



Figure 2 Novel therapies and next generation therapies are predicated on the use of established as well as new, but not yet validated, technologies. The inherent risk in new technology is unknown and may be high.

With the ongoing implementation of guidelines from the International Conference on Harmonization (ICH), the geographical regions of the United States, Europe and Japan have standardized approaches to the drug development process. However, while these guidelines provide a flexible and innovative basis for preclinical drug evaluation, they serve as a minimum requirement for achieving drug approval. It is generally accepted that additional studies may be required during the development process and that regulatory authorities amongst the three regions may have different scientific opinions on an acceptable preclinical development program.

The reader is cautioned that the ICH guidelines only constitute a minimum requirement and rarely encompass a development program that will be acceptable to the innovator company or all regulatory agencies. While the reader is encouraged to review and utilize these guidelines, a rational