ISO 13485:2016 Result Charts

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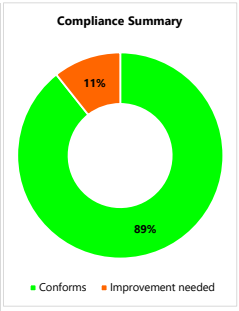
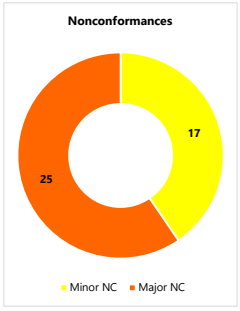
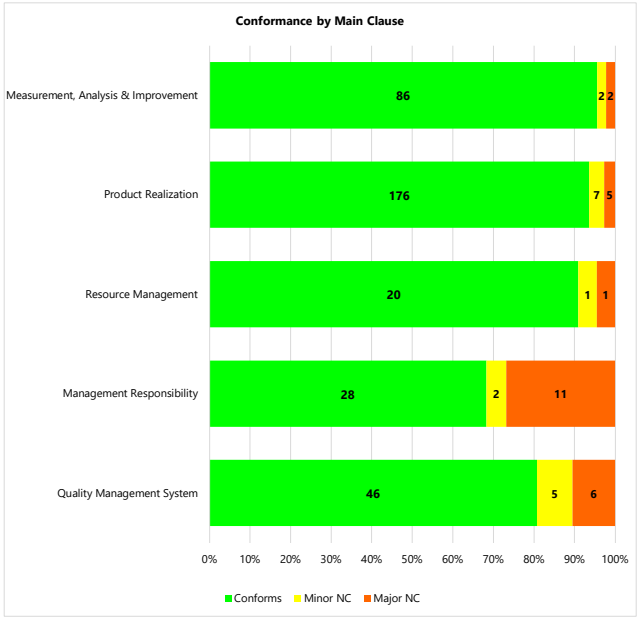
Summary of Compliance

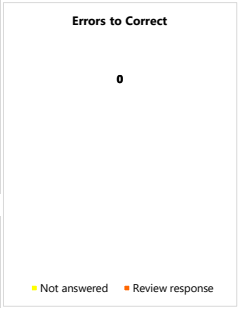
Monitor, evaluate, and report the status of your internal audits in real time. Based on audit findings, the charts below quantify and visualize levels of conformity with ISO 13485:2016. The number of nonconformances, depending on their severity, are shown by the yellow and orange doughnut charts. The audit findings 'traffic lights' are intended to visually communicate the risk posed by the cumulative audit findings to the processes being audited. The rating system is stratified from 'complies' to 'major nonconformance' to convey a concise and consistent method for scoring each process. >85% = Low risk, 60-84% = Medium risk, and <59% = High risk.

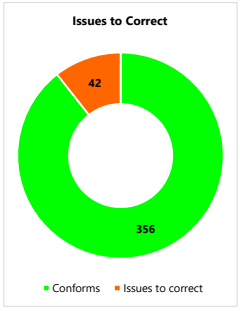
Process Name	Score	
Business Planning	88%	Low
Business Review	67%	Medium
Corrective Action	87%	Low
Customer Service	100%	Low
Design & Development	96%	Low
Facilities	83%	Medium
HR & Training	67%	Medium
I.T. & Doc Control	86%	Low
Improvement	80%	Medium
Inspection & Calibratior	100%	Low
Internal Audit	100%	Low
Management System	82%	Medium
Manufacturing	89%	Low
Operational Planning	100%	Low
Order/Quote Fulfillment	83%	Medium
Packing & Shipping	100%	Low
Procurement & Supply	100%	Low
Sales & Marketing	100%	Low
Overall	89%	Low
Conforms	**89%**	
Improvement needed	**11%**	









