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# Pharmacovigilance Inspection Metrics Report

April 2010 to March 2011

During the period 1st April 2010 to 31st March 2011 the pharmacovigilance inspectorate conducted 110 inspections of Marketing Authorisation Holders (MAHs). Of these, 86 inspections were conducted as part of the routine programme, 21 were re-inspections due to critical findings identified at previous inspections and 3 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 110 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 | 34 | 52 | 24 |

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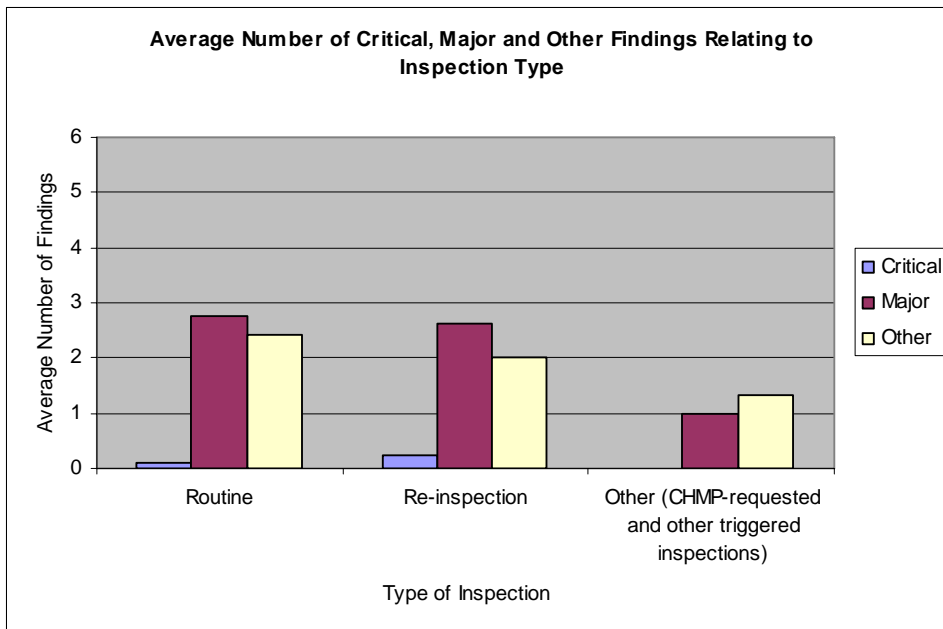
- Critical
- Major
- Other

A total of 15 critical, 296 major and 255 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:



Number of Critical, Major and Other Findings Relating to Inspection Type
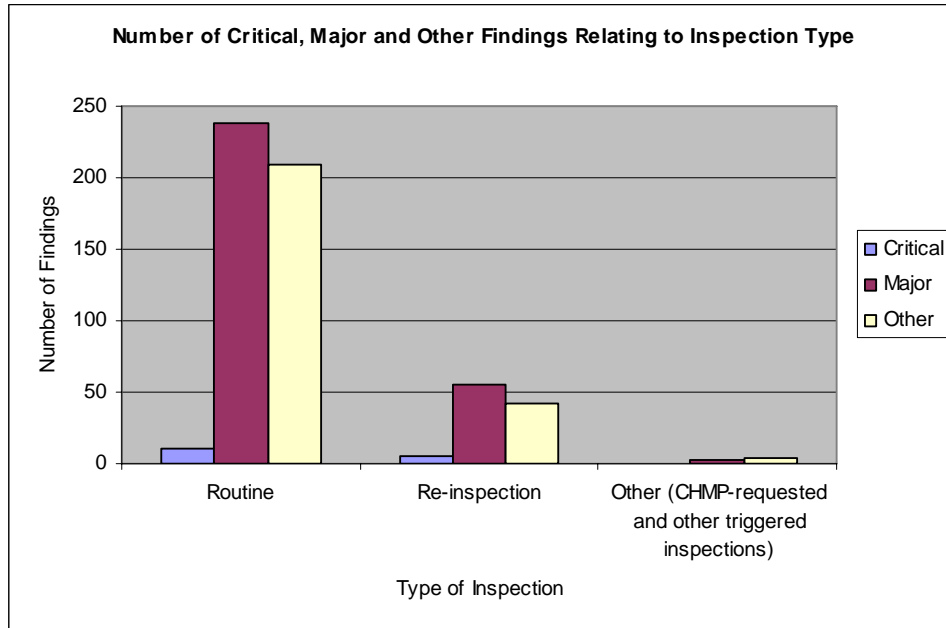
The information shown above can also be represented as the average number of findings for each type of inspection.



