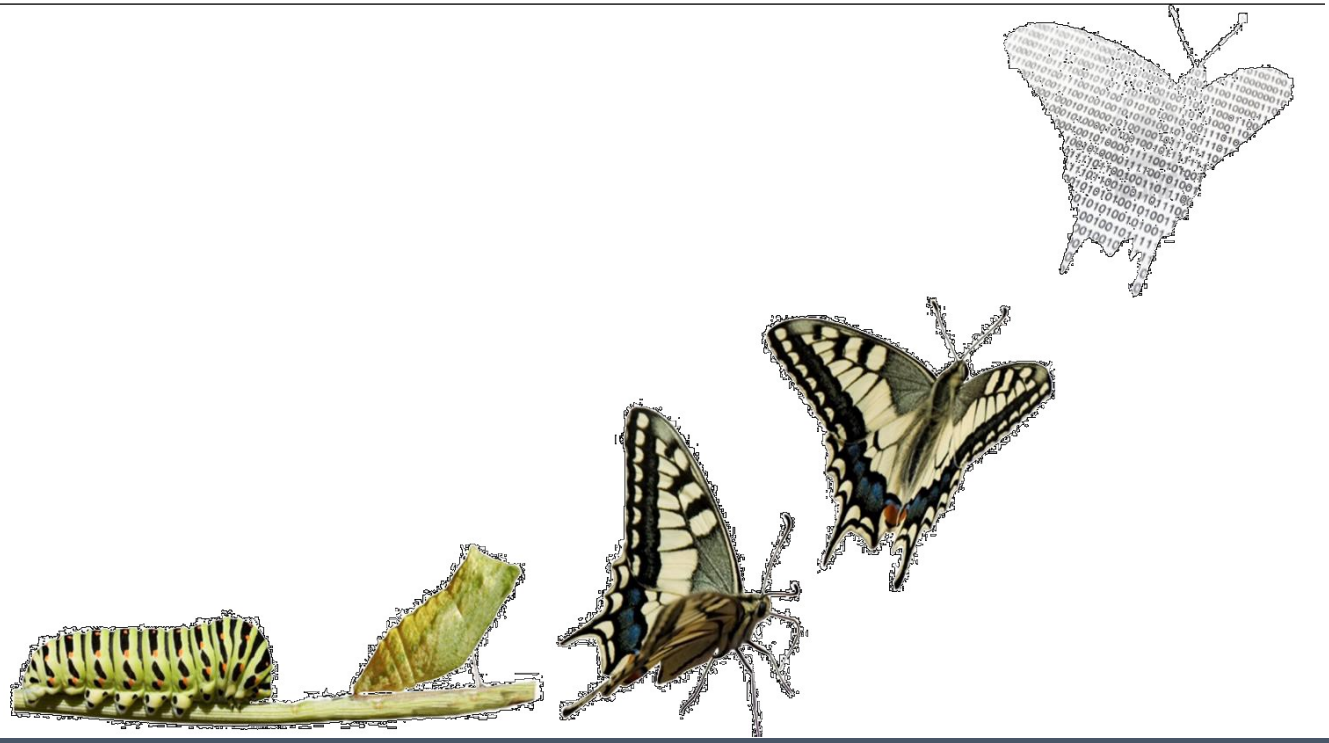


Dot Compliance

LIFE SCIENCES DIGITAL TRANSFORMATION

REGULATED QUALITY & COMPLIANCE PROCESSES

Who We Are?

DOT. Compliance Suite
Streamline Quality

GxP Compliance

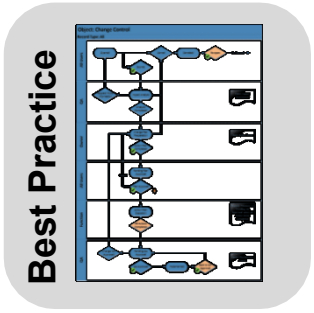
ISO

FDA 21 CFR Part 11

- **DOT Compliance Suite** is a cloud **Quality and Compliance management** solution for highly regulated industries compliant with FDA 21 CFR Part 11 and Annex 11.

