Business continuity and the matrix
Formula 1

• About **200 people** in the ‘data centre’ around the world
• **15 trucks** (~130 tonnes) worth of hardware that all sit on air pallets
• More than **110 sensors** generating about **2000 data points per minute**
• Transporting data for **real-time analysis**
Let’s discuss…

• The US FDA’s pharmaceutical quality progression

• Quality Metrics Data

• The matrix (I am still not sure if it was a good movie!)
Evolution in US FDA’s approach to pharmaceutical quality

“In recent years the FDA’s approach to quality oversight has evolved with the idea that quality metrics can drive improvement and monitor quality systems and processes.”

Transcript: FDA’s Quality Metrics Reporting Program and the voluntary submission of Quality Metrics Data

- The effect of ICH Q8, Q9 and Q10 documents on Pharmaceutical Quality Systems is continuing and profound
- Adding more strategies into the overall quality armoury
Compliance progresses rapidly

- **21st century approach** to existing manufacturing and industry wide challenges
  - The **need for and cost of innovation** in manufacturing
  - **Drug shortages**, recalls, lack of cross industry quality metrics/indicators (same theme of 483s year on year)
  - Manufacturers have **extensive knowledge** regarding CQAs and CPPs and have vested interest in realising **continuous improvements**
Build quality in to your organisation

• Quality is defined as a **mindset and culture** across an entire organisation

• This is **not a new concept**, rather the requirements manifest as measurable key performance indicators

• Quality is becoming **facility specific** as globalisation progresses

• **Tangible benefits** for the regulators, for manufacturers and most importantly customers and patients
US FDA’s commitment to change

- **Lifecycle approach** for the regulators includes assessing the need for inspection

- Qualitative metrics to monitor **Pharmaceutical Quality System (PQS) performance** and identify continuous improvement opportunities

- PQS assessment is already mandated (QMR, PQR) and most of the data—in a potentially different guise— is already being reported within PQS assessments
The intent of the criteria

- **Lot Acceptance Rate**: Robustness of commercial manufacturing processes
- **Invalidated Out of Specification Rate**: Robustness of laboratory processes
- **Product Quality Complaint Rate**: Voice of the customer and market feedback
What will the data be used for?

<table>
<thead>
<tr>
<th>The data will be used to verify and establish ...</th>
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<tbody>
<tr>
<td>drug product quality</td>
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<tr>
<td>the quality of a manufacturing site</td>
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<tr>
<td>the effectiveness of quality, manufacturing and associated systems</td>
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<tr>
<td>Specificity in site inspections and identifying potential drug shortages</td>
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Voluntary phase

• **Transparency** between industry and the regulator is **fundamental** to realising outcomes

• As with any monitoring system, the **quality of data** and **analytic processes** will dictate the **overall effectiveness**
Knowledge Management

“While some aspects of the PQS can be company wide and others, site-specific, the effectiveness of the PQS is normally demonstrated at the site level.”

ICH Q10 – Pharmaceutical Quality System, ICH 2008
What else is industry doing in addition?

- Monitoring (critical) process parameters (CPPs) using real-time data
  
  • In conjunction with process capability monitoring

  • Process performance review and maximising the output of CPPs to drive **Continuous Process Verification**, Quality Risk Management and Product Quality Review processes

  • Identify existing issues and predictive analysis
Renewed focus on data and monitoring

- Measuring performance is **not a new concept**
- **Increased transparency** between industry and regulators
- Control of processes and performance to ensure customer and patient outcomes
Cost benefit analysis

- Using a data set to fulfil multiple monitoring requirements provides an opportunity to realise efficiencies

“However, the Association for Accessible Medicines (AAM, formerly GPhA), believes the program could cost up to $1.77 billion in the first year, with recurring annual costs of up to $1 billion.”*

The matrix
Quality data input systems

- Document management systems
- Manufacturing systems
- Quality notification and management systems
- Laboratory information management systems

Input systems coordination
Information pyramid

- Data selection dynamic

Utilised data set
Selected components
Input system
Quality data

- Enterprise Resource Planning
  - Source/master system
  - Validation/verification of data and the appropriation of a single source of truth
Globalisation – the matrix

• Developing a **PQS that is appropriate** takes on new significance when multi-nationals need to share and manage real-time information **consistently**

• How many people are in your ‘**data centre**’?

• How do you manage your ‘**data ocean**’?
Performance analytics

- Real-time performance monitoring will enable an array of other systems to function and better informed decisions to be made

- Process and system capability

- Heat maps

- Regulatory specific release requirements
Conclusion

• Better outcomes for patients, regulators and manufacturers are being sought after.

• Commensurate – focus resources on factors of high public risk.

• Change Management and Knowledge Management enable continuous improvement.
Thank you

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