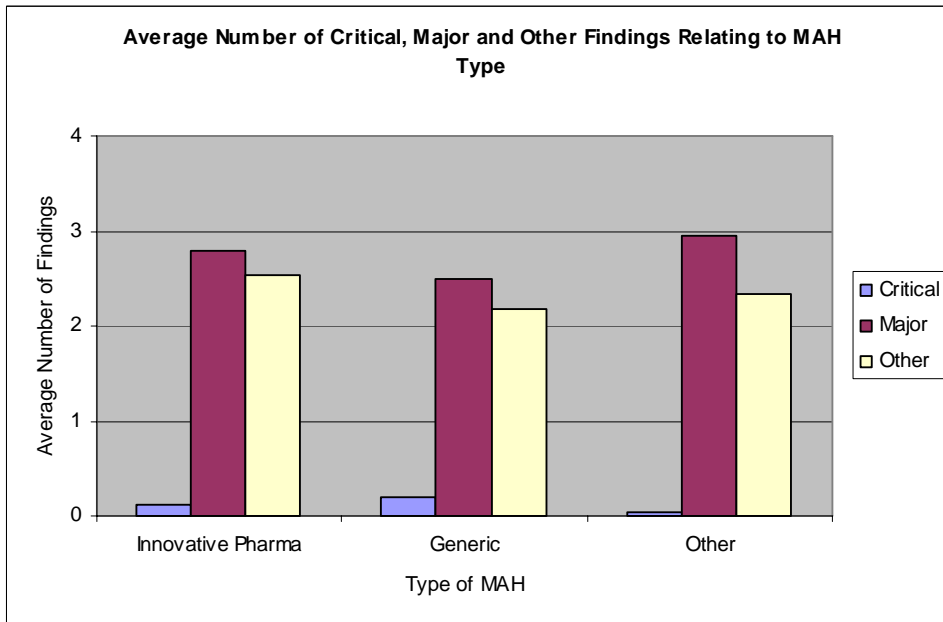Average Number of Critical, Major and Other Findings Relating to Inspection Type

