

Introducing Design Controls as a Service

– Ready-made online service for agile RegOps

AHMED Project Final Seminar

Helsinki 2022-11-22



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CEO

Taipuva Consulting was founded in 2011

Mission:

*Help Finnish companies
improve the efficiency
of R&D*

We have been successful in helping our customers!



PLANMECA

SARTORIUS

phoTono

ThermoFisher
SCIENTIFIC

KAVO KERR

XO

Innokas
Medical

MEHILÄINEN

Dvysr

bk
medical

tobii

WSAudiology

Boule

RADIOMETER

evondos

GRUNDIUM

Airsonett

ATROTECH
Atrostim® Implantable Neurostimulators

UNEEG™ medical

muRata
INNOVATOR IN ELECTRONICS

stuk

Envirotainer®
The Active Cold Chain

VTT

Millog

NIRA
DYNAMICS

Consilium

SUUNTO

Junttan

Region
Stockholm

KTH
VETENSKAP
OCH KONST

SANDVIK

SCANIA

Valmet
FORWARD

NIBE

Danfoss

VALMET AUTOMOTIVE

AHMED Context: Not just software ...but regulations – It's a different ball game!

> **70 %** of medical software
project is *documentation*

**DOCUMENTATION
TRACEABILITY**

20–25 %
(manually done)

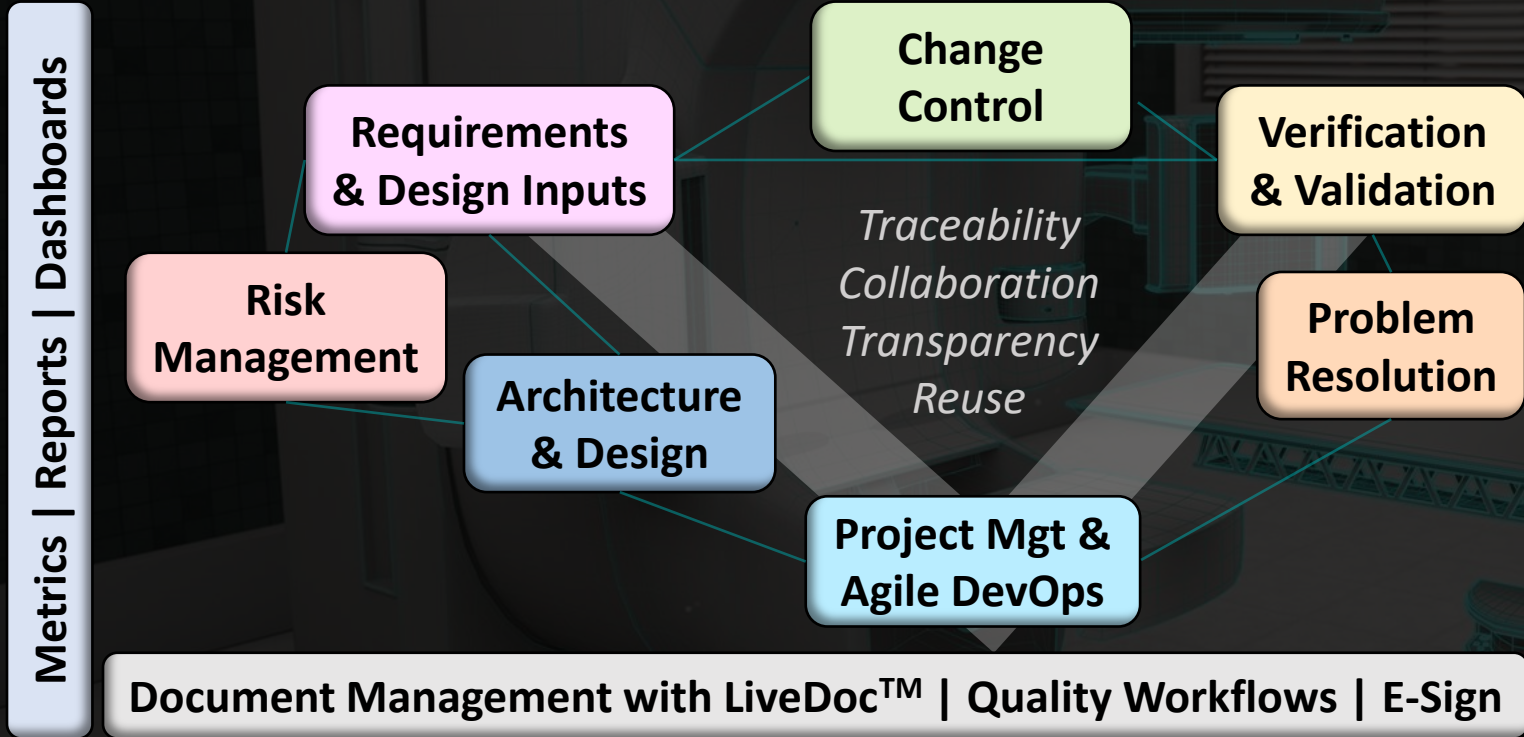
To get to the top... use the **most efficient ways of working** and
the best fitting tools available

