

Pharmacovigilance Inspection Metrics Report

January 2009 to June 2009

During the period 1st January 2009 to 30th June 2009 the pharmacovigilance inspectorate conducted 53 inspections of Marketing Authorisation Holders (MAHs). Of these, 33 inspections were conducted as part of the routine programme, 16 were re-inspections due to critical findings identified at previous inspections and 4 inspections were either triggered or carried out in response to a request from the CHMP. At the time of writing, specific data regarding inspection findings for all 53 inspections were available for analysis and inclusion in this report.

The type of companies inspected during the period is presented in the table below.

	Innovative Pharma	Generics	Other
Number of MAHs inspected	18	27	8

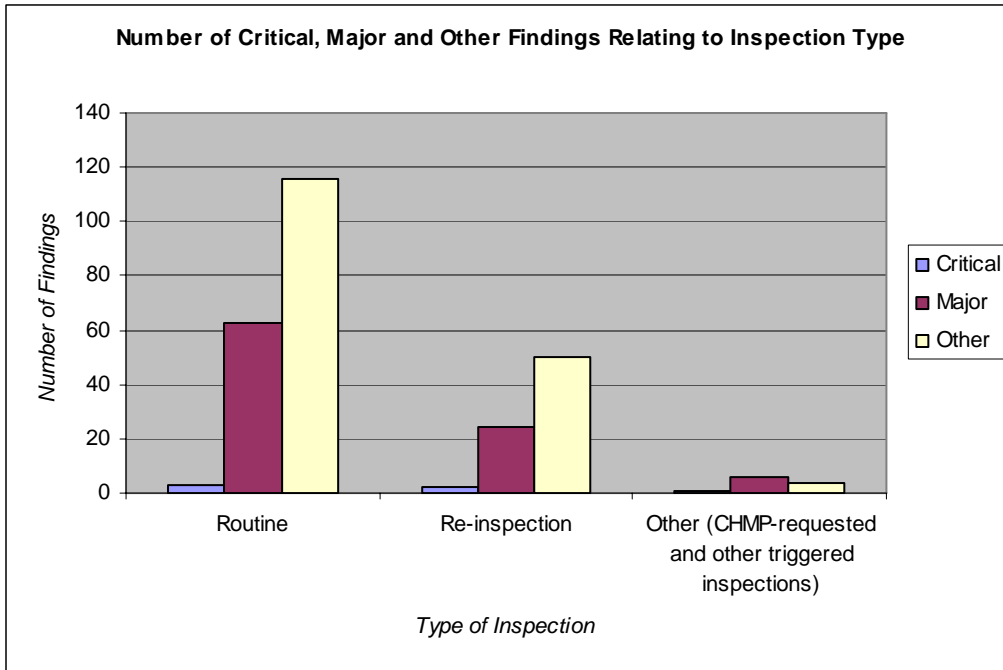
Findings identified during inspections are graded in one of three ways, the definitions for which are available on the MHRA website:

- Critical
- Major
- Other

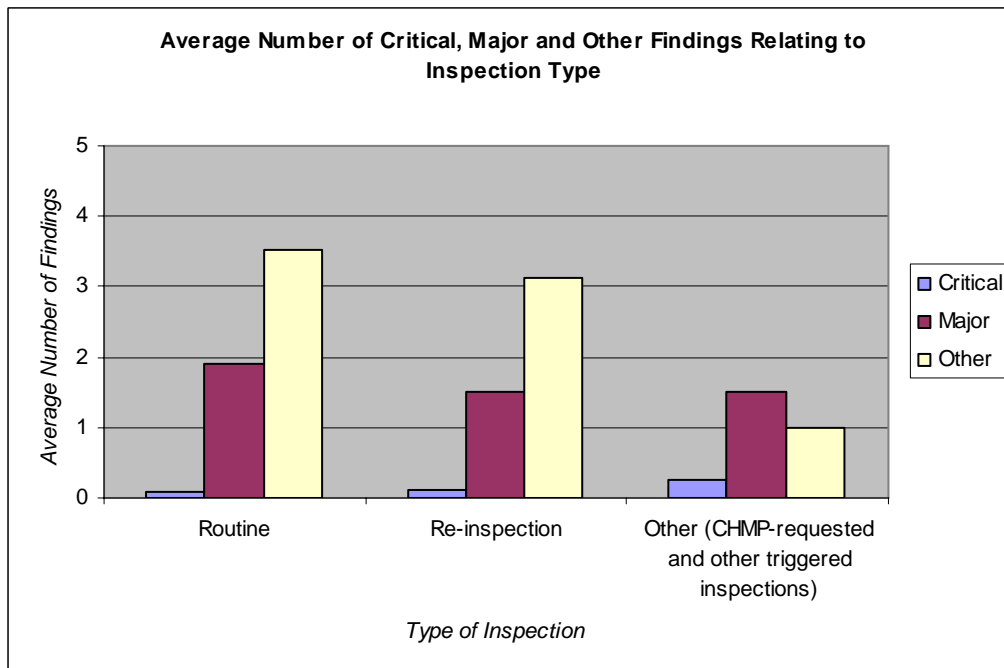
A total of 6 critical, 93 major and 170 other findings were identified during this period.