**Type of MAH**

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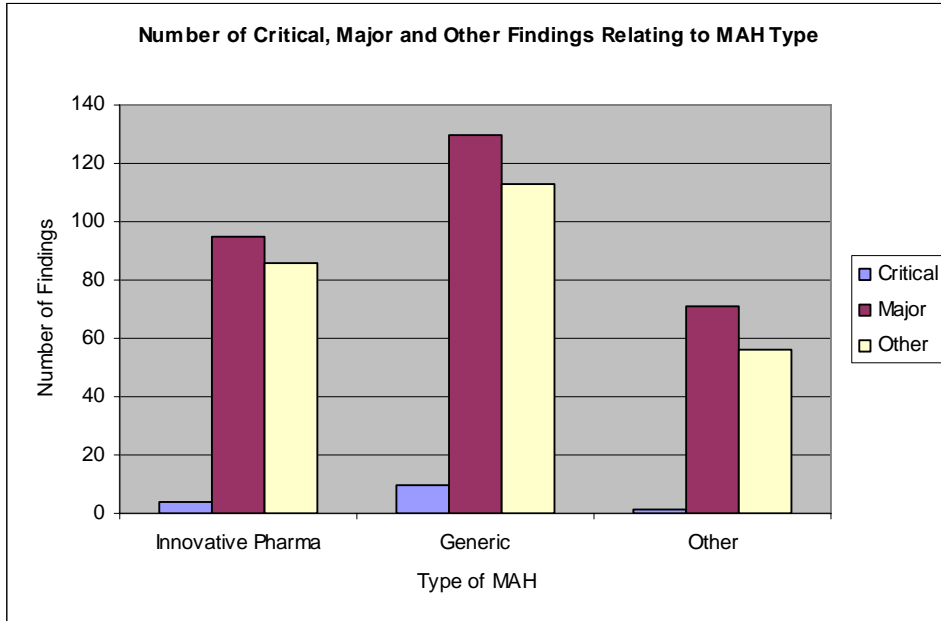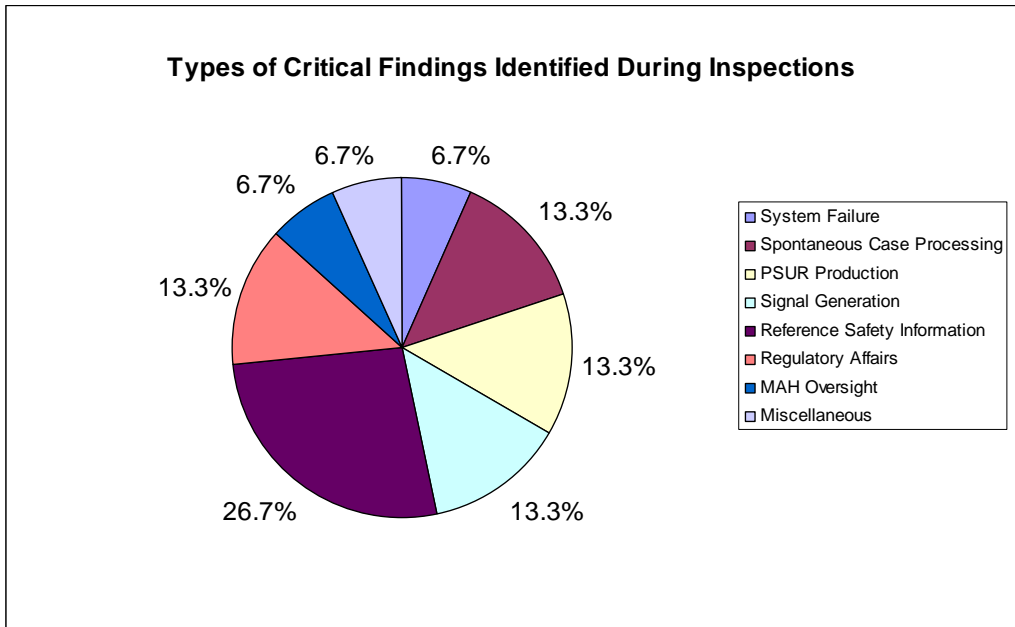


Similarly, this can be represented as the average number of findings for each type of MAH:

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### Critical findings

As stated previously, there were a total of 15 critical findings during this period, identified during 14 of the 110 total inspections that were performed.

The breakdown of critical findings by type for the current period is given below. The miscellaneous finding related to maintenance of marketing authorisations (failure to submit renewal documentation).

**Types of Critical Findings Identified During Inspections**



Legend:
- System Failure
- Spontaneous Case Processing
- PSUR Production
- Signal Generation
- Reference Safety Information
- Regulatory Affairs
- MAH Oversight
- Miscellaneous

