Handbook of Pharmaceutical Manufacturing Formulations: Sterile Products: 6

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No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing sterile products has evolved into a very sophisticated industry.

Highlights from Sterile Products, Volume Six include:

- formulations of sterile dosage forms, regulatory filing requirements of sterile preparations, and cGMP compliance, all of which are tied together in the final preparation of the CMC sections of regulatory applications
- specifications of a manufacturing facility to manufacture compliant sterile products
- NDA or aNDA filing requirements of sterile products
- an alphabetical presentation of formulations of pharmaceutical products based on their generic names

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