salesforce | 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

DOT. 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 System Challe

DOT. Compliance Suite
Streamline Quality

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 Challe

DOT. Compliance Suite
Streamline Quality

Structured Electronic Records

High Capital Investment

Long Deployment Cycles

Validation

Keep up with Regulatory Changes

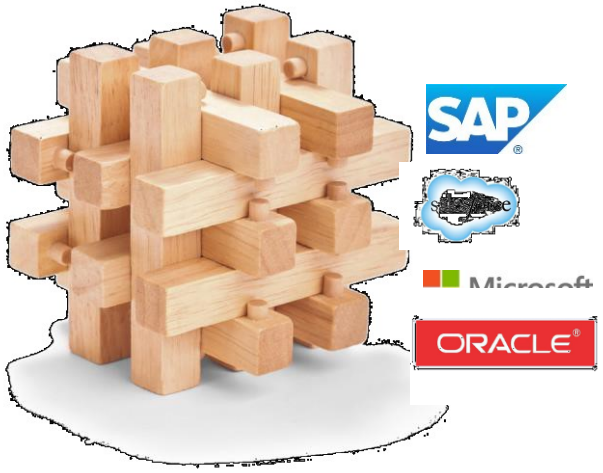
Huge Organizational Workload

Connected to IOT, Devices and unstructured data sources

DOT. Compliance Suite
Streamline Quality

Connected to devices and unstructured data sources

