HSRAA Conference 2023

Changing face of Data Integrity regulatory inspections

David Thompson

Principal Consultant
Clarity Compliance Solutions Ltd

Your compliance partner

single source • cost-effective • pragmatic solutions

clarity compliance solutions

Welcome

- My background
- Data Integrity - Coming of age
- Data Integrity Maturity
- Annex 11 update

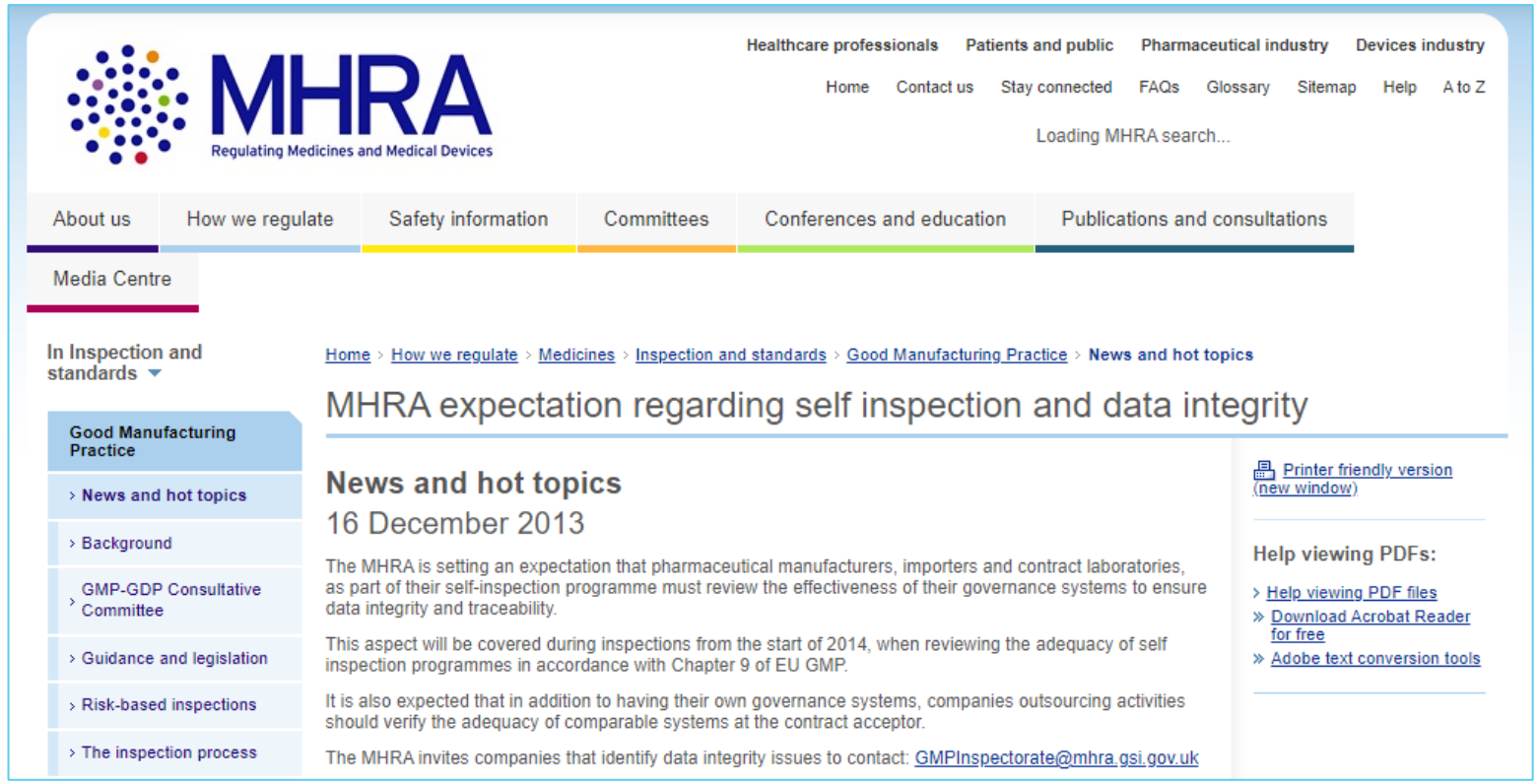
clarity
compliance solutions

My background

- 24 years CSV/DI Consulting
- Global IT program implementations
- Strategic Consulting – working in the “Grey”
  - DI/CSV Improvement programs
  - Organisational compliance
  - Regulatory response programs
    - Working in the headlights of the regulators
    - Taking (new) clients out of MHRA CMT/IAG scrutiny
- Member of GAMP DI, MES and CSA SIGs

clarity
compliance solutions

Data Integrity coming of age…..



