

Series ISSN 0793 8810 / Electronic 0793 8828
A Series Publication in association with
The International Association of Generic
& Innovative Drug Manufacturers.

Essential Pharmaceutical Generic Drug Development



☑ **Pharmaceutical**

☑ **IQOQ & Analytical**

☑ **Decision Trees**

☑ **Bioequivalency**

☑ **Microbiological**

☑ **Quality Control**

☑ **Scale-Up**

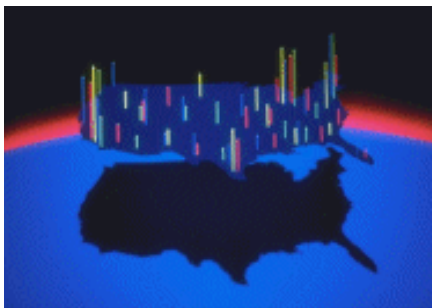
☑ **Cleaning Protocols**

☑ **All Validations**

☑ **Regulatory**

☑ **Pre Approvals PAIs**

☑ **Annual Reports**



Locum International Press
Locum Publishing House

handbooks@locumeuro.com

Electronic Standard Operating Procedures.

Available as *Electronic SOPs* on CD ROM for immediate in-house use. Guidelines provided on how to convert development SOPs into your own customized research-based-development system that meet all international regulatory guides, guidelines and regulatory requirements. **e-SOPs** can be edited to meet your development units own in-house needs. **Designed for Generic and NDA Drug Development use.**

Electronic SOPs provide a complete electronic Drug Development System, including Decision Trees, Formulation, Scale-up, Process Optimization & Qualification; pivotal and final large scale validation batches; IQOQ, Analytical, Cleaning and Process Validation. Essential technical documentation and OGD regulatory know-how that is essential for a successful product development and a speedy FDA approval, saving queue-time and development dollars.

Essential information for Development Pharmacists, R&D Chemists, QA and Regulatory personnel. Allows management to understand the nuts and bolts on Generic ANDA and EC DEVELOPMENT and filing in the most cost effective way.

CD ROM or PRINT available at: **\$299**

In association with the
International Association of Generic Drug Manufacturers

A Locum House Publication
©Copyright LOCUM 1995 -2001

handbooks@locumusa.com