- Guarantee **patient safety** and **cybersecurity** (and compliance)
- Produce **value** for customers/investors/taxpayers
- Make experts' work more **enjoyable** to keep **motivation** high!





taipuva DESIGN CONTROLS AS A SERVICE

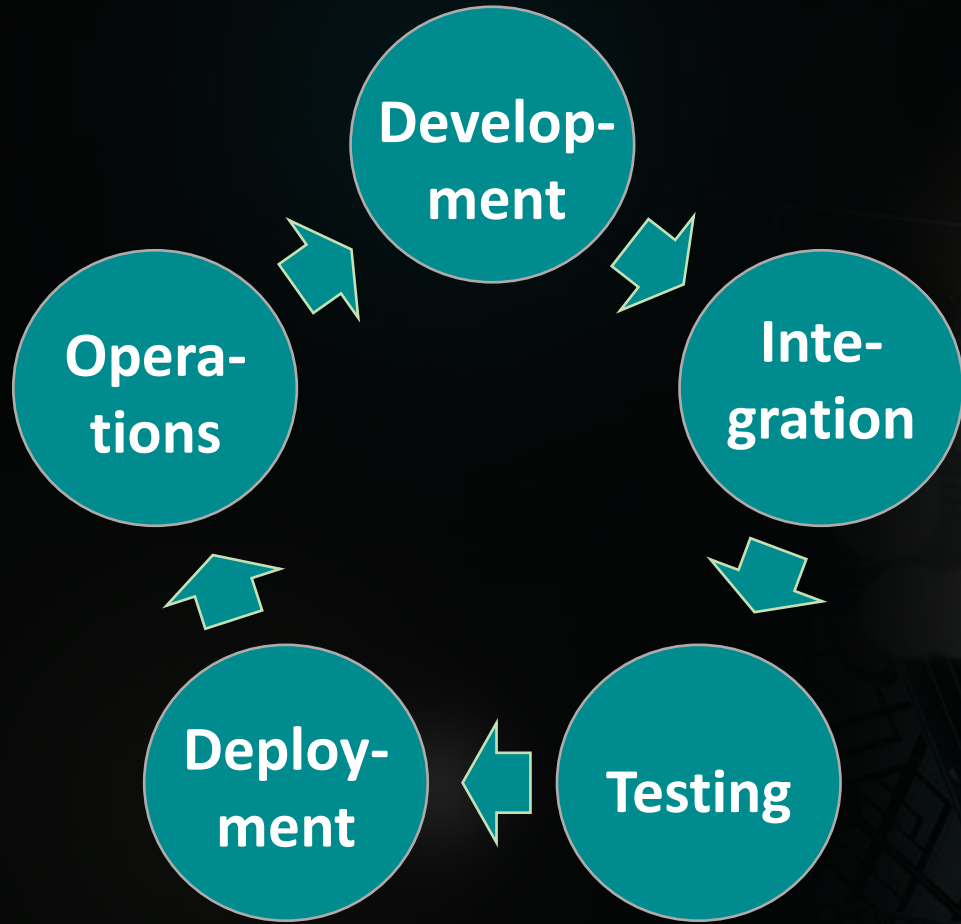


- 1) Built on a digital platform that has been designed for regulated industries: SIEMENS Polarion® ALM™
- 2) Implements best practises, simply and effectively
- 3) Online from cloud, serviced by Taipuva
- 4) Taipuva & partners' expertise service available

Benefits

- 1) Operational efficiency
- 2) Time and effort to get it into use

DevOps Cycle



In the same culture,
with the same tool chain:

