

Practical compliance issues and solutions for NHS aseptic units.

DARREN JONES

EPIC DIRECTOR & SENIOR CONSULTANT



## EPiC – Who are we?

- ➤ Group of 30 ex Inspectors and industry experts
- > Services:
  - Consultancy
  - Training
  - Gap Assessment
  - Remediation
  - QP/RP/RPi services
  - > Compliance Monitors under the MHRA Pilot scheme
  - Mentoring
  - Mock inspections and audits
- Founded 2014
- ➤ NHS, private hospital and pharma clients
- ➤ More than 300 clients in 30 countries
- ➤ GMP, GDP, PV, GCP and GLP



## EPiC Senior Management Team

**LIZ ALLANSON**Company Director

RICHARD ANDREWS

Managing Director

NICOLA JONES

Director of Finance

**DARREN JONES**Company Director









MICHELLE YEOMANS

Operations Manager

**VICKI PIKE**Operations Manager

MARK LEWCOCK
Finance Manager









## **Compliance Solutions**

- ➤ EPiC has worked with many compliant and noncompliant sites
- ➤ What differentiates the 'good' sites? They have a pathway to sustainable compliance
- ➤ The foundations of good compliance
- ➤ Not rocket science simple, sensible steps
- ➤ Not exclusive to aseptic units
- ►I have called them 'compliance solutions'
- ➤ Indicators of compliance...?





## Compliance Solution 1 - Senior Management engagement

### > Senior Management engagement:

- ➤ A clear and effective reporting restructure above the aseptic unit to the Trust Board
- > Senior Management:
  - > Understand the issues faced
  - Support and drive the quality review meeting
- ➤ The Board understand and exercise their legal and ethical duties
- > A clear escalation process to Board level
- Documented management intervention to correct issues, trends etc.
- Named persons (on MS, MIA) have adequate experience and currency
- Have Senior Management visit the unit, maybe perform a Self-Inspection? (!)
- Chapter 1: paragraph 1.5 'everything is the fault of Senior management'!





## Compliance Solution 2 - Culture

#### >Culture:

- Compliance drives the aseptic unit operations (rather than output)
- > A proactive attitude amongst all staff
- > A culture of compliance:
  - > We do the right thing
  - > We ensure suitable GMP compliance
  - Don't rely on the 'risk to the patient of no supply is greater than the GMP lack of compliance'
    - > This can be the start of the spiral of doom!
- ➤ Drive on time completion
- > Errors openly admitted and learnt from





## Compliance Solution 3 - Proactive PQS

#### **▶** Proactive PQS:

- > Remove failure modes before they occur
- Perform <u>proactive</u> system, facility and process periodic risk assessments
  - > Risk assessment is not only for deviations, OOS etc
- ➤ Robust and effective use of change control
  - > Extensive action prompt list
  - ➤ Change control committee
- ➤ A strong and challenging self-inspection system
  - > Find and fix issues before patient impact or MHRA!
  - > Include aseptic practices and sterility assurance
  - Compare how SOPs meet regulation / guidance
  - ➤ Be objective annual fresh pair of eyes





## Compliance Solution 4 - Capacity Control

#### **≻** Capacity control

- > Capacity planning includes:
  - > All PQS activities
  - Project work
  - > Training etc
  - > Audit / MHRA remediation activities
  - Planning for the average level of staff sickness
- > RAG system to monitor capacity proactively on a regular basis- weekly?
- > Escalation and management intervention to support changes to output
- > Consider proceduralised response
  - If capacity limit breached, how do we correct?
    - Output reduced by 'X' %
    - > Staff transfer
- Robust Senior Management intervention required for medium term capacity issues / trends





## Compliance Solution 5 - Staff Competency

### **≻**Staff competency

- > Invest in training and education
- > Named staff on MS / MIA are critical
- ➤ Length of service is no guarantee of currency / compliance
- Robust performance management with compliance as a key factor
- ➤ Ensure staff know 'what good looks like'
  - ➤ Gain external perspective
  - ➤ Is there sufficient external input?
    - > Staff from industry and other trusts recruited?
- ➤ Have a succession plan for key staff

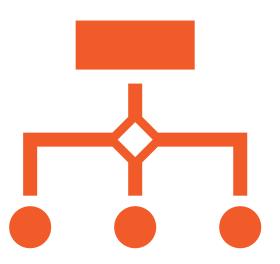




## Compliance Solution 6 - Manage Estates

#### **≻**Manage Estates

- Consider Estates staff having a dotted reporting line into the Aseptic unit management
- > Treat Estates staff as you do Unit staff for training purposes
- > Establish a service level agreement or even quality technical agreement
  - Mandate response times
    - > Including emergency response
  - > Require proactive change control
  - > Set expectations for the control of qualified and validated equipment
    - ➤ No unauthorised changes
    - > Define 'like for like' replacement of spare parts
    - > Set limits and frequency for the calibration of equipment
  - ➤ Determine calibration limits and frequency
- ➤ Include Estates in the quality review
  - > They present KPIs on calibration, PPM etc.
- Implement a GMP permit to work system





