Qualsys

Audits, inspections and reporting

Identifying risks and opportunities

20th March 2019

Chris Owen, Services Director at Qualsys

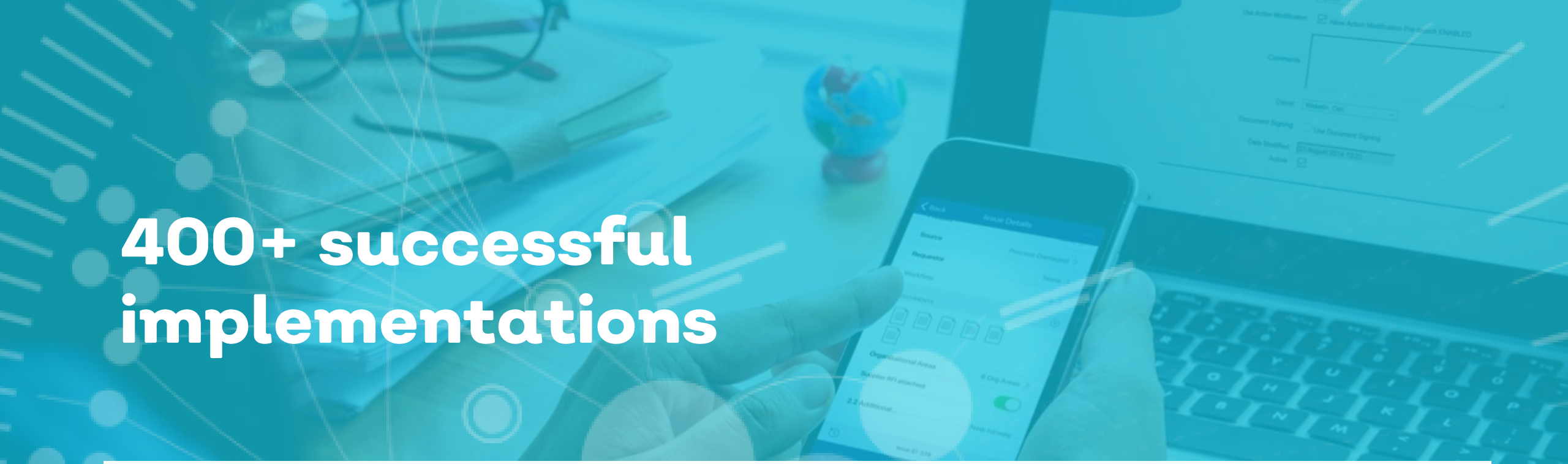
Agenda: Identifying risks and opportunities in audits

- ✓ Why audit?
- ✓ Five common auditing mistakes
- ✓ Is your auditing process broken?
- ✓ Risks and opportunity management and reporting

Chris Owen

Services Director

400+ successful implementations



Honeywell
THE POWER OF CONNECTED
DIAGEO
sodexo
UNIVERSITY OF LEEDS
THOMAS MILLER
IQE
smsplc
ENERGY assets
+well
BT
NHS
BARR SOFT DRINKS
Accolade Wines
HYBRID Air Vehicles
BUNZL
MarleyEternit
IOVANCE BIOTHERAPEUTICS
RAWSON
baywater HEALTHCARE
Alliance Medical
Intelligent imaging
EPC GROUPE
ofgem
BUCHER municipal
Virgin media

Auditing today: Preventing business disruption in a digital world

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2018-2019	2017-2018
	

'I had pain all the time': health issues after **Essure** implants

The Guardian - 25 Nov 2018

Andrea Davies, 44, from Chesterfield, Derbyshire, was given a single **Essure** implant as part of an experimental fertility procedure. She had ...