Big Data Compliance



Compliance is Transforming

DOT. Compliance Suite
Streamline Quality

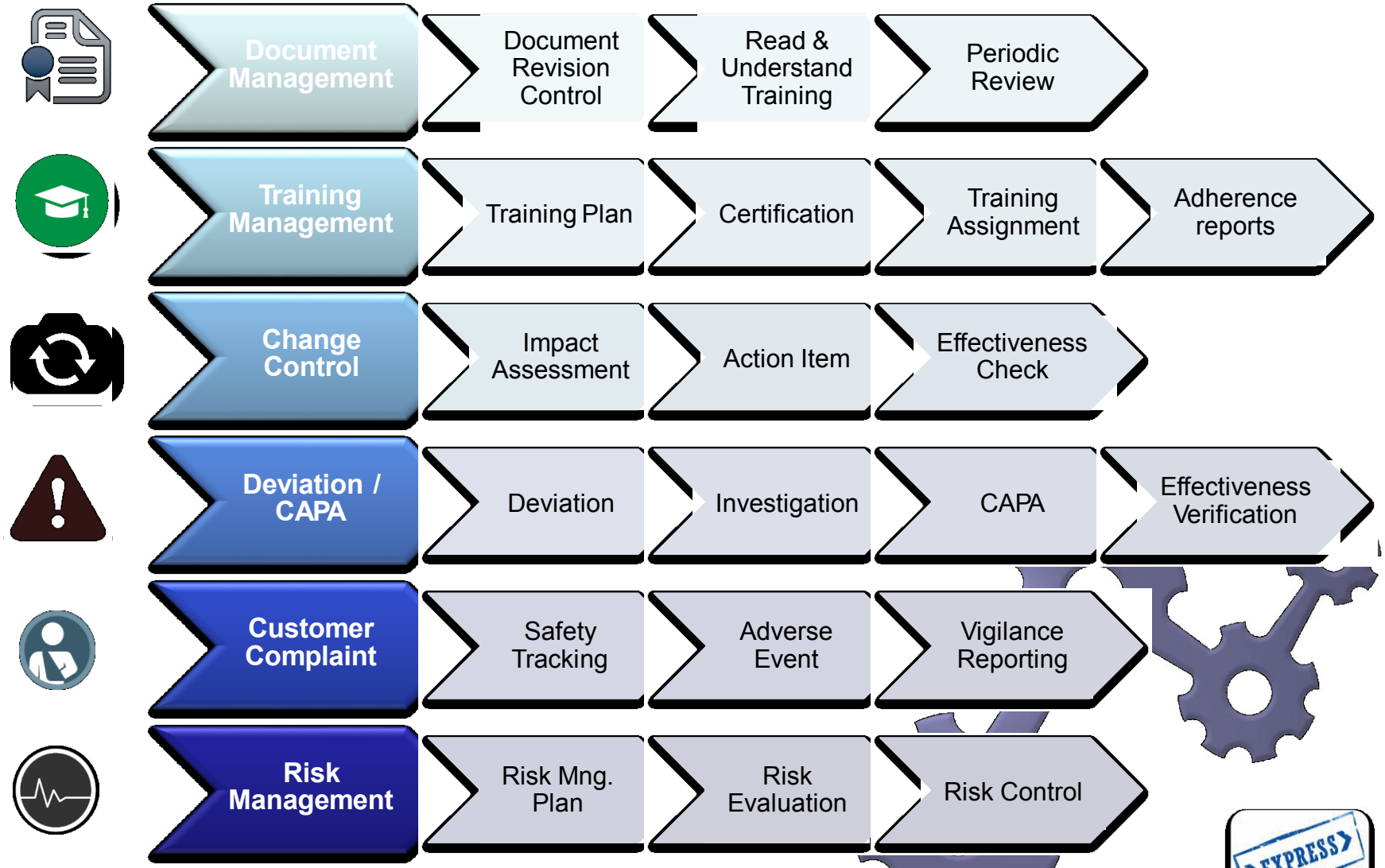
Solution for the Compliance Ecosystem

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

Dot Compliance Basic Mod

DOT. Compliance Suite
Streamline Quality

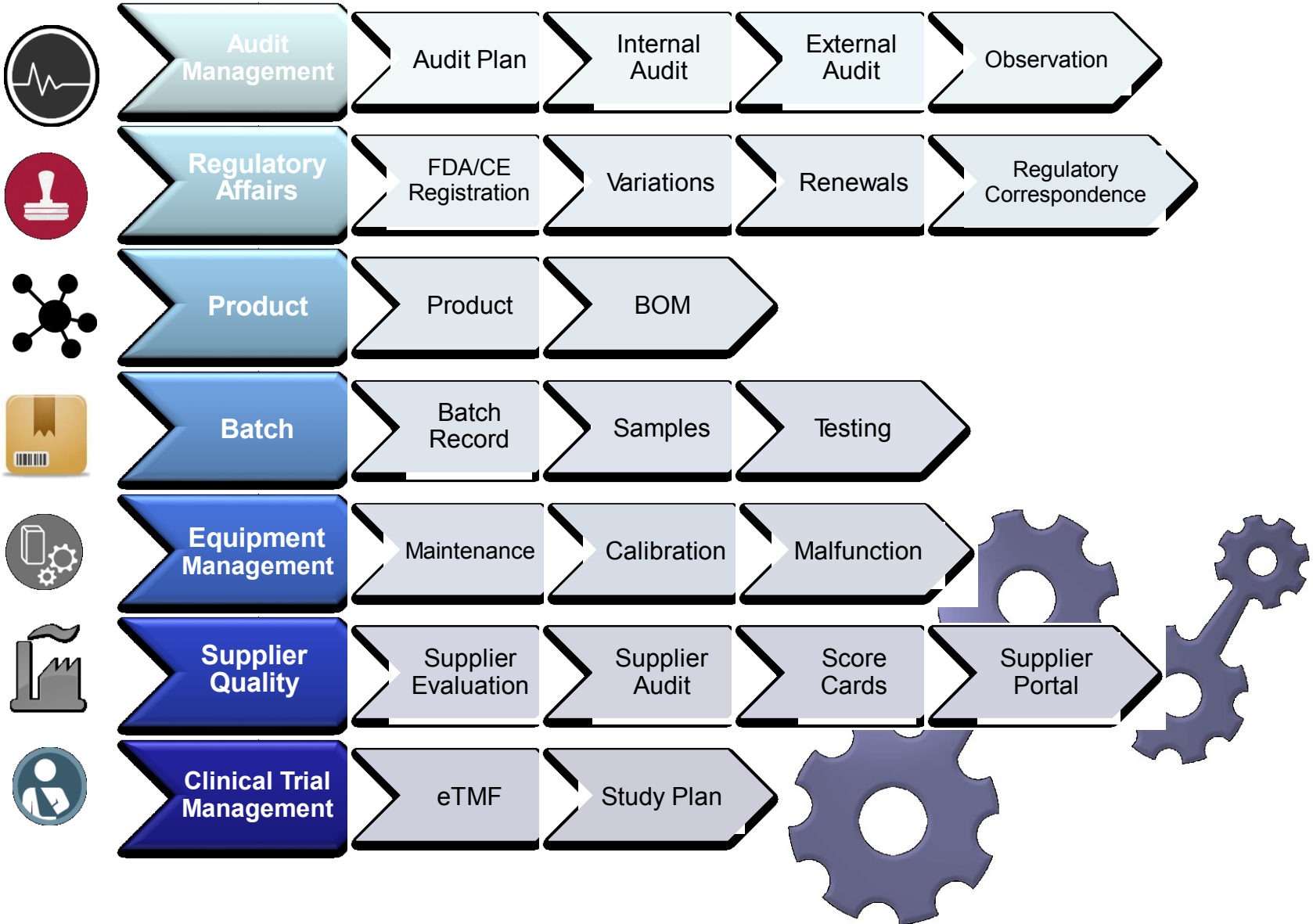
Processes Catalog



Additional Modules

DOT. Compliance Suite
Streamline Quality

Processes Catalog



Solution Benefits

DOT. Compliance Suite
Streamline Quality

Best Practices

- ✓ Over a 100 Pre-configured processes to meet industry needs and compliance requirements

