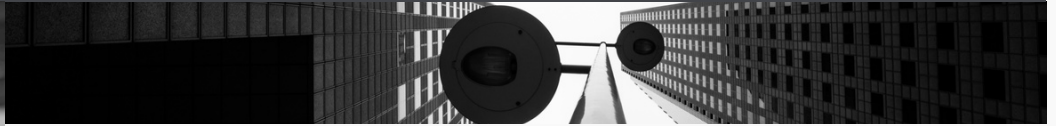# SQUARE CONSULTING
NEWSLETTER

THINGS TO CONSIDER THIS MONTH:

- Ensure your audit schedule is documented for 2024
- Determine if any new suppliers require audits for 2024
- Review your 2023 audit results to determine if any QMS areas require extra internal audit focus in 2024
- Begin to summarize your management review data from 2023
- Determine any ongoing training required for the Quality Management System for 2024

HAPPY NEW YEAR!

The start of 2024 means the beginning of a new year and the closeout of Q4 for your Quality Management System. The end of a quarter and the start of the New Year typically requires the initiation of new Quality Management System documentation.

Now is the time to ensure your 2024 QMS Audit Schedule is documented and approved for 2024. This includes internal audits, supplier quality audits, and any anticipated audits of your QMS by outside services.

5 THINGS TO INCLUDE IN YOUR AUDIT SCHEDULE

Per ISO 13485, your audit program must be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. When documenting your 2024 audit schedule, ensure these 5 things are included in the schedule:

- The QMS area to be audited. Ensure each area of the QMS is audited annually.
- The criteria for the audit. This should include a verification the QMS area conforms to regulatory requirements
- The scope of the audit. This can include procedures that will be audited.
- The interval of the audit. If the QMS area has had issues in the past, the frequency of the audit may be increased.
- The method of the audit. Will the audit be an internal audit, a 3rd party audit, etc.