- DI as a regulatory hot topic nearly **10** years old!

clarity
compliance solutions

Data Integrity insights

- Client Feedback
  - Regulators drilling deeper
  - Customer audits drilling deeper
  - Targeting Governance and Maturity

- Regulatory insight
  - Inspectors much more experienced
  - DI Program should be finished
    - ***No excuses – unless you are a new start-up!***
  - Now focussing on Holistic approach for DI Governance, DI Maturity and ongoing DI improvement

clarity
compliance solutions

Holistic approach to DI

- Various activities being carried out in an un-coordinated manner by untrained personnel or pockets of expertise, following unapproved, inconsistent or not best practice methodologies

Or

- Well thought out and managed programme, being delivered by qualified and trained personnel following approved methodologies and procedures, within a tightly controlled governance framework embedding DI (& CSV) into the fabric of the organisation, actively supported by senior management

clarity
compliance solutions

Holistic approach – 6 key objectives

- Business processes are in place to ensure senior management Ownership, Governance and Oversight of DI (& CSV)
  - DI (& CSV) is a top-down activity
- DI (& CSV) methodology meets current industry expectations and best practice
  - Company has the right DI (& CSV) methodologies
- Company has structured IT system/project implementation lifecycle with stage gate controls mechanisms in place
  - Company has the right implementation processes

clarity
compliance solutions

Holistic approach – 6 key objectives

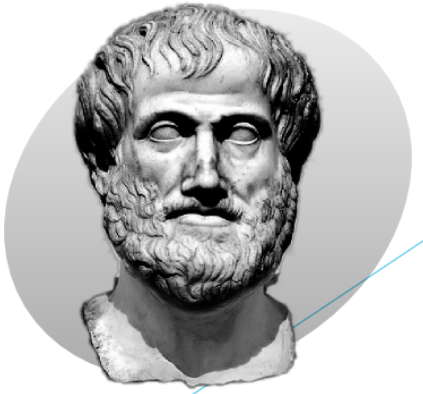
- Company has structured processes in place for the ongoing operation and maintenance of computerised systems
  - Company can maintain the level of compliance during operation
- Existing legacy systems are reviewed against the new DI (& CSV) methodologies and any deficiencies resolved
  - Company can ensure legacy systems are compliant
- An appropriate Organisational and Cultural Behaviour plan or activities are in place to support overall compliance
  - Company has the right quality and compliance mindset

clarity
compliance solutions

Data Integrity is Management led

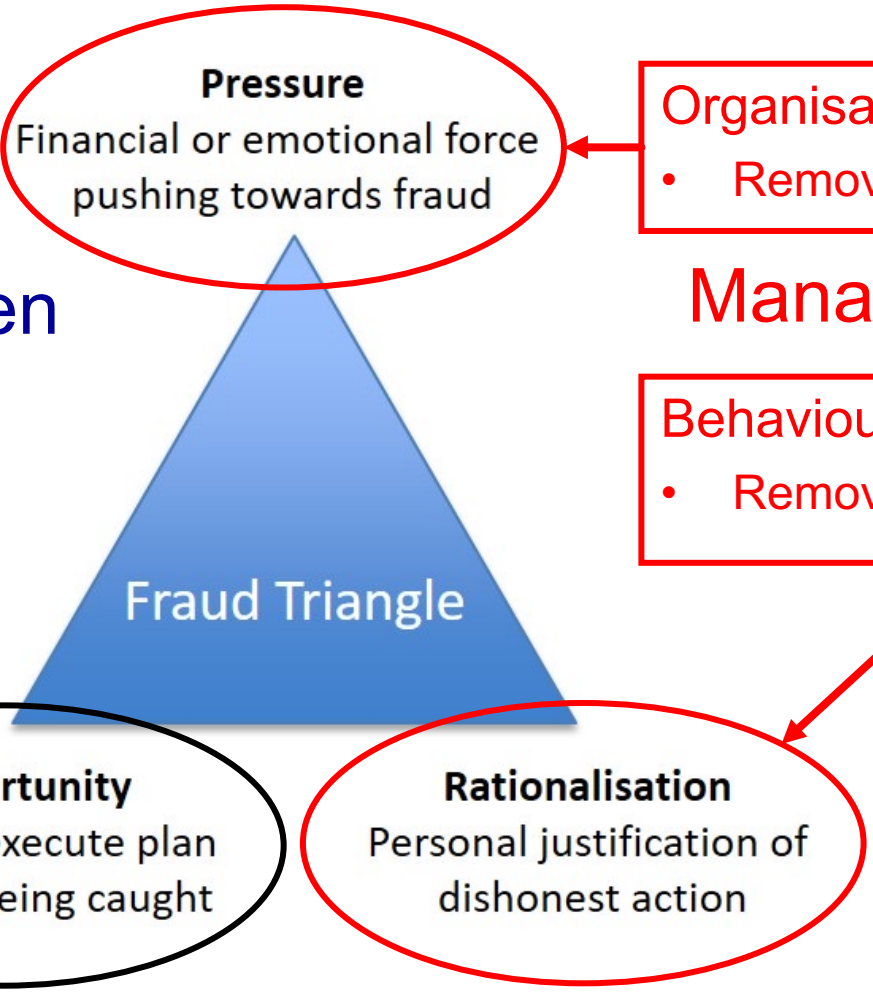
- “To remove the incentive to manipulate, re-create or amend data, the managerial response to ‘bad news’ must be fair and consistent, and not based on a fear of consequences”
- “Leadership, engagement and empowerment of staff at all levels in the organisation can then combine to identify and deliver systematic data integrity improvements where good practice becomes automatic.”
- David Churchward MHRA