Type of inspection

A breakdown of the number of critical, major and other findings for each type of inspection (routine, re-inspection or other) is shown here:

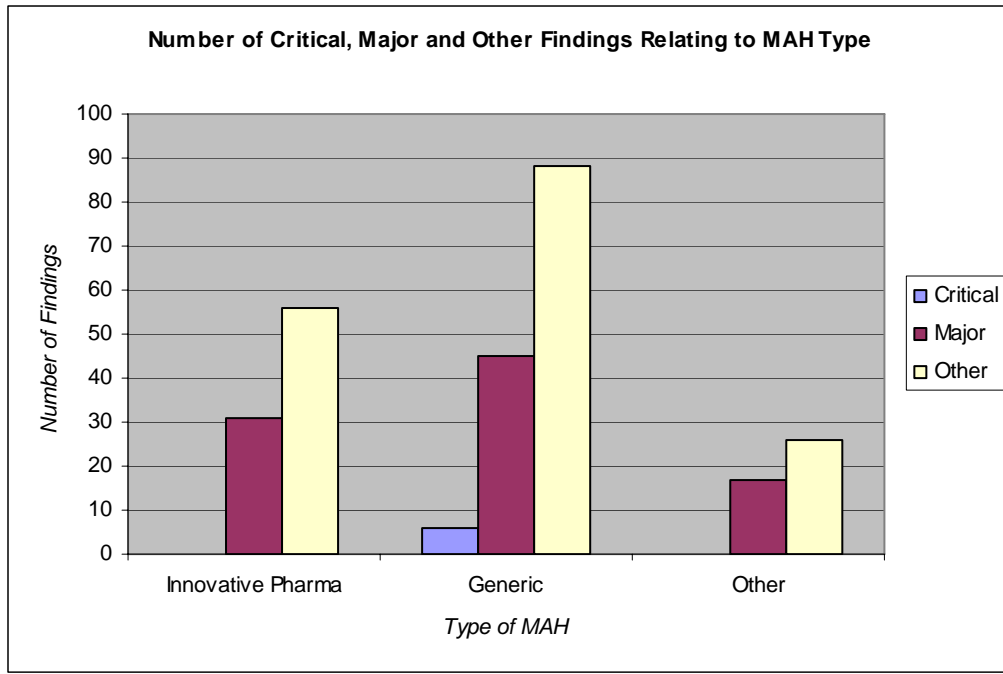


The information shown above can also be represented as the average number of findings for each type of inspection. It can be seen that the average number of critical, major and other findings is similar on routine versus re-inspections.

