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| Clause | Key checks |
| **4.1 – General requirements** | * Check that the organization is ensuring outsourced processes are controlled, especially those which affect product conformity with requirements * Check that the control of such outsourced functions is identifiable within the quality management system * Has the organization implemented a documented quality management system and is it maintaining its continued effectiveness in accordance with this international standard and any other applicable regulatory requirements? * Does the organization document the roles undertaken by the organization under the applicable regulatory requirements? * Check whether your organization is determining the processes needed for the quality management system and the application of those processes organization-wide * Check whether your organization is applying a risk-based approach to the control of the appropriate processes needed for the quality management system * Check that your organization is determining the sequence and interaction of these processes * Check whether the organization is determining suitable criteria and methods required to ensure the operation and control of processes is effective * Ensure the availability of resources and information necessary to support the operation and monitoring of these processes * Document and implement actions necessary to achieve planned results and maintain the effectiveness of all relevant processes * Do you monitor, measure, and analyze these processes for adequacy? * Have you established records needed to demonstrate conformance to this international standard and compliance with applicable regulatory requirements for each quality management system process? * Does the organization monitor and ensure control of any outsourced processes that affect product conformity to requirements? * Does the organization retain responsibility of conformity to this international standard and to customer and applicable regulatory requirements for outsourced processes? * Are the controls proportionate to the risk involved and the ability of the external party to meet the requirements? * Do the controls include written quality agreements? * Check that the organization is clearly documenting procedures for the validation of the application of computer software used in the quality management system * Are records of all such activities as mentioned above being documented, maintained, and reviewed? |