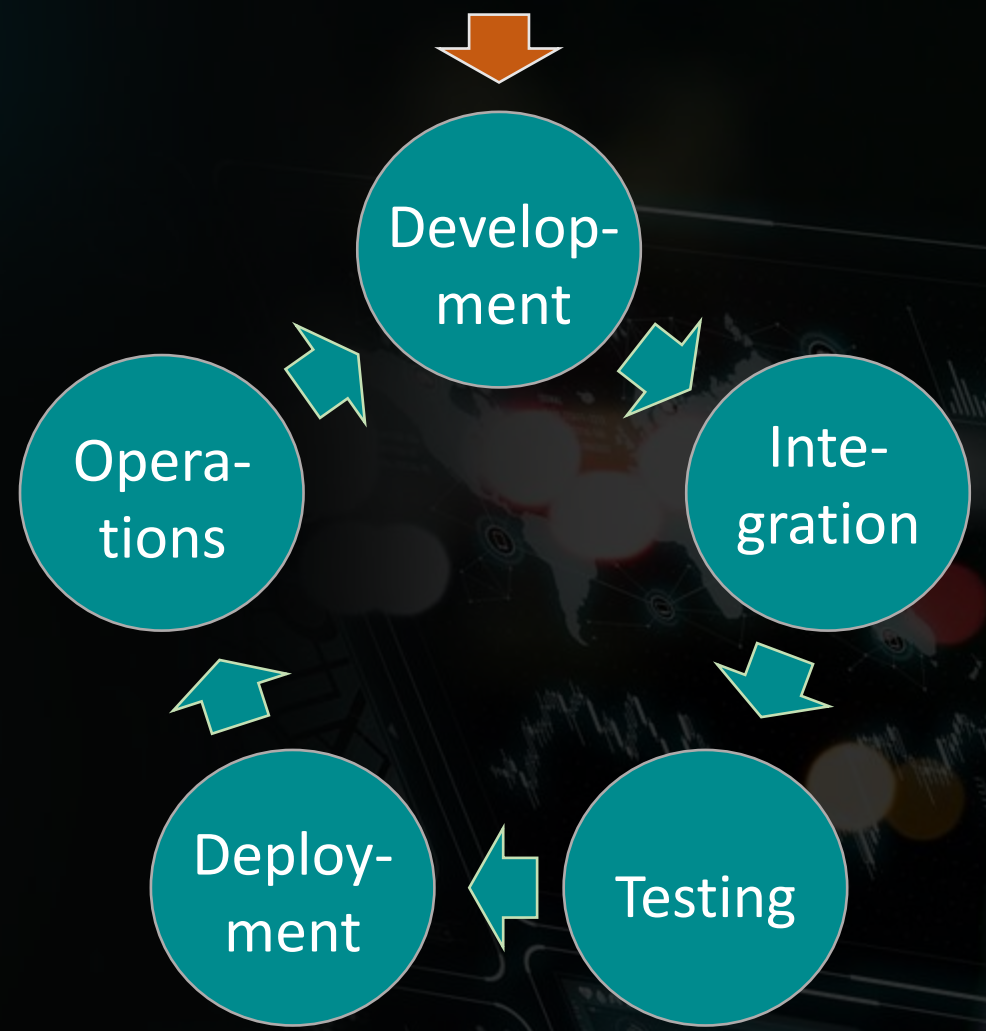
INTRODUCE NEW REQUIREMENTS

- Documentation
- Process Control

> 70 % of project effort



QA/RA Experts

