



Current Good Manufacturing Practices Handbook: 21st century pharmaceutical regulatory expectations

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Regulators, whether drugs or devices, have always had a single point agenda: minimise risk to patient. Different agencies have gone about the task in different ways, but the objective has remained the same. Yet another common feature is that each has specified the “minimal” requirements for compliance. Broadly, these expectations have large areas of overlap; in matters of fine detail, however, there are divergences. If you pick one agency’s regulations and endeavour to comply, chances are that you may fall short of another agency’s expectations. If you endeavour to comply with all, and succeed, you will surely exceed any individual agency’s expectations. It is to facilitate such an effort that this book has been compiled - so that you have all national and international expectations between the covers of one single book.

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