|  |  |  |
| --- | --- | --- |
| Audit.Status | Frequency | Percentages |
| Not In Scope | 26 | 27% |
| Closed | 19 | 20% |
| Pending | 14 | 15% |
| Completed | 4 | 4% |
| In Progress | 18 | 19% |
| Scheduled | 11 | 11% |
| Cancelled | 4 | 4% |
| Total | 96 | 100% |

Discussion:

Total of 96 audits are being tracked in this dataset for 2017 GxP areas.

Most audits are in the not in scope status (26 or 27%)

Closed and completed audits make up 23% - it is unclear if closed and completed are in the same status.

19% are in progress 11% are scheduled and 15% are pending. It is unclear is scheduled and pending audits are in the same status.

|  |  |  |
| --- | --- | --- |
| In/Out USA | Frequency | Percentage |
| USA | 51 | 53% |
| OUS | 45 | 47% |
| Total | 96 | 100% |

Discussion:

Out of 96 audits 53% are in the USA and 47% are outside of the USA.

Would it be beneficial to add in more options by separating the outside of USA audits into their countries?

|  |  |  |
| --- | --- | --- |
| GxP.Area | Frequency | Percentage |
| GCP | 34 | 35% |
| GLP | 13 | 14% |
| GVP | 6 | 6% |
| GMP | 27 | 28% |
| GDP | 7 | 7% |
| GMP/GDP | 2 | 2% |
| GMP | 6 | 6% |
| GLP | 1 | 1% |
| Total | 96 | 100% |

|  |  |  |
| --- | --- | --- |
| GxP.Area | Frequecy | Percentage |
| GCP | 34 | 35% |
| GLP | 14 | 15% |
| GVP | 6 | 6% |
| GMP | 33 | 34% |
| GDP | 7 | 7% |
| GMP/GDP | 2 | 2% |
| Total | 96 | 100% |

Discussion:

In this dataset there were 7 values that had spaces after them which caused them to not be counted with their correct criteria. After removing the spaces, 6 criteria were evaluated for the 96 audits.

35% of the audits were good clinical practice audits. 34% were Good Manufacturing Practice audits at manufacturing sites. 15% were good laboratory practice audits. 7% were good distribution practice audits of distribution and logistic partners. 6% were good vigilance practice audits of pharmacovigilance service providers and the remaining 2% were both good manufacturing practice audits of manufacturing sides and good distribution practicing audits of distribution and logistics partners.

For the remaining 2% it appears that these sites are both manufactures and distribution centers. Perhaps duplicating these two sites and counting them both separately would provide more clarity.

|  |  |  |
| --- | --- | --- |
| Audit.Type | Frequency | Percentage |
| Qualification | 38 | 95% |
| Requalification | 48 | 120% |
| Requalification/Q | 3 | 8% |
| (Unknown) | 5 | 13% |
| Requalification | 2 | 5% |
| Total | 40 | 100% |

|  |  |  |
| --- | --- | --- |
| Audit.Type | Frequency | Percentage |
| Qualification | 38 | 40% |
| Requalification | 50 | 52% |
| Requalification/Q | 3 | 3% |
| (Unknown) | 5 | 5% |
| Total | 96 | 100% |

Discussion:

For the audit type data there was again a criteria that had a space after it. After cleaning that up the data was sorted into 4 criteria.

52% of the audits were Requalification with another 40% qualification and 3% that are requalification’s with a questionnaire.

5% were unknown.

|  |  |  |
| --- | --- | --- |
| Audit.Method | Frequency | Percentage |
| None | 24 | 25% |
| On Site | 52 | 54% |
| TBD | 2 | 2% |
| Questionnaire | 10 | 10% |
| Q in 2016 | 1 | 1% |
| (Unknown) | 4 | 4% |
| On Site  \*CSQA did not participate | 1 | 1% |
| Remote | 2 | 2% |
| Total | 96 | 100% |

|  |  |  |
| --- | --- | --- |
| Audit.Method | Frequency | Percentage |
| None | 24 | 25% |
| On Site | 53 | 55% |
| TBD | 2 | 2% |
| Questionnaire | 10 | 10% |
| Q in 2016 | 1 | 1% |
| (Unknown) | 4 | 4% |
| Remote | 2 | 2% |
| Total | 96 | 100% |

Discussion:

The methods for the audits are noted here. 55% of them happened on site.

Removal of the audit that CSQA did not participate in as a separate value and adding it to the other on side audits cleaned up the data. A separate note about this site else ware would be more appropriate so the data is no skewed.

25% had a questionnaire in 2016. Do these sites not have to participate in 2017? Should these sites be added to None which make up 25% of the sites?

11% have questionnaires and 2% were remote. Are remote audits and questionnaire audits the same?

2% are TBD and 4% are unknown.

|  |  |  |
| --- | --- | --- |
| Proposed.Quarter | Frequency | Percentage |
| Q2 | 27 | 28% |
| Q1 | 23 | 24% |
| Q3 | 21 | 22% |
| Q4 | 17 | 18% |
| (Unknown) | 5 | 5% |
| Q3 - Q4 | 3 | 3% |
| Total | 96 | 100% |

Discussion:

The proposed quarter in which the audits will happen at the 96 sites. 28% are in quarter 2, 24% in quarter 1, 22% in quarter 3 and 18% in quarter 4.

There is an additional 3% that are do be done in quarter 3 and 4. It would be beneficial to sort both of these into both quarter 3 and 4 to get an accurate count of the work that is to be done those quarters.

If we add those 3 sites into both quarters, quarter 3 would have 24 or 25% and quarter 4 would have 21 or 22%. This would help to level out the audits done in each quarter.

The remainder 5% that are unknown could be spread out into the other quarters equally.