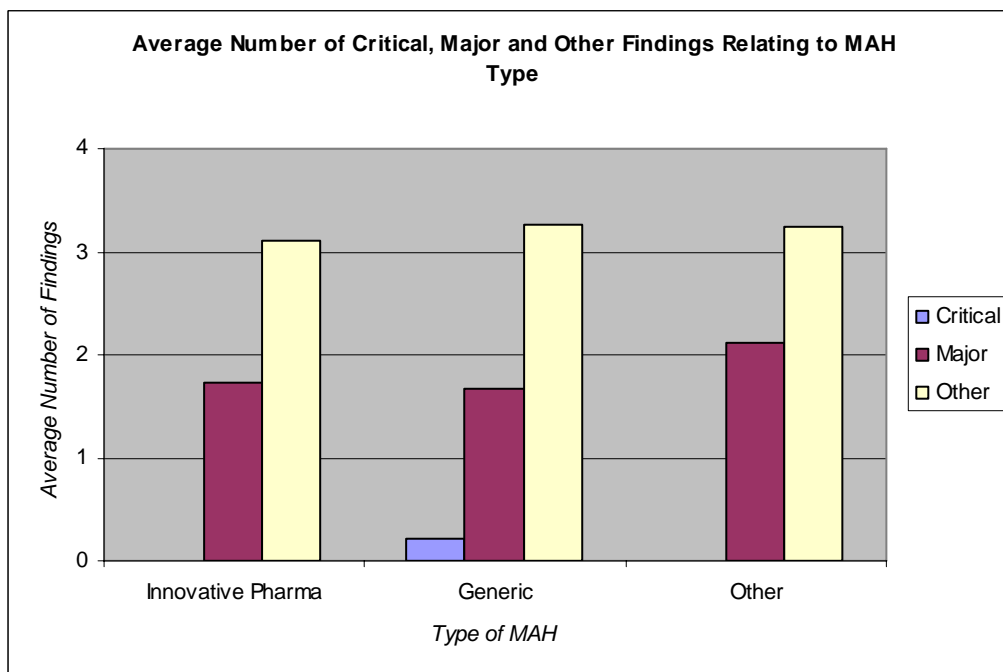


Type of MAH

A breakdown of the number of each grading of finding for each type of MAH is given below:



Similarly, this can be represented as the average number of findings for each type of MAH:

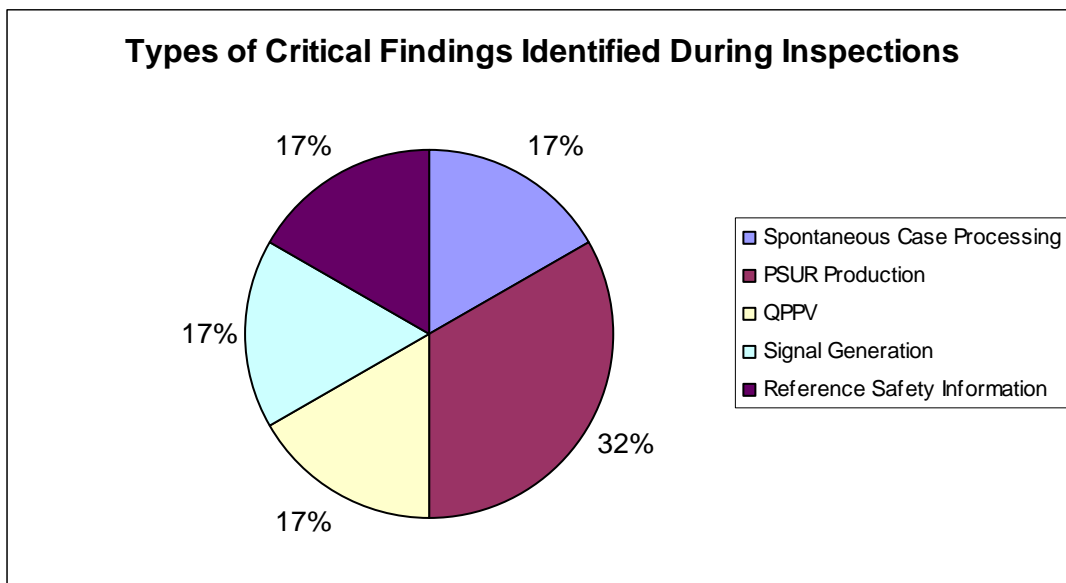


The average number of major and other findings is similar across all types of MAH but critical findings during this reporting period were exclusively identified at those MAHs classified as 'Generic'.