The graph below shows that over time, the average number of critical findings per inspection has decreased significantly since Jul-Dec 2007.
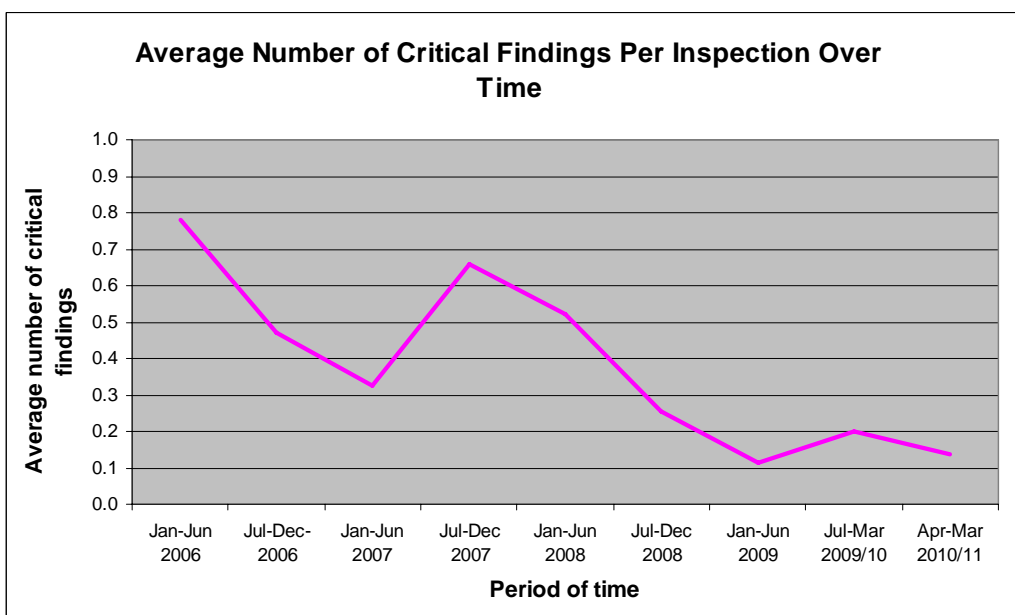
**Average Number of Critical Findings Per Inspection Over Time**

The graph below illustrates the areas in which critical findings were identified versus the different types of inspection:
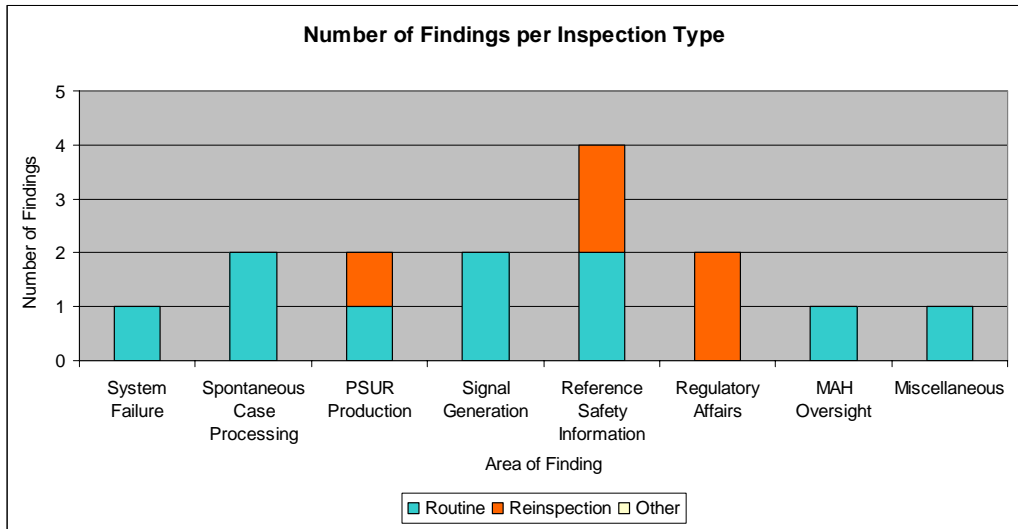
**Number of Findings per Inspection Type**



