How to ensure high quality output in a constantly changing work environment?

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**Statement of the Problem:** Since 2012, constantly the requirement for pharmacovigilance has changed. The new GVP modules within the EEA provided guidelines, but could still be interpreted differently by competent authorities and MAHs leading to differences in feedback from authorities, between authorities and constantly changing working instructions within companies. Very likely this had an impact on data quality and interpretation of pharmacovigilance data. To ensure high quality data output and performance, constant training is required. This is done usually via annual re-fresher trainings following success control via tests, but lacking efficacy and risk assessments of trainings. New changes in requirements results in 'best to one's knowledge' practice, waiting for feedback from authorities.

**Methodology & Theoretical Orientation:** Lack of training results in incorrect or missing activities of MAHs. Authorities can find these deficiencies through inspections of MAHs. Therefore, the public pharmacovigilance metrics reports from the MHRA were analyzed to see the changes in the number of findings over time.

**Conclusion & Significance:** The introduction of the new pharmacovigilance guidelines in 2012 led to another peak of findings in the period April 2013 to March 2014. The current general trend in total numbers is showing a decrease in findings but if this really means increase in data quality cannot be evaluated. It is suggested that following GMP guideline for qualification and validation, a more life-cycle-approach for pharmacovigilance training is chosen which means continuous monitoring of personal qualification, effectiveness of training, and risk management.

**Biography**
Anika Staack studied Biology at the University of Marburg (Master degree). She started working as Clinical Research Associate for cancer studies for 1.5 years and switched then into the field of drug safety. For more than 14 years she is working in the area of drug safety/pharmacovigilance and people management. Main areas of research interest are the impact of change in the pharmacovigilance legislation and its influence on quality as well as training. Currently she is working as EU-QPPV for a pharmaceutical company. Further education includes certified business trainer and meditation therapist.

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