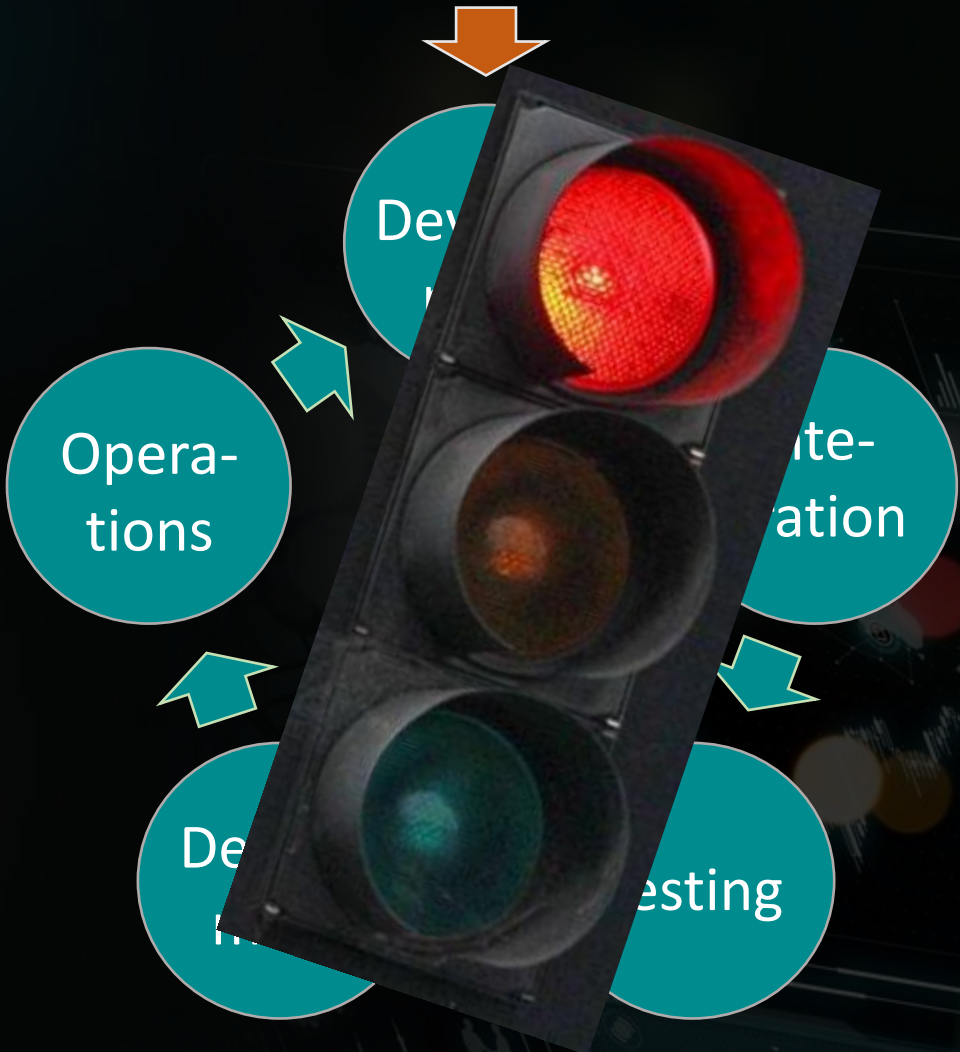


> 70 % of project effort

Documentation Process Control

QA/RA Experts

Agile?
Ability to change fast?