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

**Number of Findings per Type of MAH**

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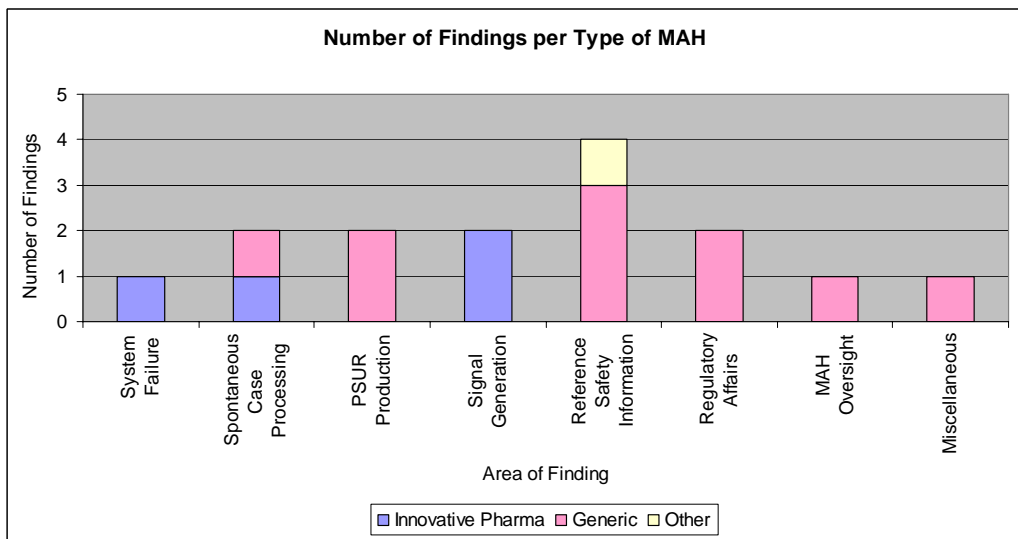
### Major Findings

