ADDITIONAL CONSIDERATIONS

- **ADDITIONAL INDUSTRY-SPECIFIC STANDARDS**

The medical device industry has many interrelated and collateral standards. For instance, in terms of risk management, the industry relies on ISO 14971 which is referenced in ISO 13485 but not explicitly required. This is further compounded in the sense that active medical devices usually are shown to be compliant to the IEC 60601 which itself requires that some, if not all, of the requirements of 14971 are addressed. Similarly, the industry relies heavily on standards such as ISO 11135 and 11137 for validating sterilization and the ISO 10993 series for demonstrating biocompatibility. In addition, many topics are also routinely addressed by ASTM methods or AAMI documents. It is advised to be aware of the role and impact of these standards.

- **ADDITIONAL RESOURCES**

A useful tool to consider would be to consider the "outcomes" at the start of each chapter of the MDSAP Audit Model and its Companion document. This provides insights into the general objectives or outcomes desired by regulators. The use of the MDSAP Companion document (the MDSAP AU G0002) can also provide additional insights. These documents can be used in addition to the clause comparison, as the MDSAP audit model breaks down the QMS audit into a discrete number of tasks with specific intentions.

- **ADDITIONAL REGULATORY OBLIGATIONS**

As with other industry sectors, Medical Device Manufacturers have obligations that reach beyond the standard; the regulations may require certain procedures or documents. This is generally linked in the standard by statements like "as required by regulatory requirements". Without knowing these regulatory requirements, a manufacturer could overlook them. As mentioned above, the MDSAP audit model and its Companion document are good tools since they consistently point out these requirements in the regulations.

- **AREAS OF EMPHASIS**

Risk management (e.g. similar to ISO 14971) is emphasized throughout the standard. It has been noted that different industry sectors may focus on different aspects of risk management. For medical device manufacturers, minimizing product risk is paramount. Similarly, demonstrating traceability from design inputs through to post-market activities is essential, including, but not limited to, risk mitigation activities. A recommendation is that the organization consider recording everything of note.

- **NEW PRODUCT INTRODUCTION (NPI)**

An increasing focus in the medical device industry is the collection, analysis, and use of post-market data, especially in the context of risk management and the evaluation of the risk/benefit ratio performed at the outset during the new production introduction (NPI) phase. While the NPI cycle may follow the organization's existing process, special attention and consideration must be paid to unique medical devices industry sector requirements.