## Compliance Solution 7 – Prevent Compliance Drift

#### Prevent compliance drift:

- > Avoid the creep of non-compliance!
  - > 'The metrics are always red...'
  - > 'The facility is so old we can't do any better...'
  - 'It must be ok, MHRA have inspected it...'
  - 'We have done it this way for years...'
  - 'We don't have enough resource to do it compliantly'
  - 'Annex 1 doesn't apply to us...'
- ➤ Challenge such attitudes
- Have a compliance improvement plan (CIP), even if MHRA have not referred you to IAG / CMT
- > Benchmark your compliance with other units / industry





# Compliance Solution 8 – Continuous Improvement

#### **▶** Continuous Improvement:

- > Perform an annual review of environmental monitoring trends and performance
  - > Derive EM limits via statistical analysis and seek to tighten over time
- > Perform an annual review of the quality review process
  - ➤ Where do we need to target improvements for next year?
  - > Where is immediate intervention needed?
- ➤ What legislation / guidance in changing in the next 24 months or so?
  - > Perform gap assessments against the draft document
- > Ask the management team- where are we weak?
- What trends are we seeing from self-inspection and audit findings?
- Update the CIP regularly
- Don't be afraid of isolators!
  - > Sterility assurance benefits
  - Likely cost savings

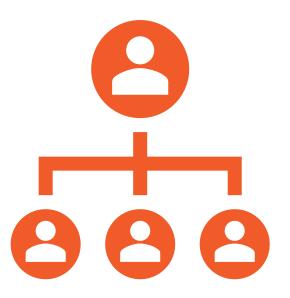




## Compliance Solution 9 - Management Review

#### **►** Management review:

- Mandate attendance of required departments e.g. Estates, IT
- ➤ Meet regularly- monthly
- ➤ Have KPI targets
- ➤ If KPI targets exceeded mandate intervention (CAPA)
- ➤ Consider using go/ no-go/ go with limitations sign off by all persons named on MS/MIA and Board level
- > Robust intervention needed to correct any 'Red' metric





## Case Study 1



#### > Aseptic MS Unit

- Modern facility with a leading product and process
- Lack of Senior Management oversight and quality leadership
- Unit staff did not know what 'good looked like'
- > MHRA Inspection IAG and suspension of MS
- Compliance Drift had resulted in significant noncompliance

#### > EPiC Gap Assessment:

- > Relatively simple to fix
  - > PQS required strengthening
  - QA needed to 'raise the bar of decisions' a mentoring programme
  - ➤ Above unit management needed greater oversight e.g. metrics, intervention to adverse trends etc
  - > The unit was very insular External staff recruitment recommended to widen the experience level



## Case Study 2



#### Radio pharmacy MS unit

- Old facility of suboptimal design
- > IAG referral
- Struggle to recruit and retain suitably qualified and experienced staff – capacity issues
- ➤ Compliance culture was not robust

#### > Improvement process

- > Greater use of metric 'red lines'
- EPiC consulted regularly deviations, meetings, project support.
- Good focus on capacity
- Support with project management, qualification and validation and project oversight
- New facility constructed improved design and Annex 1 compliance



## Summary

### Know

Know thy weaknesses!

## Understand

Understand the gaps – the brutal reality should be faced – not rosetinted compliance goggles!

### Senior Management Engagment

Have a Compliance Improvement Plan (CIP), that is approved & supported by Senior Management

#### Management Review

Make sure the management review of quality is effective and objective



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Understand the gaps – the brutal reality should be faced – not rosetinted compliance goggles!

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## Any Questions?





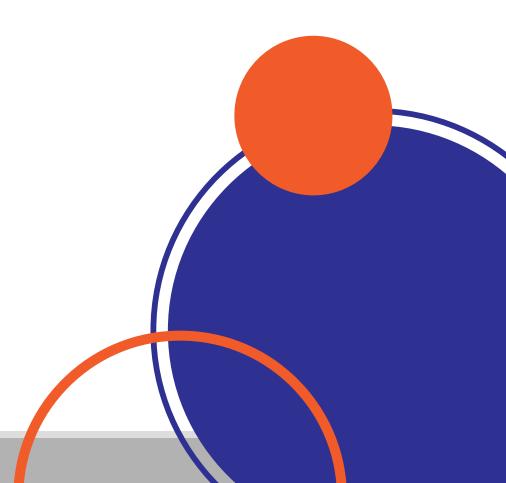


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