HEALTH NEWS NOVEMBER 16, 2017 / 6:02 PM / A YEAR AGO

Johnson & Johnson hit with $247 million verdict in hip implant trial

Allergies

Pret allergy death: Gove backs 'Natasha's law' on labelling

Minister tells teenager's parents the legislation could be in place by next summer

'His death still hurts': the smoking drug ruled to ha contributed to suicide

Daimler to recall 774,000 Mercedes models due to emission 'defeat devices'

Recall is understood to include newest, Euro 6 diesel engines; number of UK cars affected is unknown

Bayer sued over Essure contraceptive that allegedly caused nickel poisoning

Australian women launch class action over device after reports of perforations and chronic pain

FDA: Brainlab Cranial IGS system recall is Class I

JANUARY 15, 2016 BY FINK DENSFORD — LEAVE A COMMENT

cember 2018

Field safety notice Anaesthetics and 21 others Issued: 24 December 2018

Fabian +nCPAP evolution, Fabian Therapy evolution and Fabian HFO – Risk of total loss of patient ventilation (MDA/2018/037)

Facebook says 14m accounts had personal data stolen in recent breach

Hackers were able to access name, birthdate and other data in unts that were affected

probability that use of these products will consequences or death."

News

Second Pret allergy death named as 'wonderful' 42-year-old mother of five

nber

share Save

News

Australian woman accused of planting needles in strawberries 'motivated by spite'

share Save 5

The lifelong shadow hanging over the Elephant Man drug trial victims after the human guinea pigs were left horribly disfigured and fighting for their lives

- **In March 2006, eight volunteers signed up for a medical trial in London**
- **None of the eight volunteers could have known what lay ahead for them**
- **It became known as the Elephant Man trial because of it shocking side-effects**
- **New BBC documentary revisits dramatic events that left men fighting for life**

Summary List of field safety notices (FSNs) from medical device manufacturers from 03 to 07 December 2018

Field safety notice Issued: 10 December 2018

Field safety notices - 26 to 30 November 2018

Summary List of field safety notices (FSNs) from medical device manufacturers from 26 to 30 November 2018

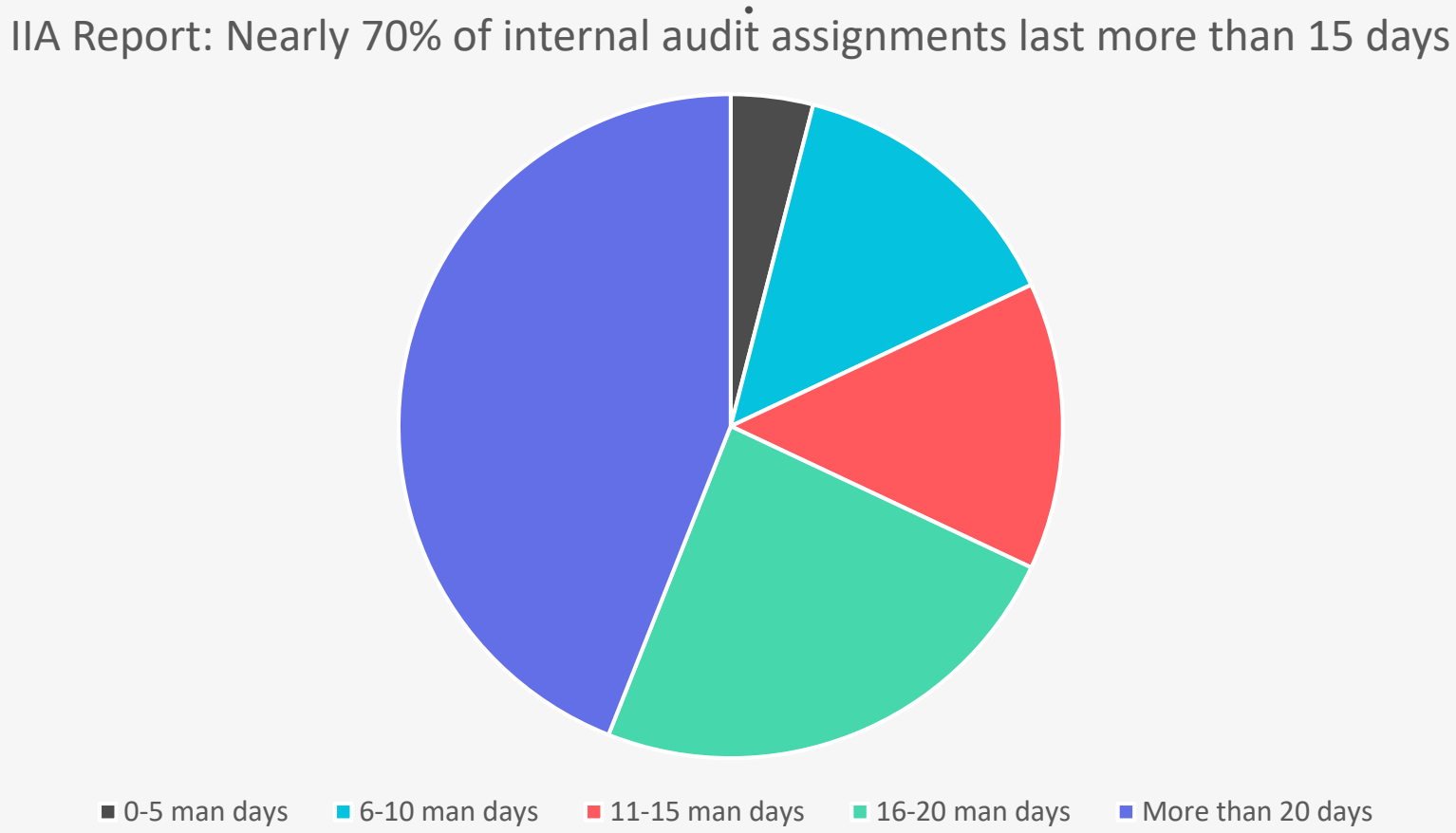
Field safety notice Issued: 4 December 2018