There were a total of 296 major findings identified during the period. Although major findings were identified in 18 different categories, spontaneous case processing, PSUR Production, Signal Generation and Reference Safety Information accounted for 62% of the total number.
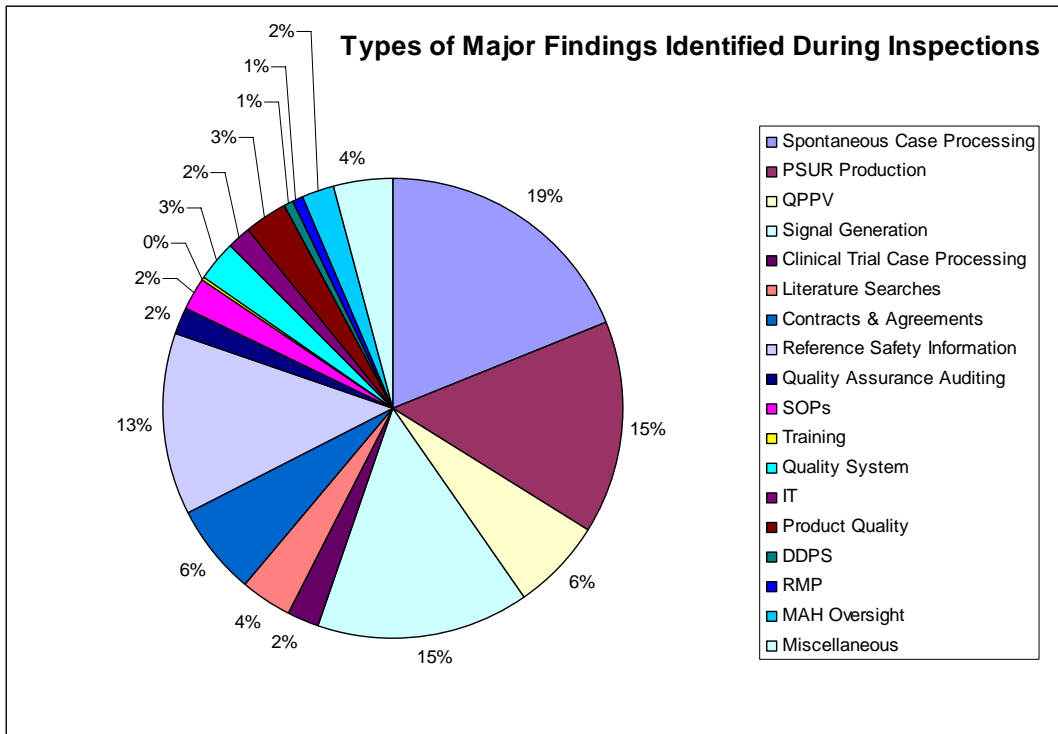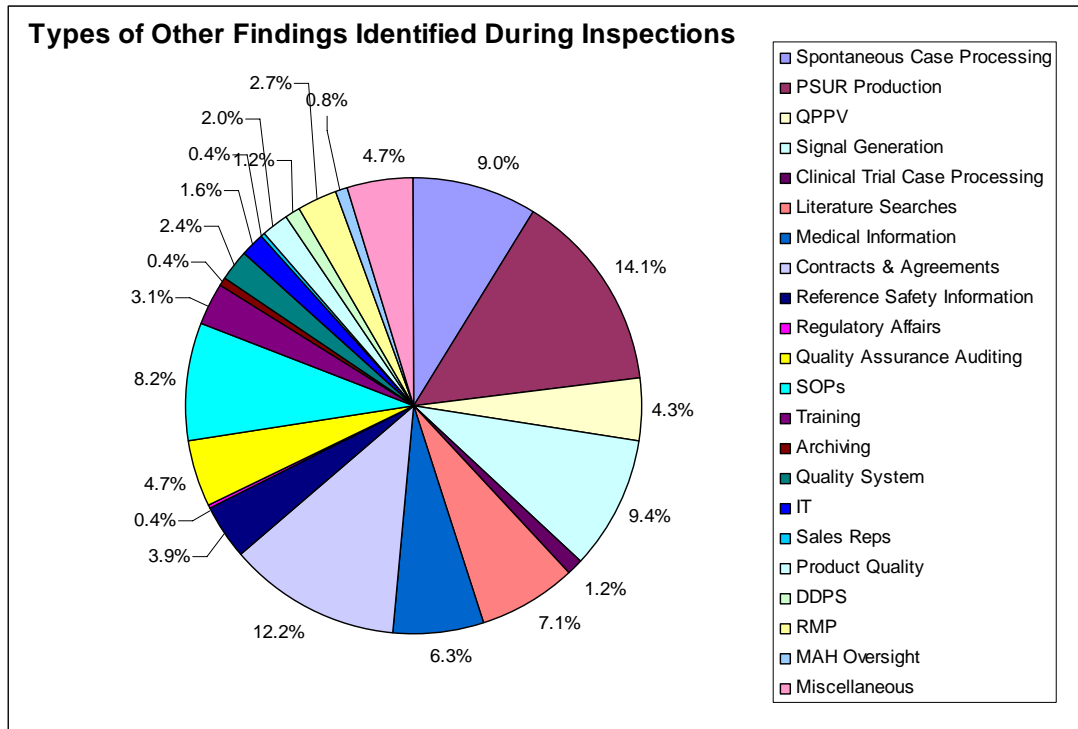
Miscellaneous findings included issues such as management of data from Patient Support Programmes (PSPs), inability to electronically report cases, failure to comply with corrective and preventative actions arising from inspections and a lack of change control processes.

**Types of Major Findings Identified During Inspections**

Legend:
- Spontaneous Case Processing
- PSUR Production
- QPPV
- Signal Generation
- Clinical Trial Case Processing
- Literature Searches
- Contracts & Agreements
- Reference Safety Information
- Quality Assurance Auditing
- SOPs
- Training
- Quality System
- IT
- Product Quality
- DDPS
- RMP
- MAH Oversight
- Miscellaneous

