Appendix 5.4.1
Common Regulatory Submission Pitfalls

Regardless of which regulatory pathway is taken, innovators and companies often make mistakes on their regulatory submissions that cause unnecessary delays and/or additional expense.

Mistake	How to Avoid
Documentation errors	Be very clear on requirements around formatting, documents, and procedures. Do not let the submission get hung up based on administrative errors.
Failure to pay attention to FDA guidance documents	FDA provides substantial information in the form of guidance documents for various technologies (and analogous products). These are available on the web and should be reviewed carefully.
Lack of regulatory involvement in design/development	A company's regulatory professional is required to translate engineering requirements into language for FDA consumption. If the person preparing the submission is not involved in the development process, holes can develop in the "story" that the submission should tell. Regulatory and design/development personnel must work hand in hand to communicate about the submission needs and engineering activities occurring within the organization.
Unnecessarily complex submission	Keep the submission as simple as possible to address the basic requirements. For example, use simple line drawings, not 3-D color images. Use clear language and well-defined arguments for substantial equivalence.
Poor communication with reviewer	FDA reviewers are people who want to help. Company representatives should seek to develop relationships with them as they would with any customer or supplier. Work reasonably and amicably. If the reviewers ask for something the company thinks is unreasonable, try to understand why they are asking for that item. Consider if there is opportunity for education. It is far easier to provide the information/data than to argue about it.
Failure to anticipate reviewer questions	A good team anticipates questions in advance and presents information in such a way as to not raise additional questions. Also, just in case, the team should have additional data "in its pocket" if/when specific questions arise. The technical team should be "on deck" to conduct testing during the review cycle if this is requested.
Lack of correspondence between marketing	Marketing materials must reflect the official summary from FDA with respect to claims for use. Ensure that summary is

Mistake	How to Avoid
claims and approval	available to and understood by the creators of this material.