Class 2 Medicines Recall: Teva UK Limited and Mylan - recall of some Valsartan containing products

Some valsartan containing products including certain batches supplied by Teva UK Limited and all unexpired batches supplied by Mylan are being recalled.

Drug alert Anaesthetics and 21 others Issued: 30 November 2018

90% of internal audit reports cost over £5,000 each



Source: https://www.iia.org.uk/media/198130/13._benchmarking_report_internal_audit_assignments_22_september_2008_1_.pdf

It's all about risk and opportunity

Auditing

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- ✓Generates valuable insights
- ✓Prevents waste
- ✓Creates value
- ✓Helps organisations to grow
- ✓Fixes leaking buckets

Auditing has an image problem

What would your organisation say about the audit function?

- Internal audit survey prior to implementation of a management system

Mistake #1: Poor communications

The auditing landscape

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1. Collect risk and opportunity data

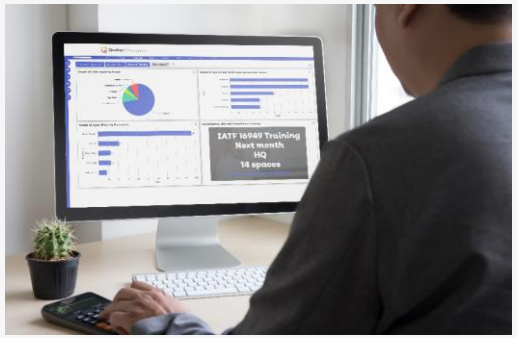
- ✓ Internal issues, NCRs, training
- ✓ Macro-environmental changes
- ✓ Inspections
- ✓ Policies & documentation

2. Audits

- ✓ Process reviews
- ✓ Culture health checks
- ✓ Department audits
- ✓ Risk and opportunity identification

3. Risk treatment

- ✓ Reports
- ✓ Business continuity
- ✓ Workflows / CAPA
- ✓ Business improvement



Mistake #2: Lack of creativity

Goldilocks auditor

- The best auditors listen, learn and guide

Overly friendly

Too rigid

Good communicators

Your internal auditors are as valuable to your business as external auditors

Mistake #3: Inconsistent approaches and experience

Audits vs Inspections

Audit	Inspections
Qualitative	Quantitative
Exploratory	Tick-box
Who, Why, What, Where, When, How?	Yes / No
Useful for: Leadership audits, risks and opportunities, improvement initiatives, operational excellence, growth, profitability, ideas and innovation	Useful for: Exposing vulnerabilities, quality control, waste reduction, fact-checking, process management.
Complex root cause analysis and problem solving	Rapid root cause analysis

Use your audit report wisely

- How can we communicate risk and opportunity in a way people are going to understand?
- How can we drive action from audit reports?
- How can we change the perception of an internal audit from a tick-box exercise to one where it drives cultural change?