“We are what we repeatedly do. Excellence, then, is not an act but a habit” - Aristotle



clarity
compliance solutions

Fraud Triangle – Senior Management Support



Organisational Culture
- Remove the Pressure

Management Led

Behavioural Culture
- Remove the Justification

Program Driven

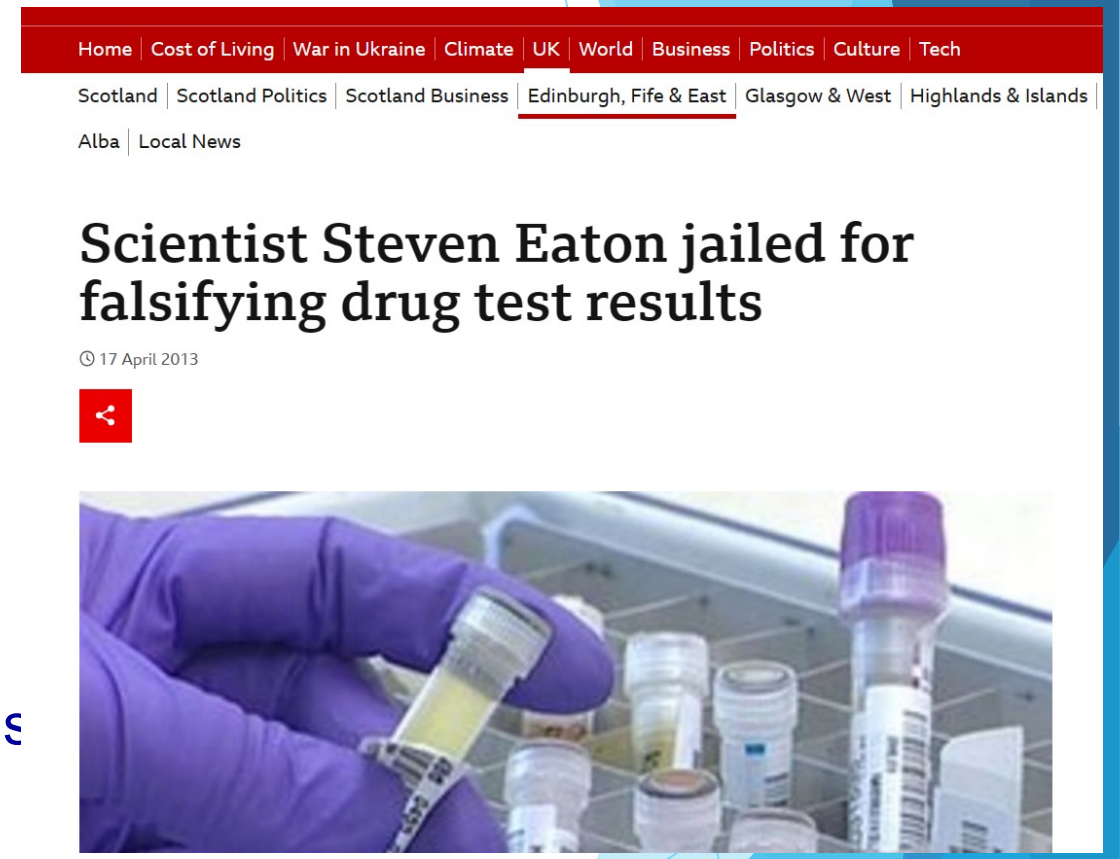
DI Assessments
- Remove the opportunity

MHRA / FDA very focused on Behavioural and Organisational Culture

clarity compliance solutions

Steven Eaton

- Falsifying results during anti-cancer clinical trial - MHRA took him to court
- Personal impact
  - Jailed for 3 months - Massive career impact
- Company (Aptuit) impact
  - Credibility on any work he had carried out
  - Wider loss of credibility on any trial if systems so weak
  - Cost of internal investigations
- Cost of impact on the anti-cancer drug trial
- Cost of loss of reputation

