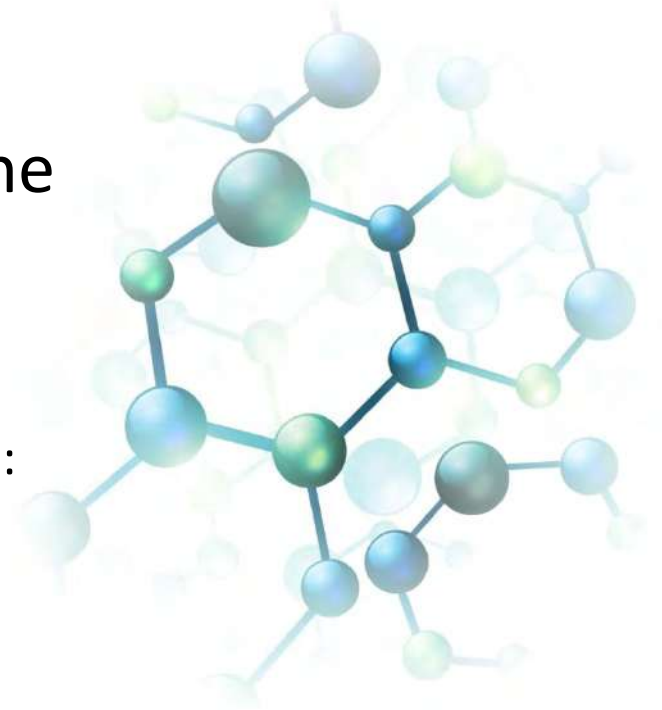


CRQA is pleased to announce the
partnership with DOT.Compliance for the
Indian market

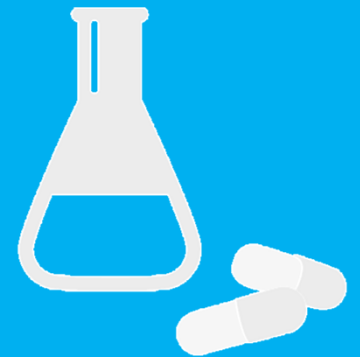
For more information and product Demo, please call :

+91 98100 68241

Email : bd@crqa.in



Compliance Suite
Streamline Quality





Compliance Suite
Streamline Quality

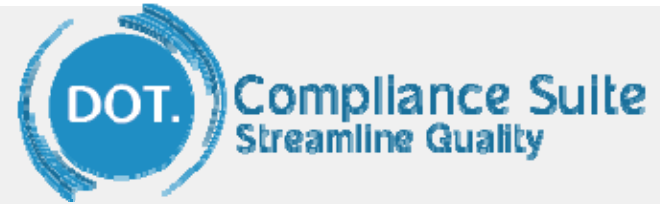


Dot Compliance

LIFE SCIENCES DIGITAL TRANSFORMATION
REGULATED QUALITY & COMPLIANCE PROCESSES



Who We Are?



✓ **DOT Compliance Suite** is a cloud **Quality and Compliance management** solution for highly regulated industries compliant with FDA 21 CFR Part 11 and ISO13485:2016/21CFR part 820.



AppExchange Program
PARTNER

✓ Developed on **Force.com** platform – the world’s leading cloud solution for maximum performance and security.



✓ The application contains industry’s **best practices processes catalog** as a starting point for easier and cost effective deployment

Compliance is transforming



Compliance Suite
Streamline Quality



Paper Based Systems

- Paper Documents and forms

Structured Electronic Records

- Automated Workflows
- Electronic signatures

Big Data Compliance

- Multi Sources
- Large sets of unstructured Data
- Need to transform data into insight and decision support
- Dynamic Processes



Paper Based Systems

- Paper Documents and forms

- **More compliance requirements**
- **Increased complexity**
- **A LOT of Paper Work!**
- **Focus is on administration instead of quality**
- **Quality is perceived as a burden**
- **No Traceability, No Insights**

Traditional Solutions Challenges



Compliance Suite
Streamline Quality



Structured
Electronic
Records



High Capital
Investment



Long
Deployment
Cycles



Validation



Keep up with
Regulatory
Changes



Huge
Organizational
Workload

Connected to IOT, Devices and unstructured data sources



Compliance Suite
Streamline Quality

Connected to devices and unstructured data sources



Compliance is Transforming



Solution for the Compliance Ecosystem



Suppliers



Contracted
Manufacturing



Production



Distribution

Quality Management Silos of Suppliers, Contracted Manufacturing (CMO), Internal Production and Distribution Chain are **transforming into a connected quality system**

Rational for Change



Compliance Suite
Streamline Quality

- Detect quality issues earlier – act faster globally
- Risk based approach
- Better control of changes

Improved Quality



- 360° process view – cross function, department, subsidiary or site
- Real time updates
- KPI and Dashboards

Better Visibility



- Compliance with FDA/EMA and ISO 13485 requirements
- Reduce regulatory compliance risks

Compliance Adherence



- Standard processes
- Standard performance measurement
- Standard tools and methods

Standardization



- Reduce manual effort
- Faster global change management & NPI
- Use global resource pool

Efficiency



- Share information across sites & functions
- Preserve knowledge
- Collaborate with Supply & Distribution

