Table 26-6 Application of the Four Specific Pharmaceutical Quality System Elements to the Four Main Components of the Product Lifecycle

Quality system element	Development	Technology transfer	Manufacturing	Product discontinuation
Process performance and product quality monitoring	Conduct quality risk management and monitoring to establish a control strategy for manufacturing	Monitor carefully scale-up activities for successful transfer to manufacturing and further develop control strategy	Apply a well-designed system to ensure performance within a state of control and to identify improvement areas	Continue stability studies to completion. Take appropriate action on marketed product according to regional regulations
Correction action and preventative action	Product and process variability explored to help when such actions are required later	Effective system for feedback and continual improvement	Apply CAPA, then evaluate effectiveness of the actions taken	Continue with impact on product remaining on the market and similar products
Change management system	Change definitely part of development process so documentation needs to be excellent. Formality of change management process will increase as product moves forward in development	Provides documentation of adjustments made to the process during technology transfer operations	Must be in place for commercial manufacturing. Oversight by the Quality Unit to provide assurance of appropriate science and risk-based assessments	Any changes afterwards should go through appropriate change management
Management review	Management needs to review adequacy of product and process design	Perform reviews to ensure that the developed product and process can be manufactured at commercial scale	Should be a structured system and support continual improvement	Continue to review product stability data and product complaints

Source: Adapted from ICH Q10.

of risks to the quality of the drug product. Such factors identified can help the establishment of risk controls. Quality risk management is an important part of science-based decision making essential for quality management of pharmaceutical manufacturing.

One of the most important applications of risk management in the sterile product field is the identification and potential control of risk factors involved in aseptic product processing. There are many risks associated with all the variables associated with aseptic processing—personnel hygiene, techniques, and attitudes; design, qualification and validation of processes, equipment, and facilities; cleaning methods, air and water quality, handling and sterilization of raw materials, sterilization and depyrogenation process validation, plus many other variables related to manufacturing in general—mixing, aseptic additions, dose control, lyophilization, labeling, secondary packaging, and so on.

One specific example is provided here on how to assess the risk of an aseptic filling process. A common tool used is called Failure Mode Effect Analysis (FMEA). Fishbone analysis can also