!Think carefully before putting a scale in the audit report

Benefits of using a scale	Disadvantages of using a scale
Simple to understand	Diversion from findings to a negotiation on a number
Provides areas of focus	Promotes competition between departments
Scale reflects risks	Repetition of recommendations against risks (no integration of activities leading to duplication of effort)
Allows committee members to assess strength of controls without reading report	Management may ignore areas of weakness or good practice
Powerful communication tool	Does not include recommendations, instead agreed management actions

Mistake #4: Not investing in auditors

Attitude, approach, communication and appearance

“Quality people are the needle and thread, stitching the whole end-to-end together. To do this you have to be a good communicator and influencer who can quickly build respect and credibility. People who can truly do this are very thin on the ground.”

Leading quality in the 21st Century – CQI & Oakland research report

Mistake #5: Poor follow up activity

Implementing Risks & Opportunities

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? What action did you take to address a problem?

? Did you carry out any trend analysis?

? How can you prevent a NCF from occurring again?

? How effective were your corrective and preventative actions?

? Have you updated your Risk register?

✓ Remember to follow-up on any audit findings

✓ See all findings as an opportunities for improvement.

✓ Discuss and report your finding at senior level.

Response needs context

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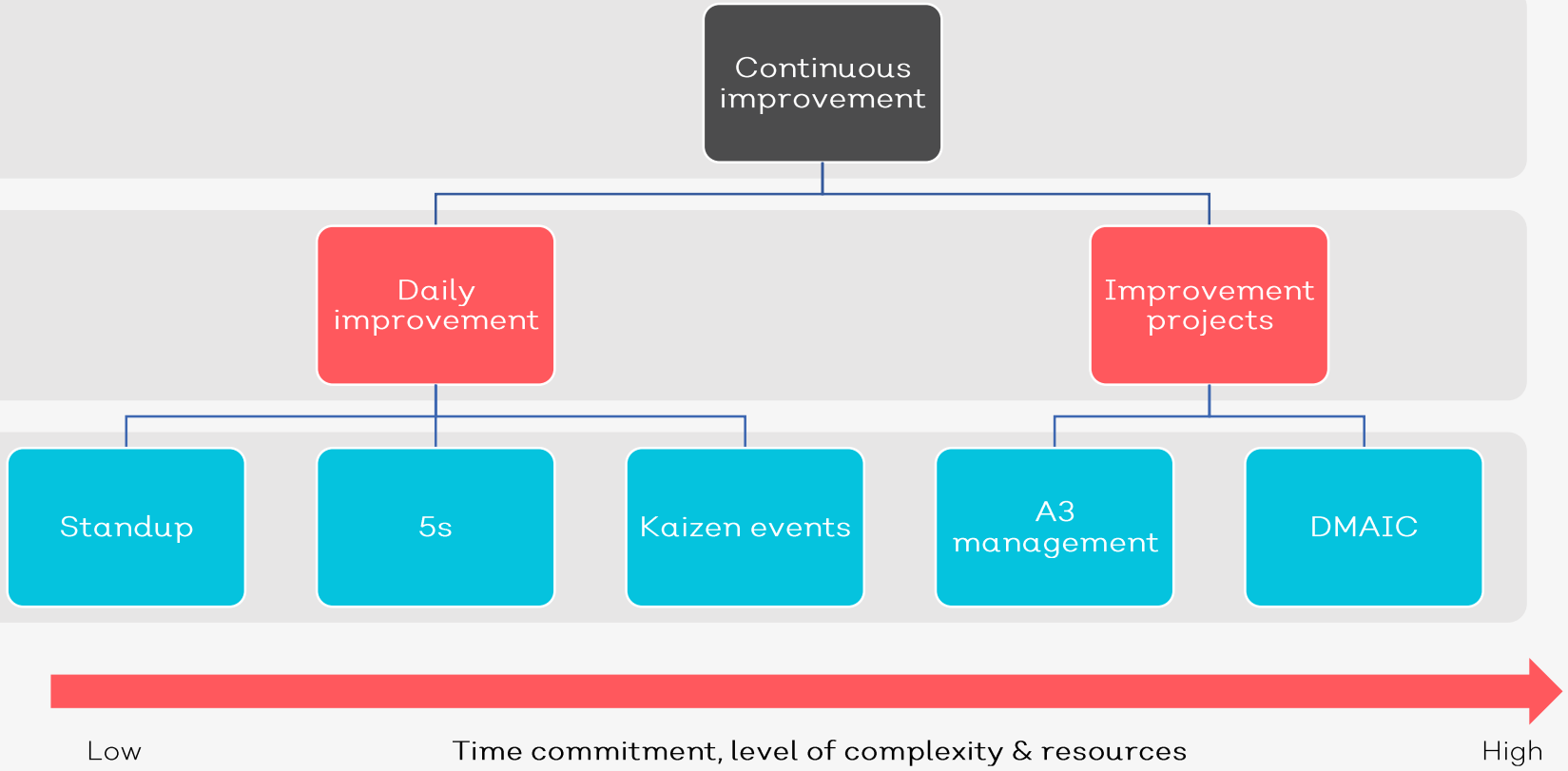
Philosophy