Collaboration



Dot Compliance Core Solutions

Out of the box ready for deployment – Express Package



Compliance Suite
Streamline Quality



Document Management

Document Revision Control

Read & Understand Training

Periodic Review



Training Management

Training Plan

Certification

Training Assignment

Adherence reports



Change Control

Impact Assessment

Action Item

Effectiveness Check



Deviation / CAPA

Deviation

Investigation

CAPA

Effectiveness Verification



Customer Complaint

Safety Tracking

Adverse Event

Vigilance Reporting



Risk Management

Risk Mng. Plan

Risk Evaluation

Risk Control



Audit Management

Audit Plan

Internal Audit

External Audit

Observation



Supplier Quality

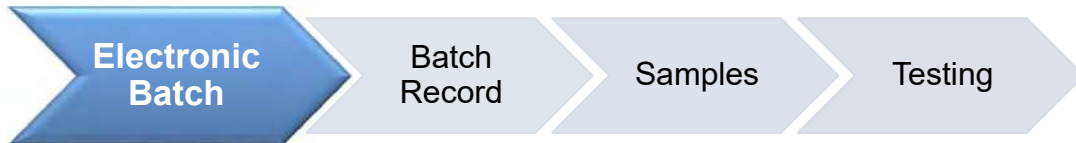
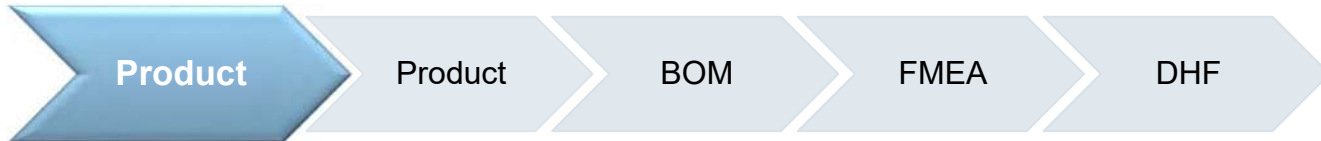
Supplier Evaluation

Supplier Audit

Score Cards

Supplier Portal

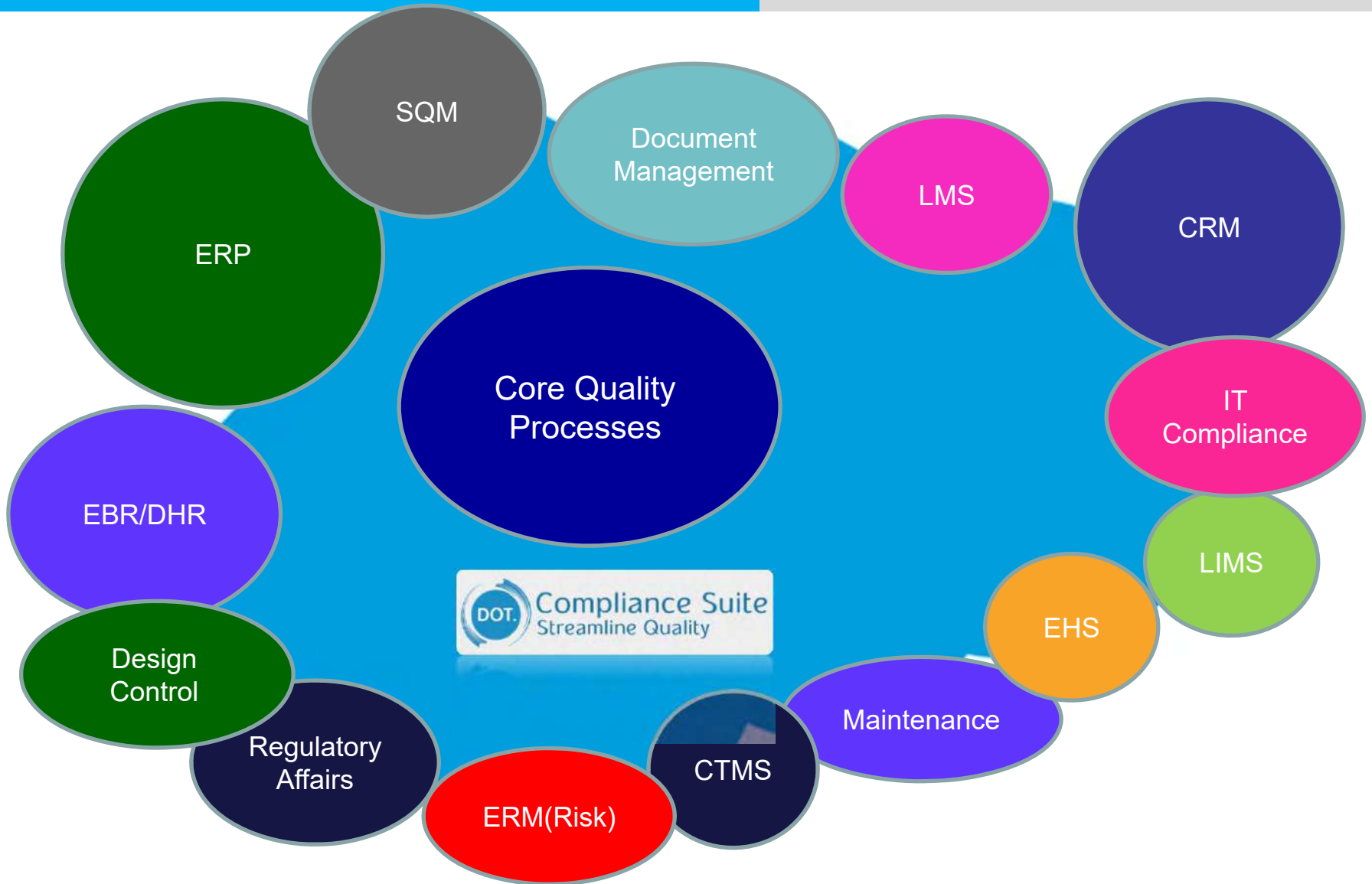
Additional Solutions



Holistic Enterprise Solution



Compliance Suite
Streamline Quality





Compliance Suite
Streamline Quality

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