

**Qualified Person
Symposium
3rd November 2009**

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Global Incidents

- Glycerol adulteration
 - *Diluted with Ethylene Glycol*
 - *Used in manufacture of children's medicine*
 - *At least 59 deaths in Haiti*
 - *Not an isolated incident with Glycerol*
- Heparin
 - *Large increase in deaths / adverse events*
 - *Potentially linked to presence of a man-made adulterant introduced in supply chain*
 - *12 different API sources / 11 countries affected*

QP incidents

- QPs asked to explain their releases on three sites in US – by the UK and France
- QPs in Spain asked to explain releases from China

The “Qualified Person” Duties 2009

- The duties of the QP continue to expand
 - GMP for APIs and “certain excipients”
 - Product Quality Reviews
 - Ongoing stability
 - Annex 19 - Retained samples
 - Anti – counterfeiting measures
 - Quality by design?

Conclusion

- The role of the QP is a tough one and is getting tougher
- Expectation and responsibilities of QP continue to grow
- Interpretation of role is not harmonised across the EU
- QPs can only do the job properly by adopting a risk-based Quality System approach

Numbers

26th March 2004 and November 2009

Number of people on register of eligibility: 1600 1500

Number of QP's named on ML's in UK: 760 985

Transitional: 640 164

Waiting list for viva assessment by JPB

See the poster!



Thanks!