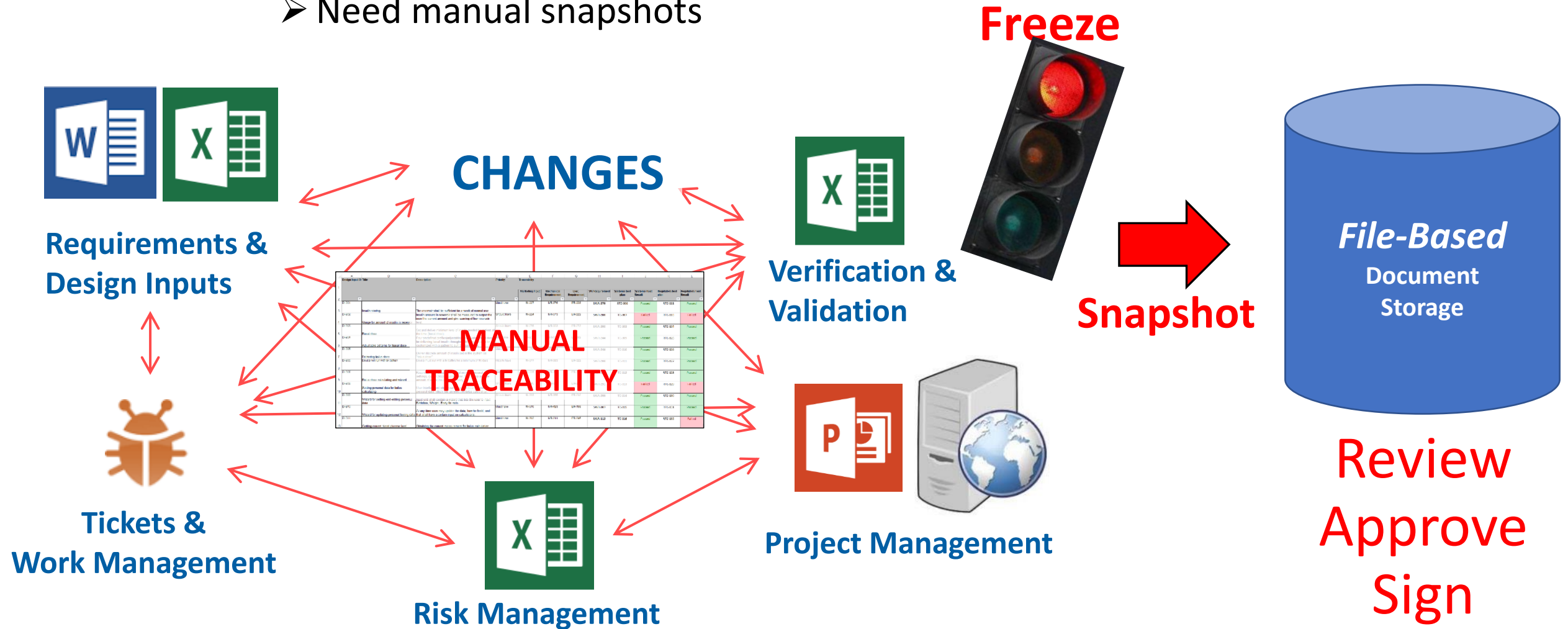
Export current documentation



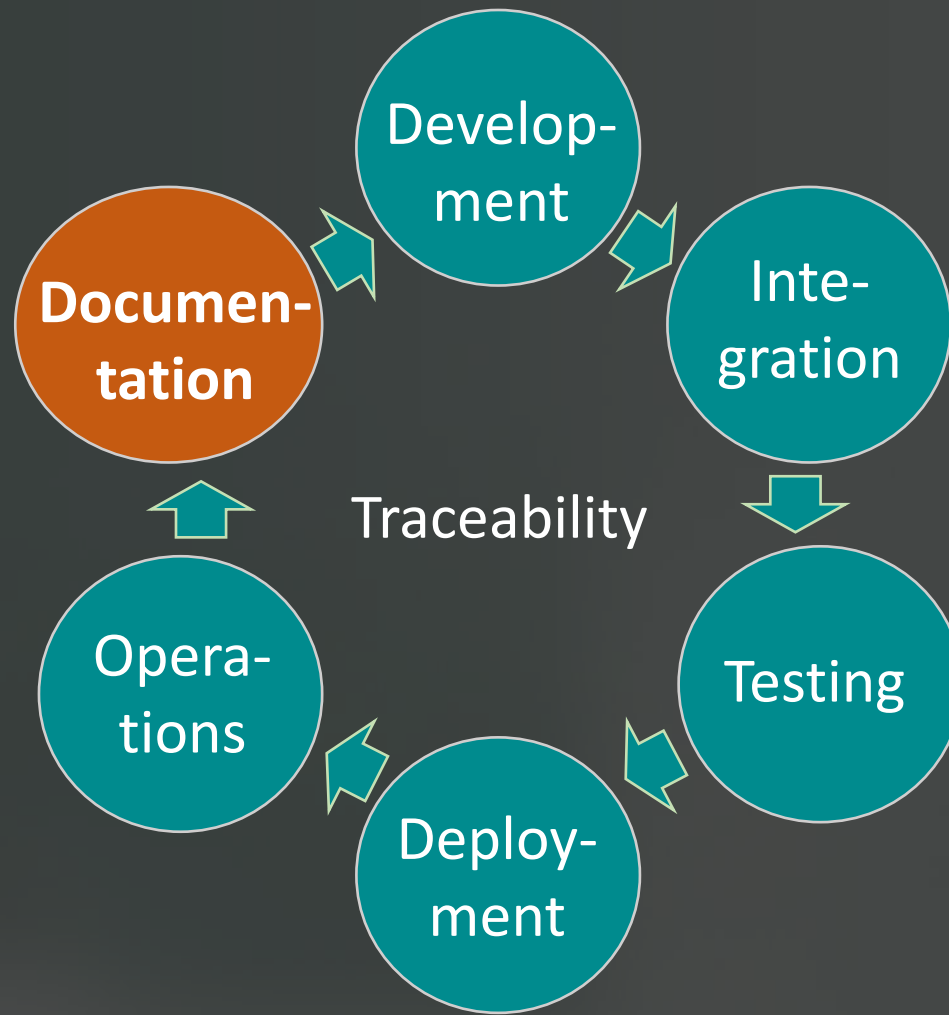
Review Approve Sign

Traceability – If it is not 100 % consistent:

- Need manual checking
- Need manual updating
- Need manual snapshots



True RegOps Cycle



**Savings
> 20 %**

- Tool chain & cycle includes documentation (with needed review, approve, e-sign)
- History archives everything consistently
- Process control built in

2) Time & effort to build a similar setup



Thank You!

Questions?

Feel free to contact & connect on LinkedIn

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