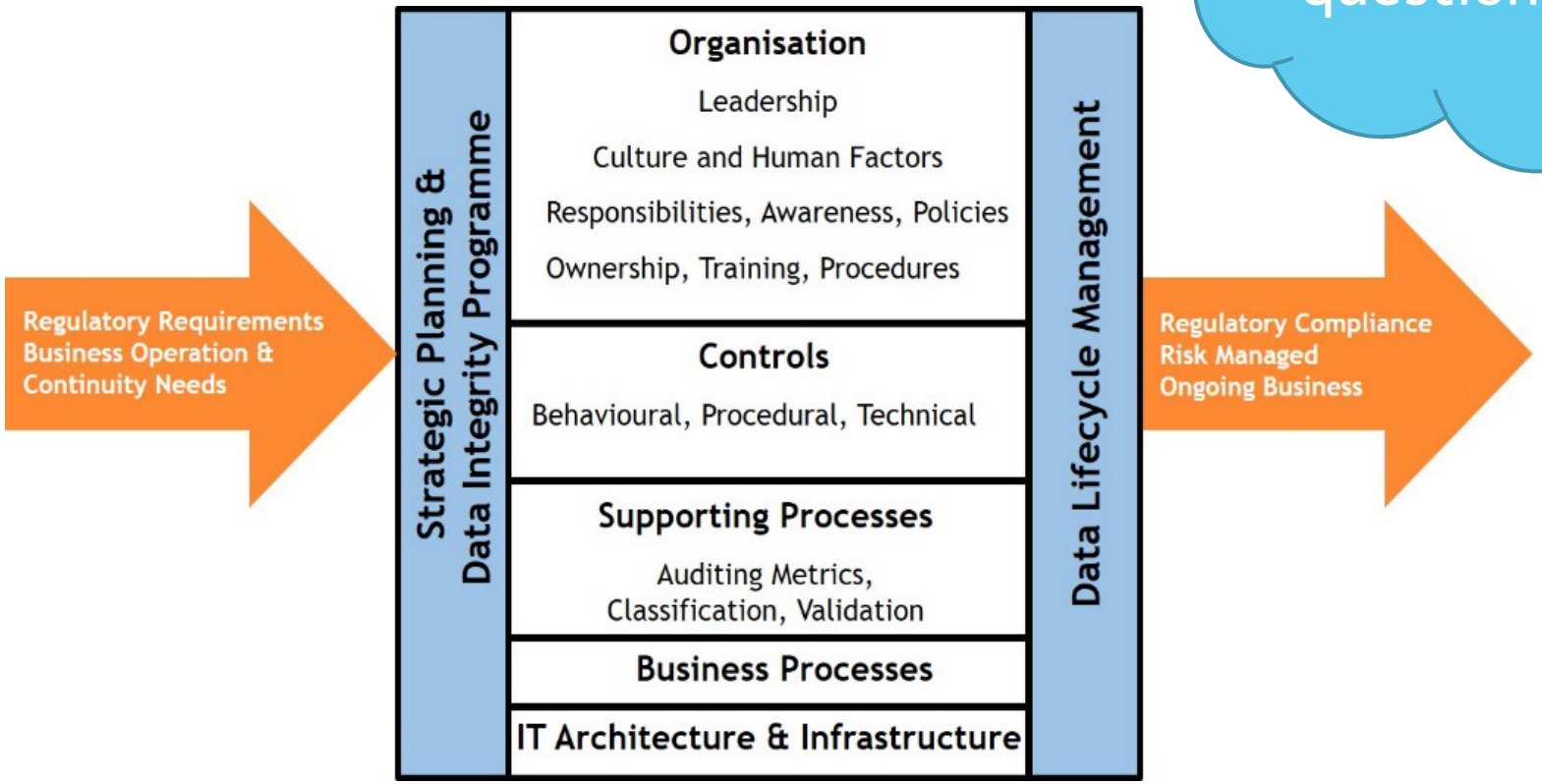


clarity
compliance solutions

Holistic approach

- Data Governance Framework

Data Integrity is NOT just a spreadsheet questionnaire!