Organisation

Discipline



Example of 5s Performance & Grading Grid

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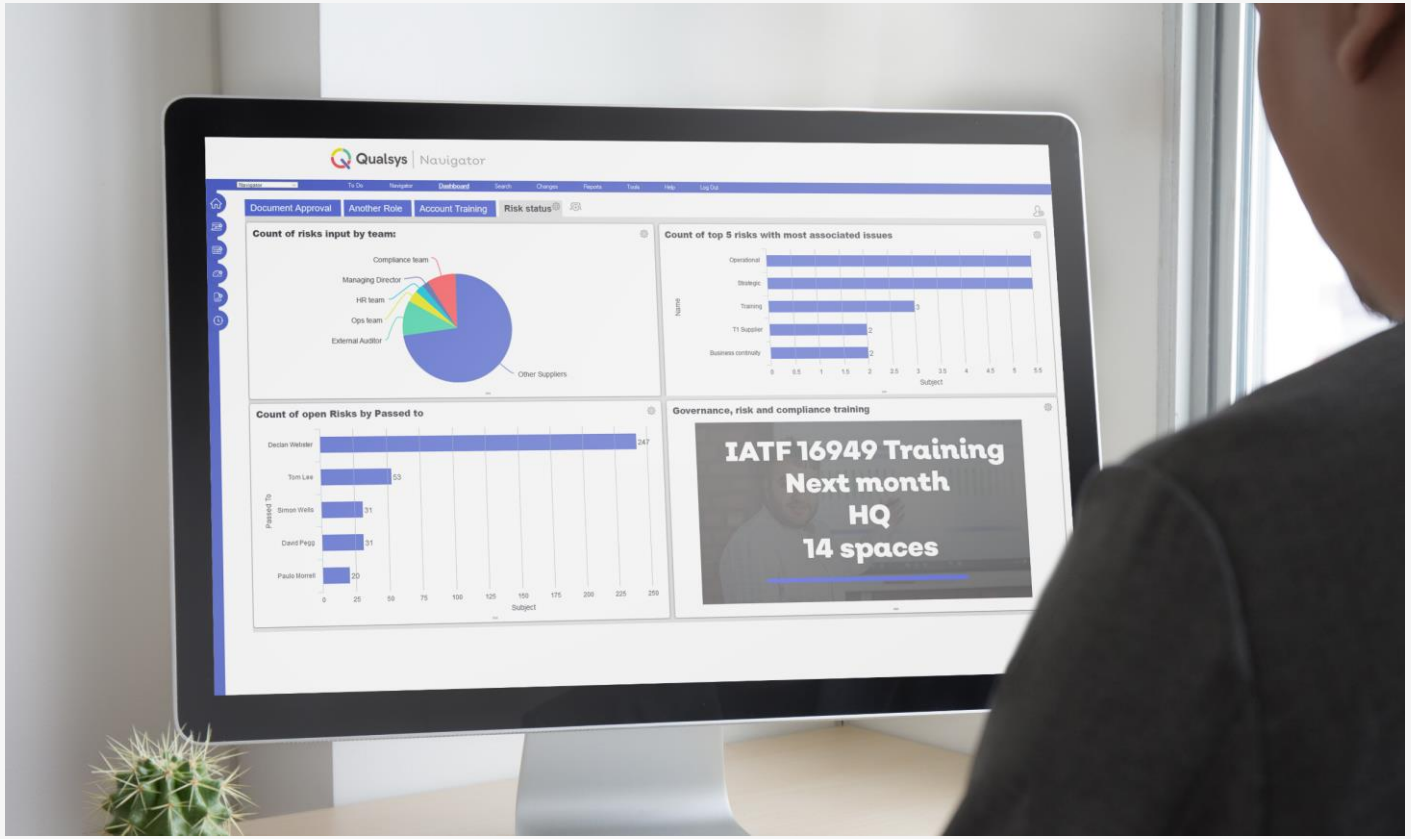
	LEVEL			
	1 POOR	2 →	3	4 EXCELLENT
STEP 1 – (Sort) ORGANISATION Seiri	A cluttered workspace with many unneeded items in random locations. Haphazard	Some unneeded items remain. Somewhat easier to find needed items	Only needed items remain but quantities required are not defined	Only the bare essentials remain. Only defined quantities of items evident
STEP 2 – (Set in order) ORDERLINESS Seiton	No organisation. Essential items are lost in the clutter	Some organisation of items. All locations not dedicated. Some visual clues	All items neatly arranged. Dedicated locations and visual cues	A visual work environment. "A place for everything and everything in its place"
STEP 3 – (Shine) CLEANLINESS Seiso	Dirty area with no evidence of systematic cleaning	Area is generally clean. Routine not in evidence. Inspection not part of routine	Cleaning and inspection of equipment clearly in evidence	A spotless, inviting environment. Attention to detail obvious
STEP 4 – (Standardize) STANDARDISATION Seiketsu	No evidence of a documented routine	Procedures exist but not evident in workplace. Inconsistently applied	Procedures in place and beginning to be practiced	Clearly defined, effective cleaning process is in constant use
STEP – (Sustain) DISCIPLINE Shitsuke	No evidence of management, monitoring or support	Visual measures of 5s performance posted	Continuous improvement process in place. Evidence of follow-up management	Primary focus is prevention. Standards constantly being upgraded

Let technology help

The art of data storytelling

- Use reports to paint a picture of the business
- Develop a flexible approach to dashboards
- From many data systems to snapshots of an individual process step