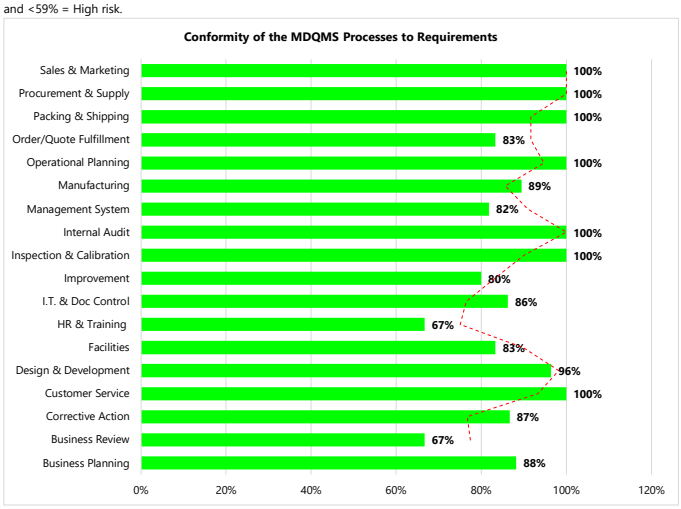


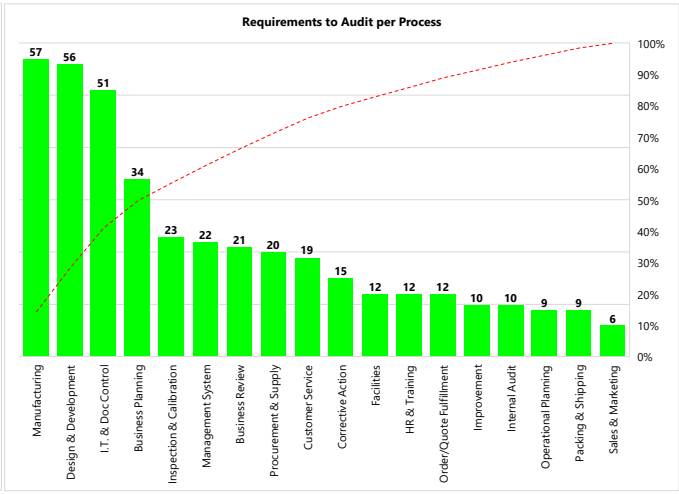
Fix the 'Entry Errors' in the checklist:	
Not answered	0
Review response	0
Total Errors	0

Improvement Recommendations	
>85%	Processes are effective. The process is fully documented and implemented and demonstrates compliance as well as effectiveness. Continue to monitor trends and indicators for change and encourage improvement.
60-84%	Processes have minor nonconformances. Current practices conform but are not documented. Deviation from practice is unlikely to result in the failure of the MDQMS or process. Implement corrective action.
<59%	Processes have major nonconformances. Likely to have a significant adverse effect on customer satisfaction, product quality, delivery, or profitability. Take immediate corrective action and investigate root cause(s).