clarity
compliance solutions

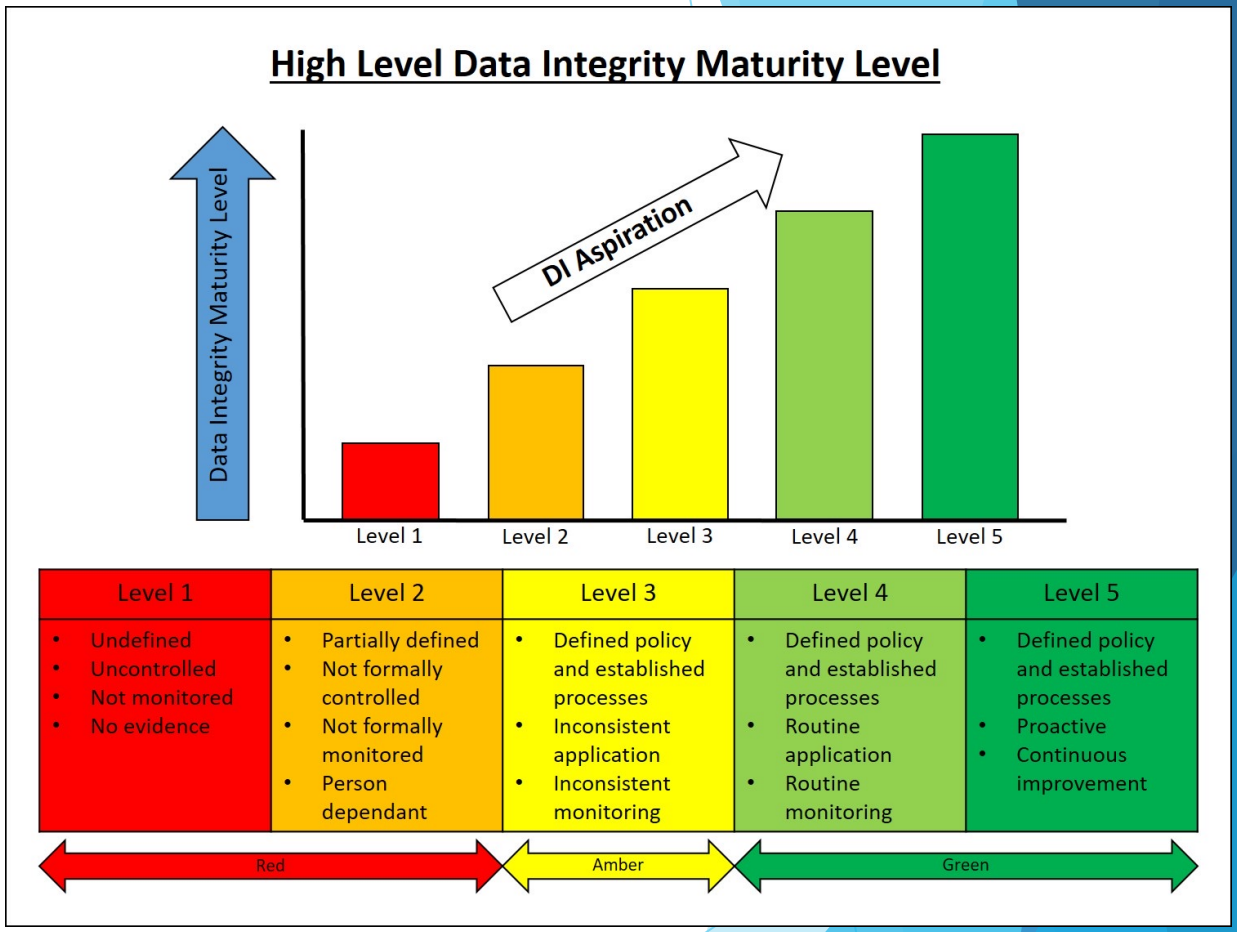
Data Integrity Maturity

- How do you assess Data Integrity Maturity?
- What tools are available?
- How do you utilise and present
  - Internally
  - During inspection or customer audit?

clarity
compliance solutions

Data Integrity Maturity

- ISPE GAMP® Maturity Model
- Key Topic Areas
  - Culture
  - Governance and Organisation
  - Strategic Planning and Data Integrity Project
  - Regulatory
  - Data Life Cycle
  - Data Life Cycle and Supporting Processes
- Repetitive process to demonstrate improvements



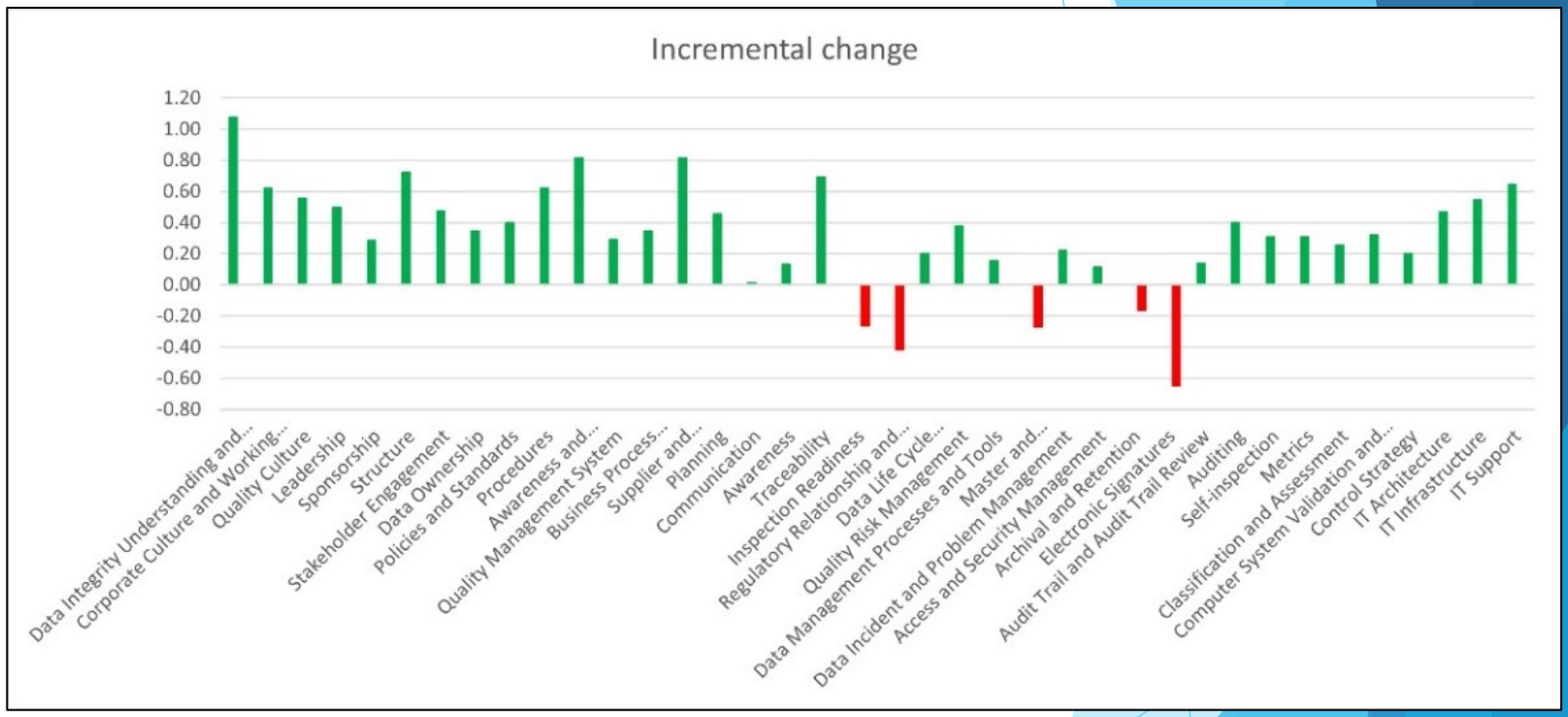
"Source: Figure 7.1, ISPE GAMP® Records and Data Integrity Guide.
© Copyright ISPE 2017. All rights reserved. www.ispe.org"

