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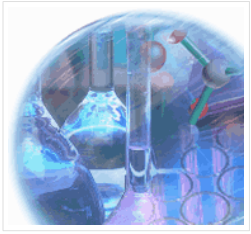

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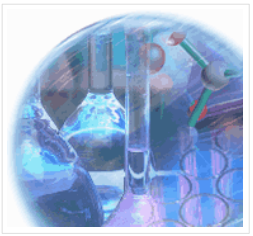

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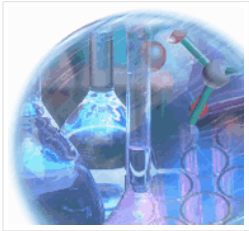

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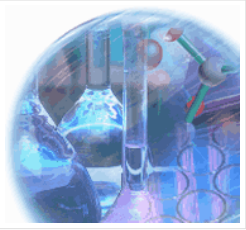

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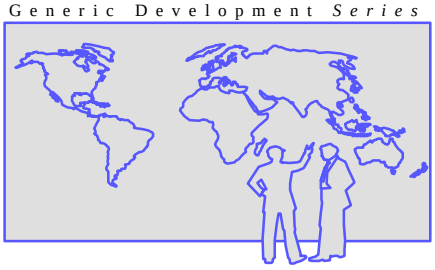

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EDITORIAL PREFACE

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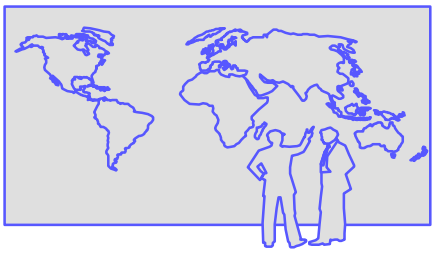
This expanded International Edition of the Handbook **24** volume *series* of the ongoing of Generic Drug Development and appears under the cumulative title of the Handbook *Series* of Generic Drug Development. The ongoing series is updated annually at the end of each year. This is an ongoing process as new data, specifications and process techniques are added on a continual and expanding basis. This handbook is continually updated and revised, 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 continue to be added year by year as the global product data base expands.
Currently over 150 scientific publications and drug development conferences are annually referenced in the **24** volume Handbook *series* of Generic Drug Development.

This mammoth task presents a continual ongoing commitment by the scientific review committee to the improvement of the technical databases and the product specific drug development requirements and know-how technology accessed through the world wide IAGIM joint ventures and know-how projects currently active in over 15 countries.
The Handbook is available in electronic format (CD ROM) and the e-format is up-dated annually to association members of IAGIM.

This international edition of the Handbook is redesigned to meet the latest - Guidance for Industry - Organization of an Abbreviated New Drug Application as well as all key draft and final FDA guidelines and requirements of the Center of Drug Evaluation and Research (CDER - OGD 1) - Editor-in-Chief.



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