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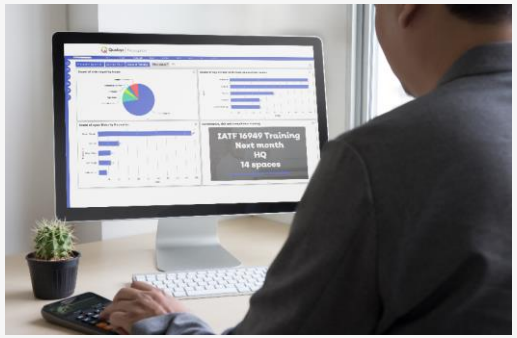
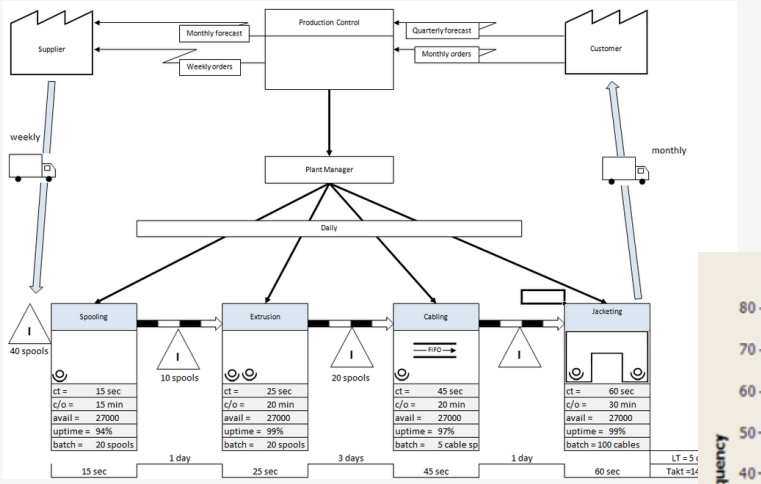
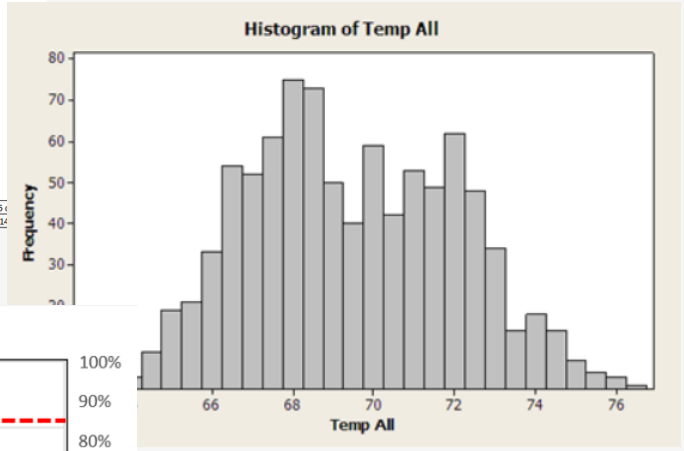
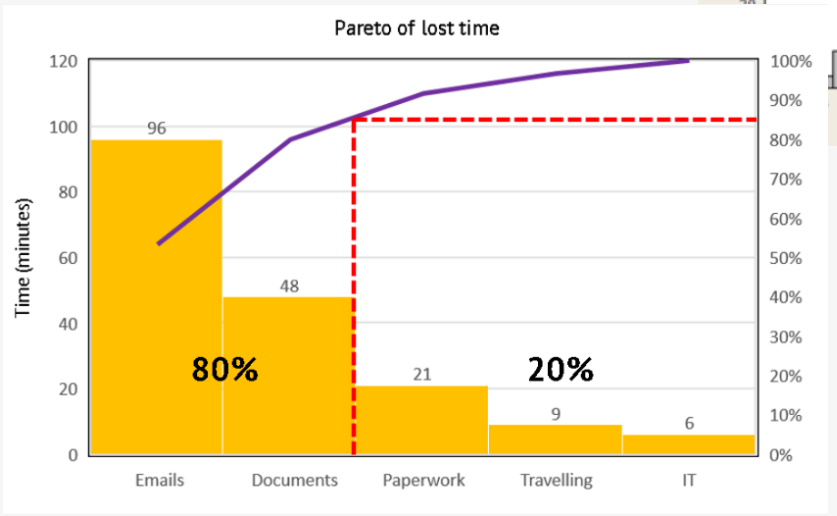


Let data be the guide

- Descriptive statics:
  - Variance
  - Range
  - Standard Deviation
- Histograms
  - Good for Qualitative , discreet data, understanding the variations
- Pareto Analysis
- Value Stream Mapping
- Fishbone Analysis using the 6Ms







Learn from your mistakes

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