friendly incident creation
- Full C.A.P.A. compliance methodology
- Who, When, What, Where, How Much, How Often
- Risk Assessment KPI's
- Root Cause Analysis
- Cause / Effect Analysis
- Automated generation of Word/PDF reporting document, exact copy of the Regulation Template

Change Requests Management

- Project / Tasks / Sub-tasks
- Delegation of duties
- Milestones setting
- Infrastructure/Products affected
- Progress Report
- Change Risk Tracking
- Risk Assessment KPI's

- Large documents volume
- Scalability
- High Availability
- Web Interface
- Full Audit Tracking

- Strong Security Model
- Role-based access rights & navigation
- Strong authentication via Active Directory
- Unparalleled Search capabilities of:
  - Transactional Records
  - Metadata
  - Document Content

SharePoint

on premises or cloud-based

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at a glance

Optimizing & Automating Business & IT Operations

➡ **Custom Software Solutions**

➡ **Software Testing**

➡ **Business Intelligence**

➡ **Infrastructure Management**

➡ **Business Function Specific Solutions**

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