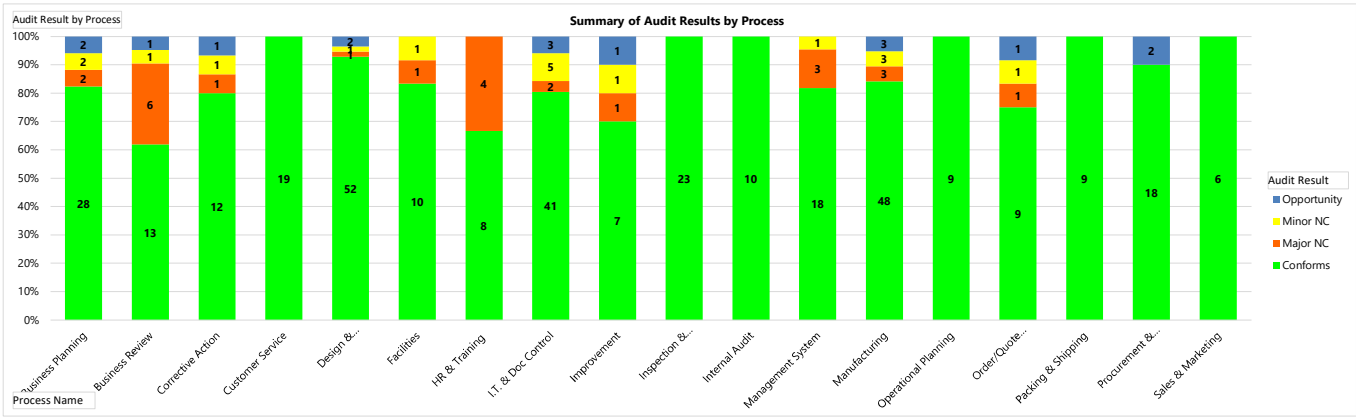
Process Conformity

The results charts quantify and visualize the conformity of your medical device quality management system to the requirements and clauses of the standard. The bar chart is based upon the percentage of audit questions that conform and the percentage that need improvement. The data labels summarize the percentage. The rating system is stratified from 'compliant' to 'major nonconformance' to convey a concise and consistent method for scoring each process. >85% = Low risk, 60-84% = Medium risk, and <59% = High risk.



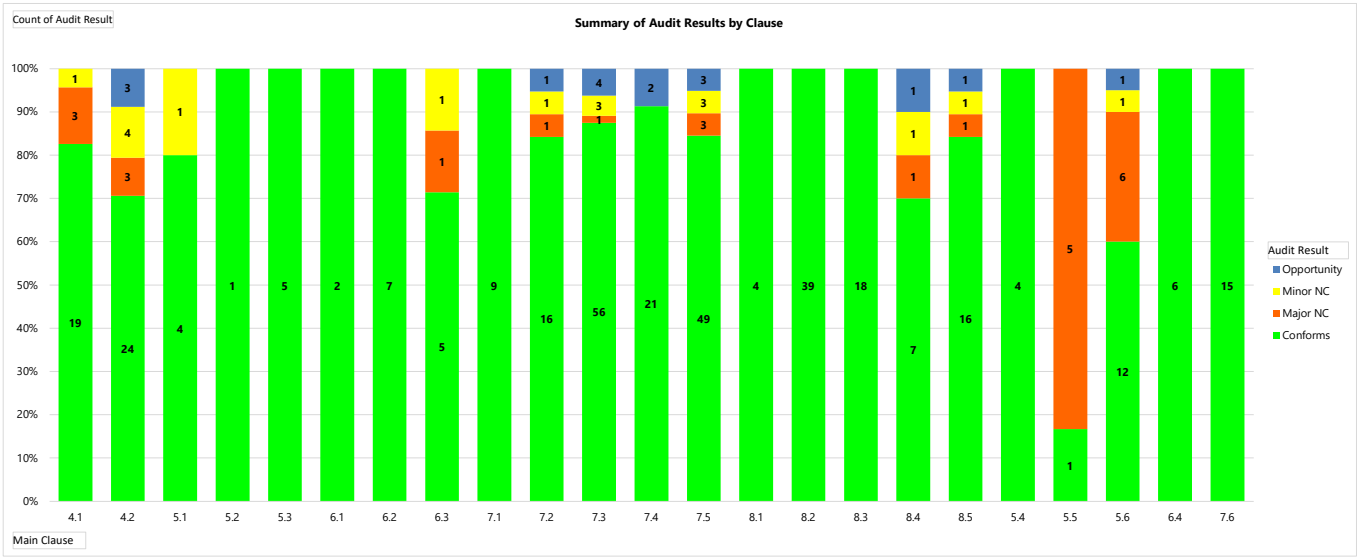


The Summary of Audit Results by Process chart below is interactive and is linked to the 'Process Report' tab. Right-click the chart and the pivot table and select 'Refresh' when new data is entered into the tracker. Use the 'Process Name' button to select and filter which process(es) the chart displays. Use the 'Audit Result' button to select and filter the audit results.



