Written in a clear and concise style by experienced authors, this book covers regulatory affairs in all major global markets for pharmaceuticals and medical devices.

Following a look at drug development, complete sections are devoted to national and EU regulatory issues, manufacturing license application and retention, and regulation in the USA. Other topics include CDER, CBER and marketing and manufacturing licenses, the ICH process and Good Laboratory/Clinical/Manufacturing Practices.

The book covers everything pharmacologists, bioengineers, pharma engineers, students in pharmacy and those working in the pharmaceutical industry need to know about medical regulatory affairs.