"Source: Appendix M2 Data Integrity Maturity Model
ISPE GAMP® Records and Data Integrity Guide.
© Copyright ISPE 2017. All rights reserved. www.ispe.org"

clarity
compliance solutions

Data Integrity Maturity

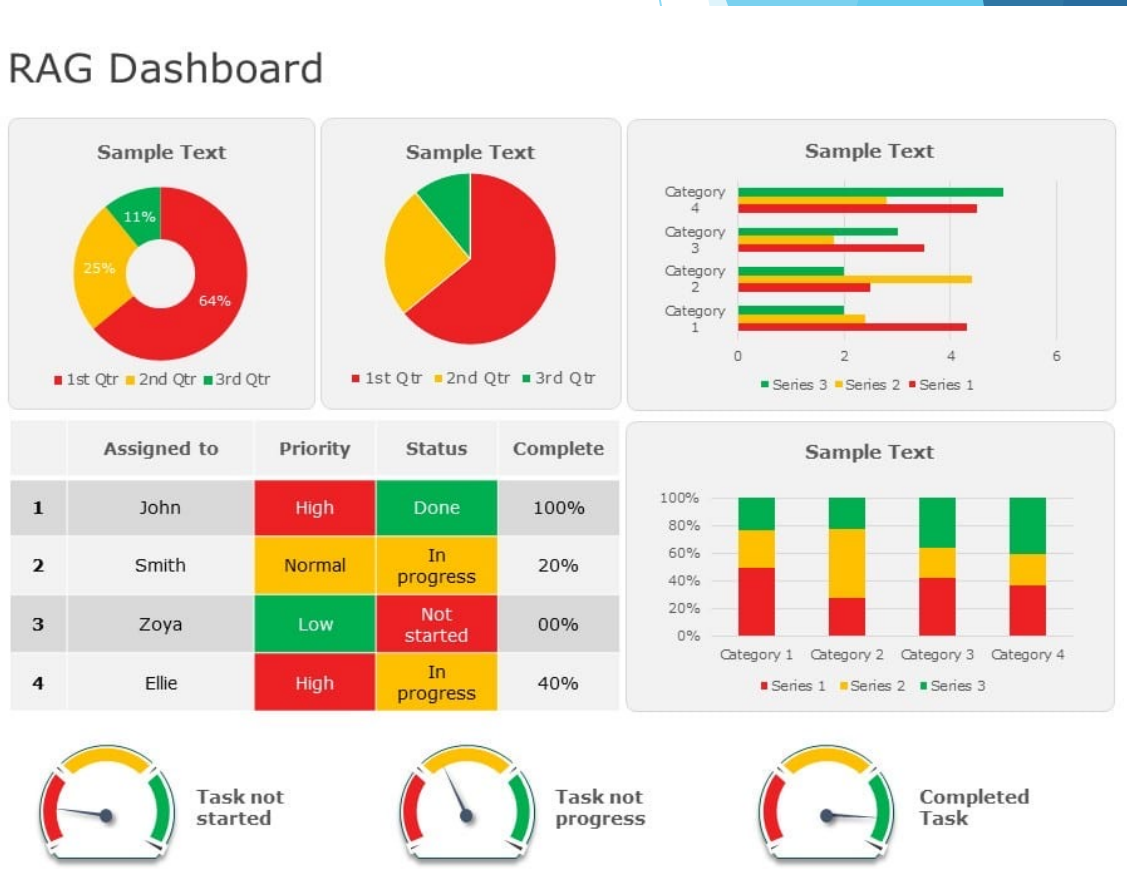
- Comparing to previous
  - Improvement
    - Learn and apply
  - Reduction
    - Provide attention