Pie chart values: 19%, 15%, 6%, 15%, 2%, 4%, 6%, 13%, 2%, 2%, 0%, 2%, 3%, 3%, 2%, 1%, 1%, 2%, 4%
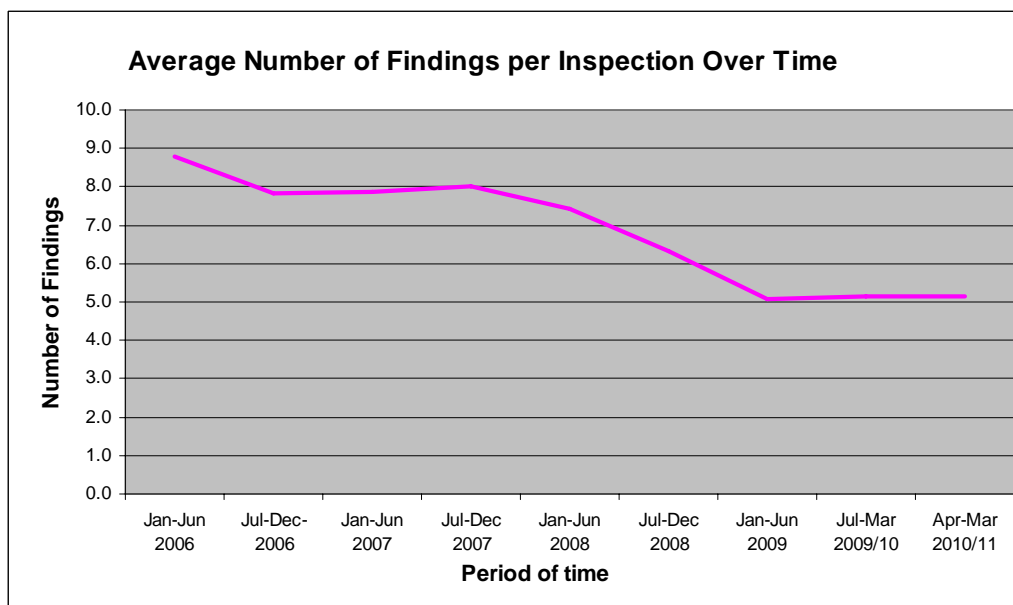
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### Other findings

255 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:

**Types of Other Findings Identified During Inspections**

Legend:
- Spontaneous Case Processing
- PSUR Production
- QPPV
- Signal Generation
- Clinical Trial Case Processing
- Literature Searches
- Medical Information
- Contracts & Agreements
- Reference Safety Information
- Regulatory Affairs
- Quality Assurance Auditing
- SOPs
- Training
- Archiving
- Quality System
- IT
- Sales Reps
- Product Quality
- DDPS
- RMP
- MAH Oversight
- Miscellaneous

Pie chart values: 9.0%, 14.1%, 4.3%, 9.4%, 1.2%, 7.1%, 6.3%, 12.2%, 3.9%, 0.4%, 4.7%, 8.2%, 3.1%, 0.4%, 2.4%, 1.6%, 0.4%, 2.0%, 1.2%, 2.7%, 0.8%, 4.7%

The graph below shows the average number of total findings (critical, major and other) identified per inspection.

**Average Number of Findings per Inspection Over Time**

Y-axis: Number of Findings (0.0 to 10.0)
X-axis: Period of time — Jan-Jun 2006, Jul-Dec-2006, Jan-Jun 2007, Jul-Dec 2007, Jan-Jun 2008, Jul-Dec 2008, Jan-Jun 2009, Jul-Mar 2009/10, Apr-Mar 2010/11

**Conclusions**

The decrease in the average number of findings per inspection that was observed during the period Jan-Jun 2009 has been maintained during the current reporting period. The average number of findings identified at inspections has decreased significantly since 2006.

Of the fifteen critical findings identified during the period, ten were identified during routine inspections versus five at re-inspections. However, 86 routine inspections were performed during the period versus 21 re-inspections.
Ten of the critical findings were identified during inspections of MAHs classified as Generic  versus four during inspections of MAHs classified as Innovative.

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. However, major findings have also been identified in new areas such as the handling of data from PSPs.