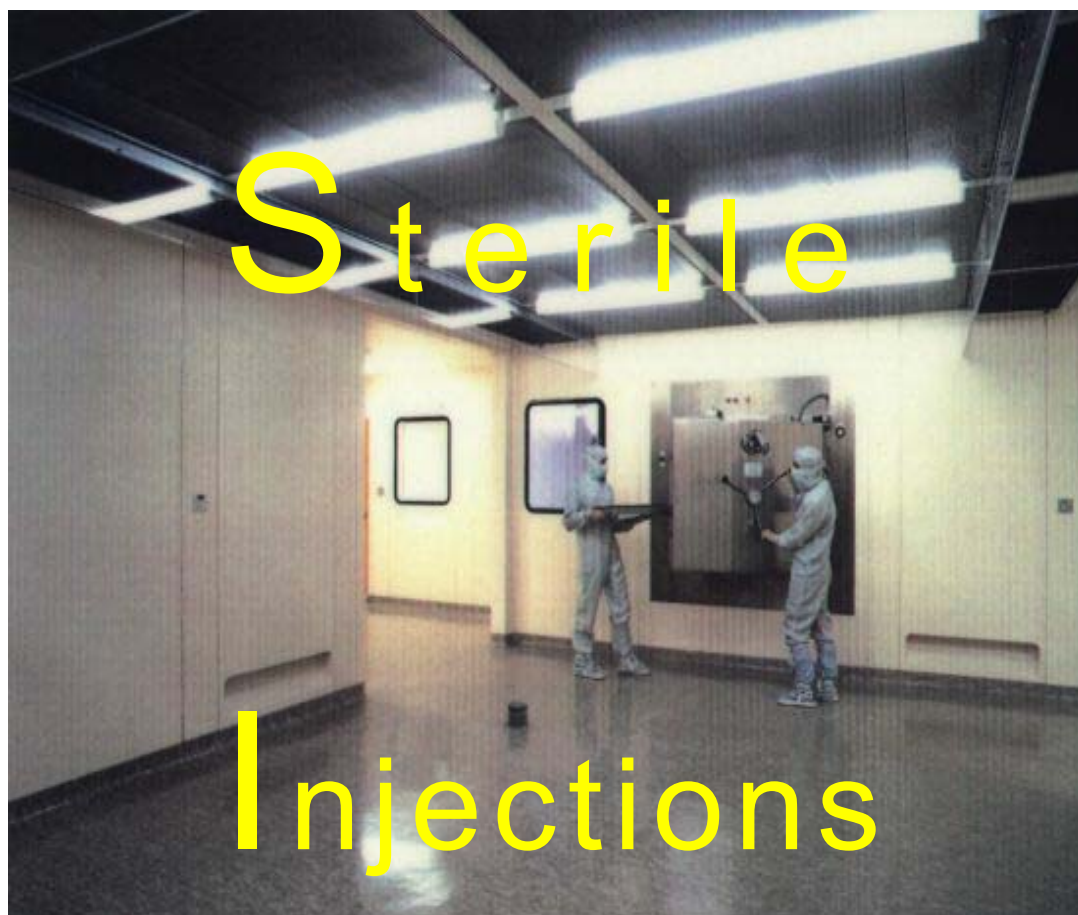


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VOLUME 20 - **Part One**
Drug Development - Sterile Injections

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Handbook of Pharmaceutical
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Part One Drug Development

Sterile Injections

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24 Volume Series
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EDITOR'S NOTE

Handbook of Generic Development Series - Sterile Injections

This handbook represents the **current** International Edition of the ongoing 24 volume series of Generic Drug Development and appears under the cumulative title of the Handbook series of Generic Drug Development. The ongoing series is updated annually at the end of each year. This is an ongoing process as new data, specifications and process techniques are added on a continual and expanding basis. This handbook is fact never fully complete, as each new annual edition brings an enlarged and extended profile in the drug development process, as well as new agency rules, guidelines and guidance to industry which continues year by year as the global product data base expands. Over 150 scientific publications and drug development conferences are annually referenced in the 48 volume Handbook series of Generic Drug Development.

This mammoth task presents a continual ongoing commitment to the improvement of the technical databases and the product specific drug development requirements and know-how through the world wide IAGIM joint ventures and know-how projects currently active in over 15 countries.

The Handbook is available in electronic format (Online and CD ROM) and the **e-**format is up-dated annually to Association Members of IAGIM.

This current international edition of the Handbook has been redesigned and updated to meet the current Guidance for Industry - Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application as well as all current approved and key draft FDA guideline requirements of the Center of Drug Evaluation and Research (CDER) up to current date.

Editor-in-chief

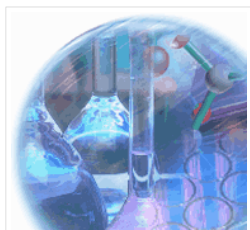


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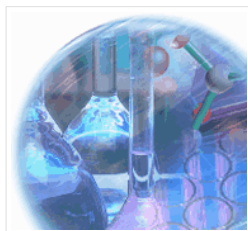


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