clarity
compliance solutions

Senior Management Governance and Oversight

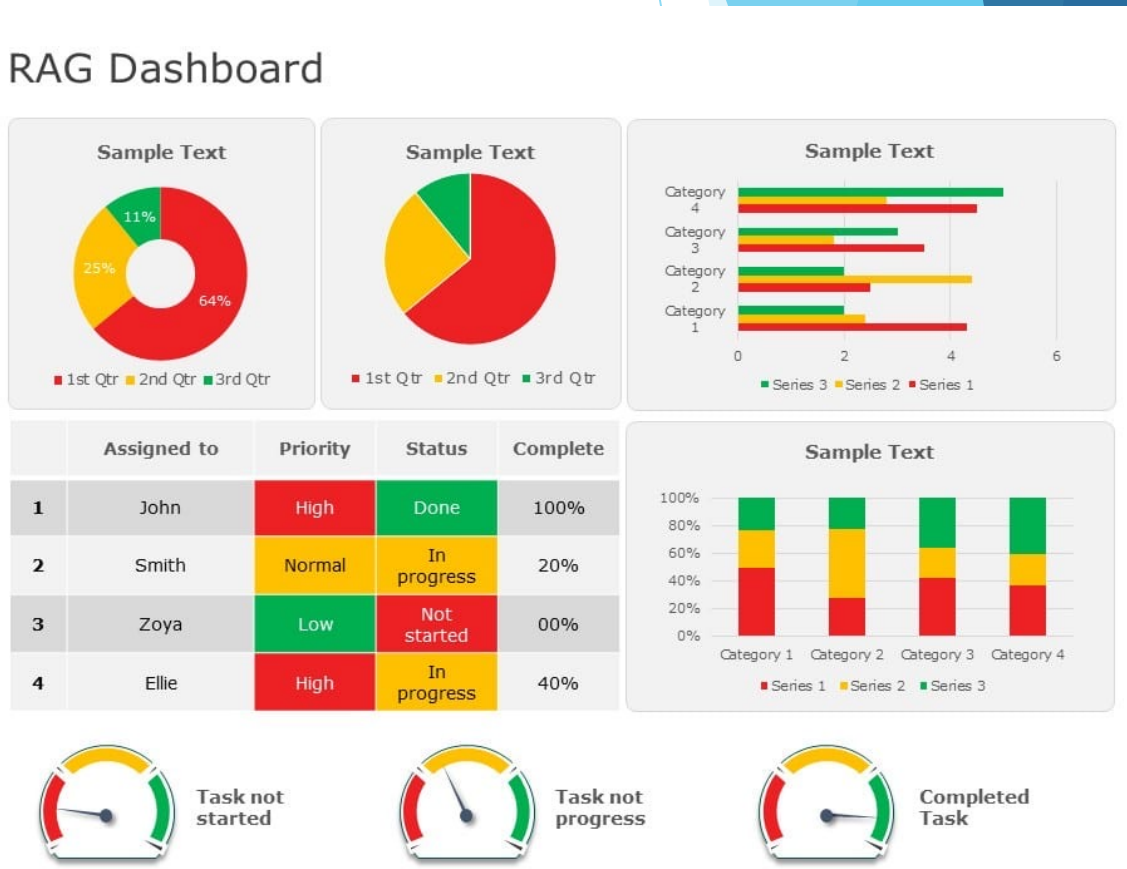
- Regulators want to see management actively leading and involved !
  - Data Integrity included in
    - SLT meetings
    - Quality Council
    - DI Steering Committee meetings
    - Departmental meetings
    - Gemba Walks



compliance solutions

Senior Management Governance and Oversight

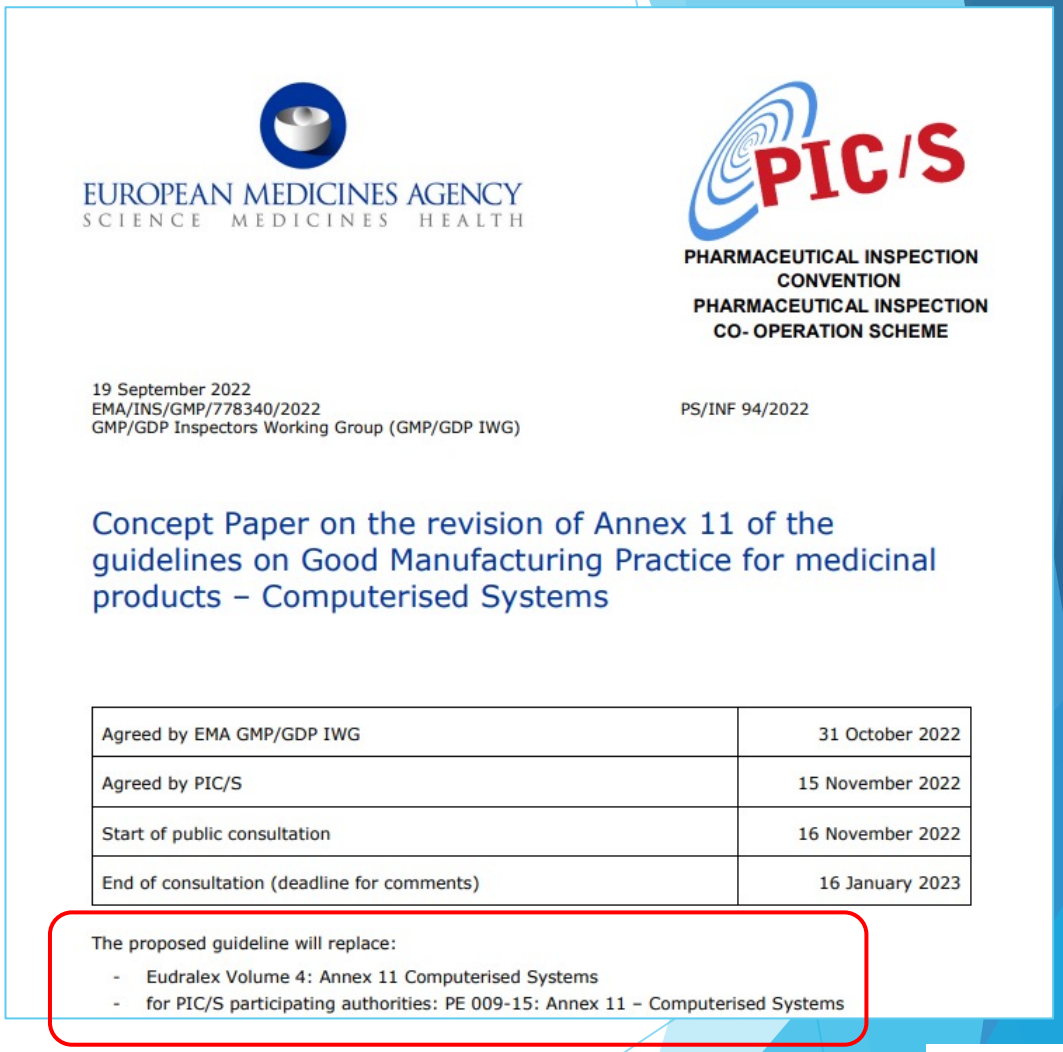
- Metrics, Metrics, Metrics
  - DI Issues & DI improvements
  - R/A/G Status's
    - Documentation errors at QA review
    - Periodic Reviews
    - Back-up / Restore
    - Independent Audit trail reviews
- "Content Rich" Inventory List
  - Basis for many metrics
  - Aim for the regulator "Wow" effect