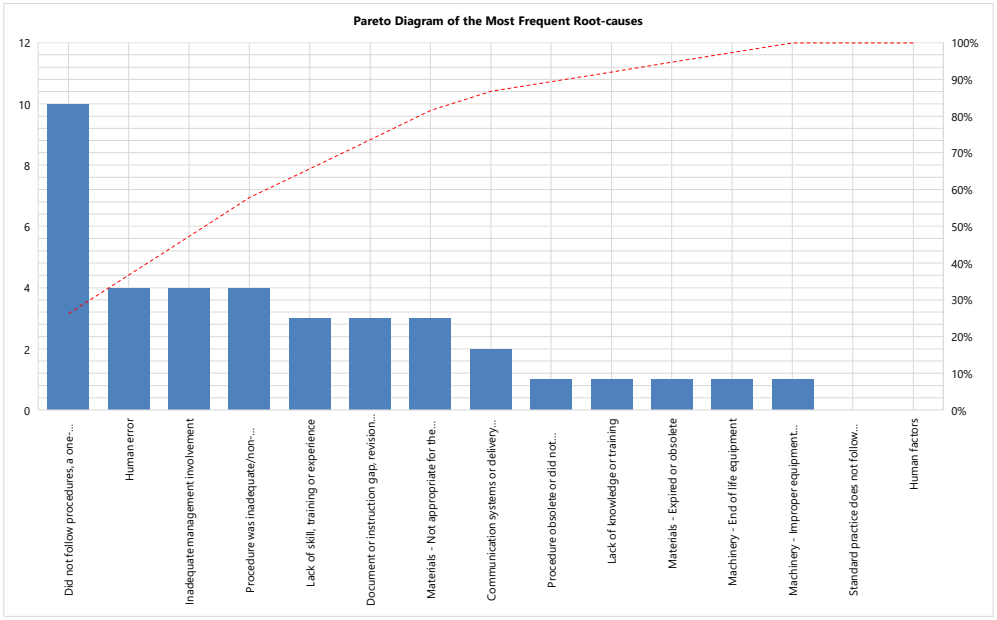
Clause Conformity

The Summary of Audit Results by Clause chart below is interactive and is linked to the 'Clause Report' tab. Right-click the chart and the pivot table and select 'Refresh' when new data is entered into the tracker. Using the filters, the chart can be interrogated to display the audit results for one, some, or all clauses, or filtered to show the audit results. Use the 'Main Clause' button to select and filter which results the chart displays. Use the 'Audit Result' button to select and filter the audit results.



Root-causes & Action Plans

The Pareto diagram is a special type of bar chart that shows the most frequent problems in a prioritized order from left to right. Check the diagram is counting the all of the root-causes, by right clicking the chart and choosing 'Select Data' and modify the coloured boundary box to suit the data area. Expand or reduce the boundary box to capture all positive root-cause counts as needed. To reorder the list after input changes, highlight all relevant cells in Columns AA31 to AB79 and go to Home > Sort & Filter > Custom Sort > Sort by 'Count' > Order 'Largest to Smallest'. The diagram is linked to the source data Columns AA31 and AB79 of this worksheet.



About the Pareto Diagram:

Statistical quality tools, such as Pareto diagrams are graphical methods that help to diagnose problems and suggest appropriate approaches to resolve them.

The Pareto diagram will help your team concentrate its efforts on the factors that have the greatest impact. It also helps your team communicate the rationale for focusing on certain areas.