Flexible

- ✓ Agile and cost effective customization
- ✓ Full API and integration support

Reliable

- ✓ High Availability
- ✓ Disaster Recovery
- ✓ ISO 27001 Security certification
- ✓ Scalable

Cost Effective

- ✓ No capital investment
- ✓ 3 upgrades per year
- ✓ No additional IT costs

User Experience

- ✓ Easy to use
- ✓ Customizable
- ✓ Multilingual
- ✓ Consistent user experience globally

Accessible

- ✓ Mobile/Tablet access.
- ✓ IOS and Android support.
- ✓ Consistent reliable performance globally

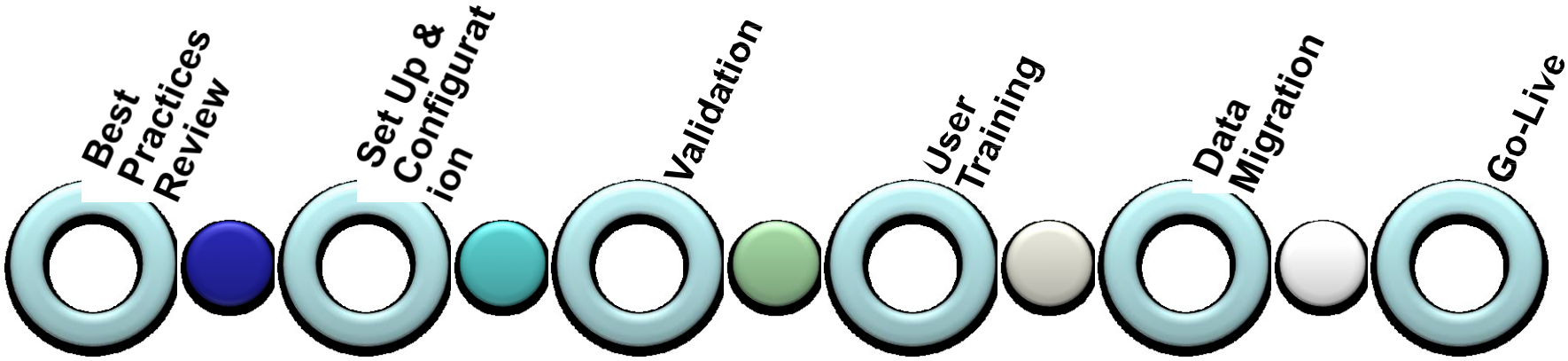
Eco-System Support

- ✓ Secured portal access to suppliers and external labs allowing them to view and update relevant data

Analytics

- ✓ Built-in flexible reporting.
- ✓ KPI's and Scorecards
- ✓ Easy Data export

Deployment Methodology



- DOT Compliance Suite is designed for **Agile Phase Implementation** approach: Start with few core processes and as your organization grows and mature deploy additional required processes.

What do our Customers thi

DOT. Compliance Suite
Streamline Quality

Yaron Ziv
Director QA

"Great software. After I tried it, I did not want nothing else for my company! Interactive. Easy to use…. Simplified my work and allowed me to concentrate on quality…"

★★★★★

Sasha Nezlin
VP Quality
Intec Pharma

Excellent e-QMS suite, combining ease of implementation with ease of use…"

★★★★★

Shulamit Ben Shimon,
Director QA
Mitsubishi Pharma

"... By using this system, I have confidence with the documentation and control other quality related processes…"

★★★★★

Guy Sadhe,
CIO
Insightec

"…Great QMS complaint solution for Medical device firms. ... this is probably the best investment out there"

★★★★★

Some of our customers

DOT. Compliance Suite
Streamline Quality

Zenabis™

savyonDIAGNOSTICS
Member of the Gamida Diagnostics division

UroGen Pharma

נובולוג Novolog
Company of Pharm-up

PROPHARMA GROUP®

Occlutech

scientia
CLINICAL RESEARCH

REKAH PHARMACEUTICAL INDUSTRY

Johnson & Johnson

Medtronic

IMP
THE WHOLE PACKAGE

TEVA
SLE Division

Inspiring the Art of Surgery
Mazor Robotics

SciVac
For Life

NeuroDerm
Mitsubishi Tanabe Pharma

Phibro
ANIMAL HEALTH CORPORATION™

INTEC PHARMA

INSIGHTEC

BI
Biological Industries

one1

maxQ
Artificial Intelligence

Enlivex
Therapeutics

QCORE medical

artiHeal
Future of Joint Repair

TSO3

TANTALUS

For more information, demo and quote please contact CRQA – Dot Compliance's India Partner:

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