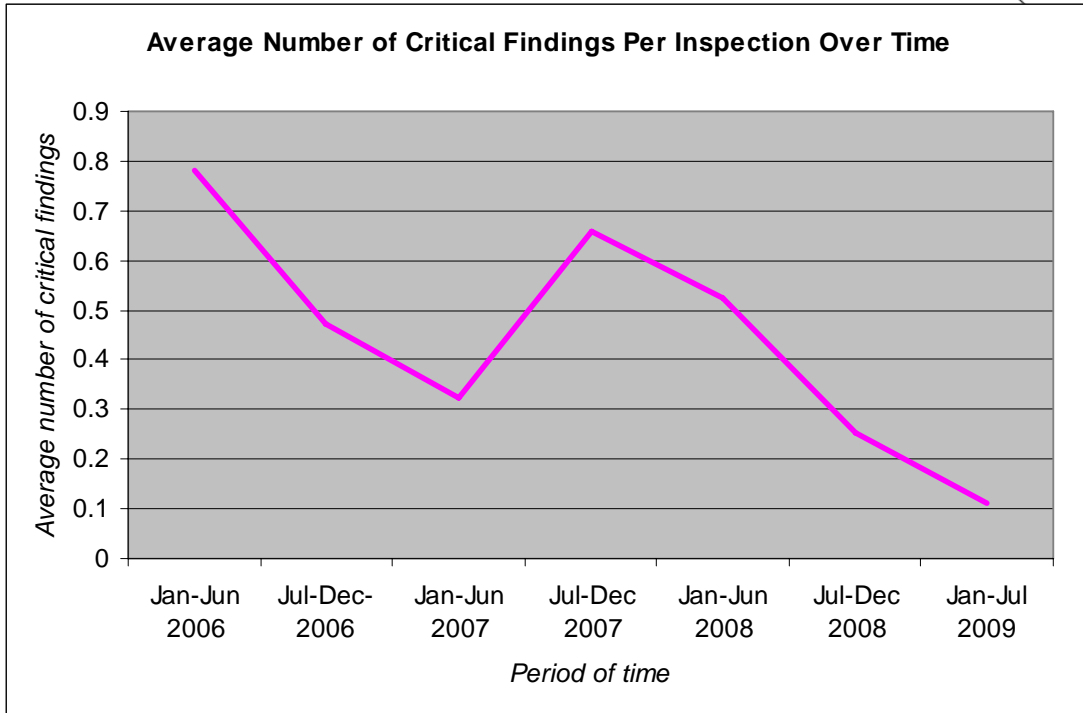
Critical findings

As stated previously, there were a total of 6 critical findings during this period, identified during 4 of the 53 total inspections that were performed. This is the lowest number of critical findings that have been identified during any six-month period since metrics began.

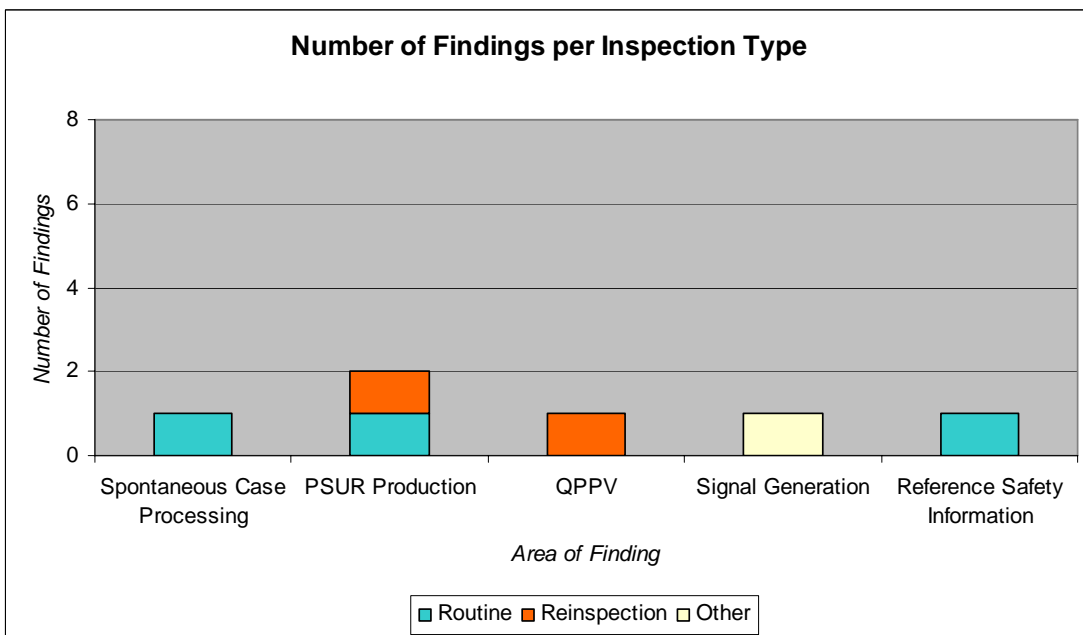
The breakdown of critical findings by type for the current period is given below.



Looking at data relating to critical findings since metrics began, the graph below shows that over time, the average number of critical findings per inspection has been decreasing since Jul-Dec 2007 and has decreased further during the period of this report.