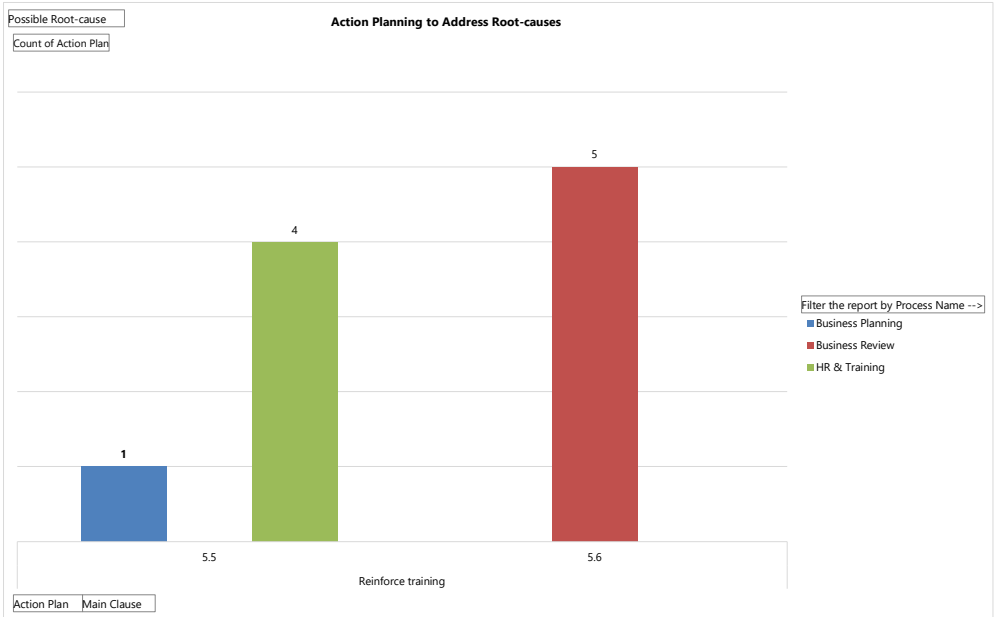
Interpreting the Pareto Diagram:

Red line = cumulative percentage curve
Blue bars = ranked bars in descending order
Left axis = number of occurrences
X axis = description of the root-cause
Right axis = percentage scale

The diagram shows that there are in total, fifteen root-causes that occurr 49 times within the system which contribute to 100% of the nonconformances.

By applying the 80/20 rule, draw a line starting at 80% on the percentage scale on the right hand side, running parallel to the x-axis and stopping where it contacts the cumulative percentage curve.

The causes that fall to the left of this point are the causes that are the 'vital few' that contribute to 80% of the audit nonconformance problems, while the causes to the right are less important and considered to be the 'trivial many'.



About the Action Planning Chart:

The action planning to chart is interactive and may be filtered to display the root-causes and their frequency within the affected processes and related clauses.

Interpreting the Action Planning Chart:

Looking at the Pareto diagram, you can see that the most frequent root-cause is not following procedures with 10 occurrences.

In order to know where to apply the corrective actions to fix the problem, use the 'Possible Root-cause' filter to select 'not following procedures'. The chart will show the corresponding actions, the clause number(s) and the process(es) in which the corrections need to be made.

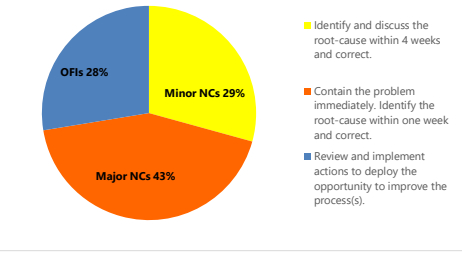
You can use the 'Possible Root-cause' filter to select individual or multiple root-causes.

The 'Filter by Process Name' will filter the actions that apply to each process and clause. Ensure the 'Possible Root-cause' filter is set to 'Select Multiple Items', and that the 'All' option is ticked in the filter drop-down menu.

The chart is linked to the data in the pivot table in the 'Action Report' worksheet. Right click the chart and the pivot table and select 'Refresh' when new data is entered into the checklist.

Improvement Opportunities

Opportunities for improvement (3.3.1) See ISO 9000:2015 or recording good practices. (3.10) Note 2 ISO 19011:2018. Minor problems exist, with weaknesses, bottlenecks, or potential deficiencies, which, if not improved, may lead to nonconformity in the future. Negative or positive situations are noted by the Auditor but do not relate to a requirement in the standard. Examples of good practice in one area that could be adopted in other areas to aid overall improvement.



Using the Opportunities by Clause Chart

Whilst the root-causes and action planning charts deal with how the minor and major nonconformances are to be dealt with, these charts relate to the actions needed to address any opportunities for improvement.

The opportunities by clause chart is interactive and may be filtered to display the improvement actions and their frequency within the affected clauses. The chart shows that there are 16 OFIs, 11 related actions, accross 8 separate clauses.

The chart is linked to the data in the pivot table in the 'Opportunity Report' worksheet. Right click the chart and the pivot table and select 'Refresh' when new data is entered into the checklist.

