EPSC Conference
November 2019

Who are we?

40

Approximate % of children world-wide receiving at least one GSK vaccine

The Safety Video

Key features of the industry

- Plant and equipment:
  - Multipurpose – frequently cleaned and reconfigured
  - Manual, semi-automated, fully automated
  - Indoors – for process equipment
- Process scale small but inventories often high and high value – raw material to final product efficiencies less than 2% by weight
- Highly regulated for product quality (FDA/MHRA) but may not be regulated for Process Safety
- Novelty is normal; “registered” manufacturing methods
- Off site consequences more likely to result from non-process or utilities operations; on site consequences often result from direct interventions made in normal operating conditions

Learning from Incidents and Near Misses

Sieve Fires

EHS Alert – Sieve Fire

Incident

- Alert raised due to repeat sieve fire (Site A) occurring despite an alert being issued in 2012 (Site B).
- While loading a tote bin with powders via an integrated sieve a fire occurred.
- The ignition was due to parts of the sieve not being earth bonded. In particular the sieve mesh and a spacer ring.
- The fuel was an excipient flavour which was a flammable solid (UN DG 4.1).
- The fire did not harm people. It caused equipment damage and activated a sprinkler head positioned above the where the sieve was loaded with powder.
- Flames were drawn into the dust collection system and burnt out the flexible duct.

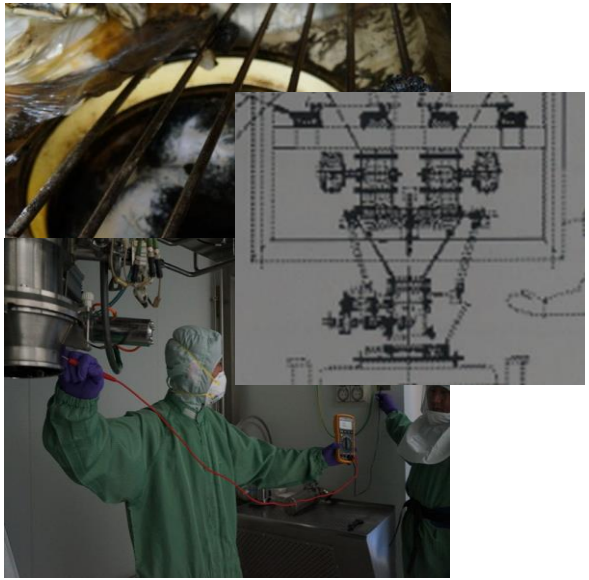
EHS Alert – Sieve Fire

Key Learnings

- The sieve had never been earth bonded; the sieve mesh and spacer were isolated from the main sieve body.
- A fire occurred previously in Site C in 2015 due to an isolated sieve mesh and prior to that at Site B in 2012.
- The fires occurred through a lack of awareness about earth bonding requirements and an inability to procure and fit appropriate measures to earth bond the sieve components.

Operators could have been seriously harmed. The fire could have spread and caused significant facility damage and business interruption. The flame could have spread into the dust collector causing further fire and explosion hazards.

Previous incidents



2015

2012

Non-GSK

Actions from internal Alert

1. Identify sieves where components may be electrically insulated from earth by gaskets and process materials are capable of fire and explosion. (If there is no data sites must assume materials to be hazardous)

2. If not already fitted, procure gaskets that have electrical resistance properties such that components achieve a resistance to earth better than 1 Mega Ohm. Earth clips alone are no longer acceptable as a means of earthing.

Engineering are working with central Quality and key vendors on suitable specifications – these will be shared with the alert

3. If not already in place, add a task that checks the resistance to earth of components on the sieve after assembly and before introduction of materials.

Deeper Learning?

- Compliance vs Risk
  - Site A (2019) had carried out a hazardous area classification exercise (AtEx) approved by their local notified body;
- “Prove safe” vs “Prove unsafe”
  - Site B (2012) had carried out a hazardous area classification exercise but the absence of material supplier explosion data was considered evidence that materials were “safe”
- Rationalisation of the status quo
  - Site C (2015) considered that as the 2012 alert specified a particular sieve manufacturer it did not apply to their sieves