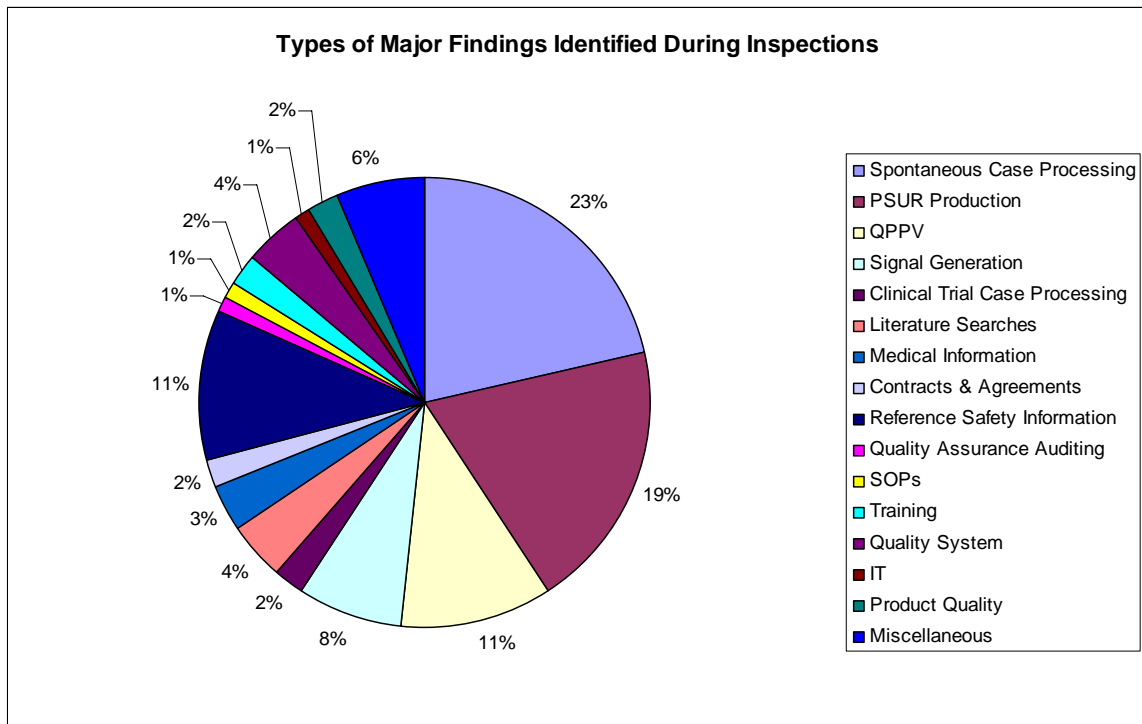
The graph below illustrates the areas in which critical findings were identified versus the different types of inspection:



Major Findings

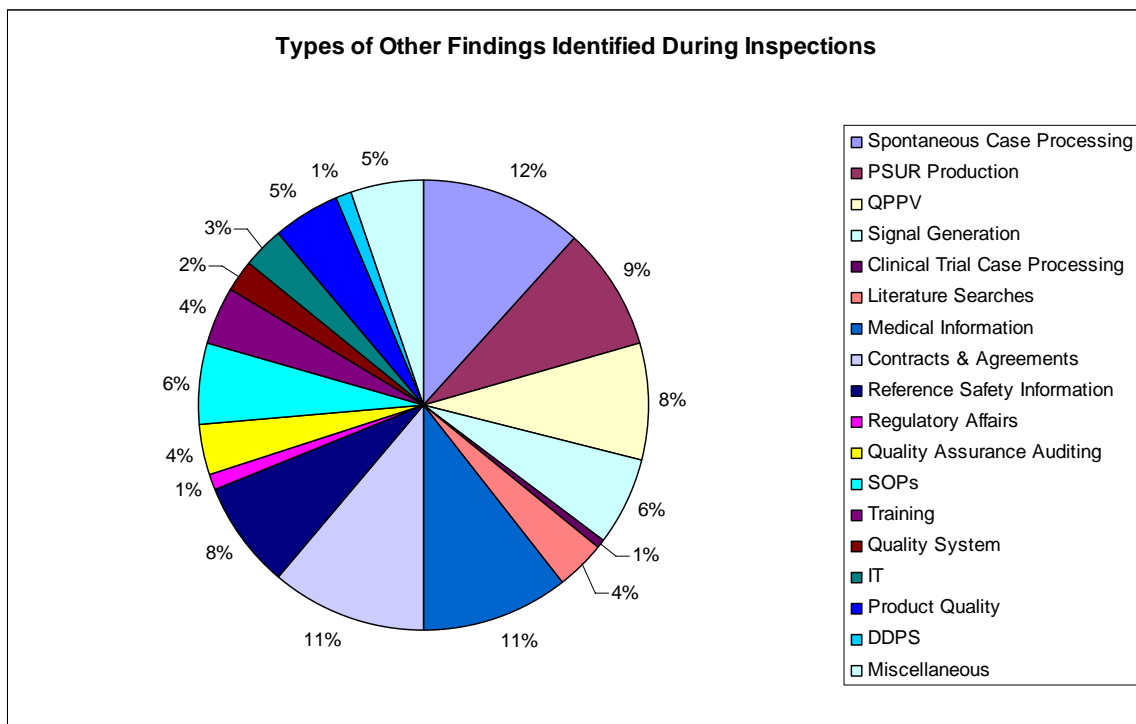
There were a total of 93 major findings identified during the period which is the lowest number of major findings identified during a six month period since metrics began. A breakdown of the types of major findings is provided below. The chart shows that 61% of major findings were identified in the areas of spontaneous case processing, PSUR production, QPPV and signal generation. This is consistent with data from previous metrics reports.