compliance solutions

Annex 11 Update

- Key Dates
  - Approval of draft concept paper by EMA GMP/GDP IWG – October 2022
  - Deadline for comments on guideline – March 2025
  - Adoption by EMA GMP/GDP IWG – March 2026
  - Publication by European Community – June 2026
  - Adoption by PIC/S Sub-committee on GMDP Harmonisation – September 2026



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PIC/S
PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO- OPERATION SCHEME

19 September 2022
EMA/INS/GMP/778340/2022
GMP/GDP Inspectors Working Group (GMP/GDP IWG)

PS/INF 94/2022

Concept Paper on the revision of Annex 11 of the guidelines on Good Manufacturing Practice for medicinal products – Computerised Systems

Agreed by EMA GMP/GDP IWG	31 October 2022
Agreed by PIC/S	15 November 2022
Start of public consultation	16 November 2022
End of consultation (deadline for comments)	16 January 2023

The proposed guideline will replace:

- Eudralex Volume 4: Annex 11 Computerised Systems
- for PIC/S participating authorities: PE 009-15: Annex 11 – Computerised Systems

clarity
compliance solutions

Annex 11 Update – DI impact examples

- Will include requirements for **‘data in motion’** and **‘data at rest**’ (backup, archive and disposal). **Configuration hardening** and **integrated controls** are expected to support and safeguard data integrity; technical solutions and automation are preferable instead of manual controls.
- Update of the document with regulatory expectations to **‘digital transformation’** and similar newer concepts will be considered.

clarity
compliance solutions

Annex 11 Update – DI impact examples

- For critical systems validated and/or operated by service providers (e.g. '**cloud' services**), expectations should go beyond that "formal agreements must exist".
- Regulated users should have access to the **complete documentation for validation** and safe operation of a system and **be able to present this during regulatory inspections**, e.g. with the help of the service provider.
- Guidelines should be included for classification of **critical data** and **critical systems**.

clarity
compliance solutions

Annex 11 Update – DI impact examples

- Important expectations to backup processes are missing, e.g. to **what is covered by a backup** (e.g. data only or data and application), what types of backups are made (e.g. incremental or complete), how often backups are made (all types), how long backups are retained, which media is used for backups, and where backups are kept (e.g. physical separation). ***[Anticipate Virtual Machines to be added]***
- An audit trail functionality which automatically logs all manual interactions on GMP critical systems, where users, data or settings can be manually changed, should be regarded as **mandatory**; not just 'considered based on a risk assessment'

clarity
compliance solutions

Annex 11 Update – DI impact examples

- It is necessary to be more specific and to name some of the expected controls, e.g. **multi-factor authentication**, firewalls, platform management, **security patching**, virus scanning and **intrusion detection/prevention.**
- It should be specified that **authentication** on critical systems should identify the regulated user with a **high degree of certainty**. Therefore, **authentication only by means of a 'pass card' might not be sufficient**, as it could have been dropped and later found by anyone
- Two important expectations for allocation of system accesses should be added either here or elsewhere; i.e. **'segregation of duties',** that day-to-day users of a system do not have admin rights, and the **'least privilege principle'**, that users of a system do not have higher access rights than what is necessary for their job function.

clarity
compliance solutions

Annex 11 Update – DI impacts?

- Annex 11 and Data Integrity go hand-in-hand
- Used by MHRA to capture Date Integrity needs
  - Annex 11 GMP -> guidance will go to the GxP guidance
- Catching up with modern IT and computerised system capabilities, tools and techniques

- Regulated Company or Solution provider
  - Keep up to date on the changes
  - Build into your methodologies now

clarity
compliance solutions

Thank You – any questions?

David Thompson

Principal Consultant

Clarity Compliance Solutions Ltd

Email: David.thompson@clarity-compliance.com

Mob: +44(0)7725744636

Your compliance partner

single source • cost-effective • pragmatic solutions

clarity
compliance solutions

☎ +44 (0)1633 400939 / +44 (0)7735 204233

✉ enquiries@clarity-compliance.com

🌍 www.clarity-compliance.com

clarity
compliance solutions