Miscellaneous findings included issues such as lack of business continuity plans, lack of MAH oversight of pharmacovigilance activities that have been outsourced and failure to adequately address requests from competent authorities.

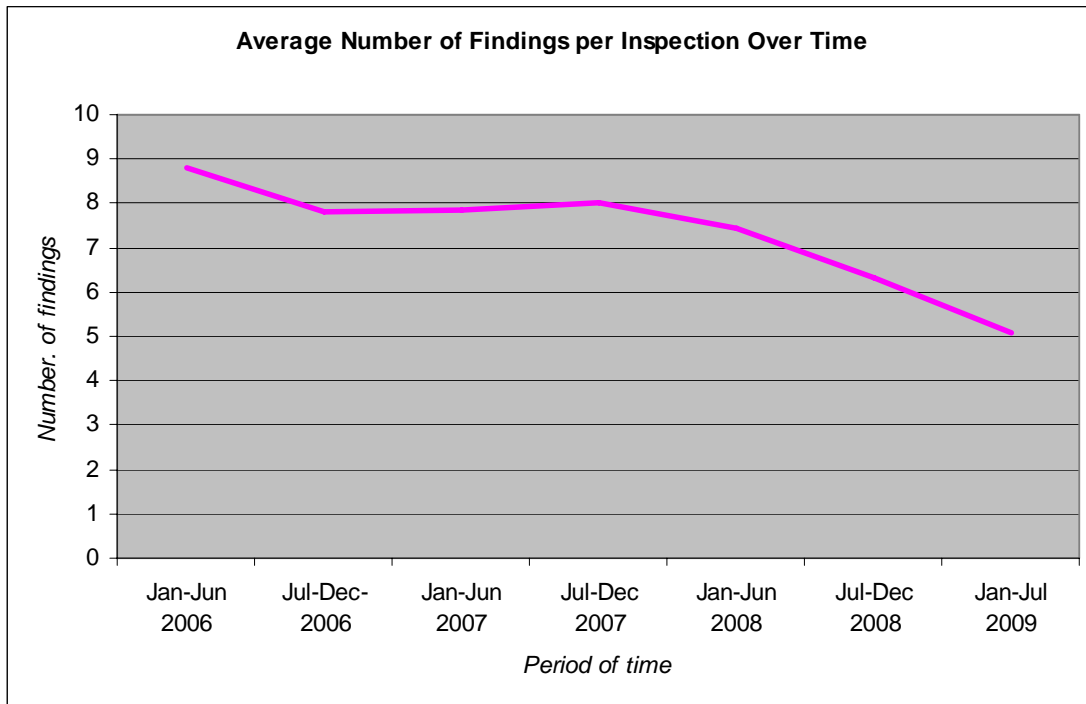


Other findings

170 findings were graded as other during this period and findings were identified in all areas of inspections. A breakdown of the types of other findings is presented below:



The average number of total findings (critical, major and other) per inspection continues to decrease.



Conclusions

The average number of critical and total findings continues to decrease over time. As per previous inspection reports, the majority of critical and major findings were identified in the areas of case processing, PSURs, QPPV, reference safety information and signal detection. This metrics report has seen the lowest number of critical and major findings ever identified during a six-month period.