

Volume 07
Pacific Rim

2002 Edition

International

Features reviews and articles on Drug Development for the Pharmaceutical RA, R&D and Manufacturing Scientist.

- Generic & Innovative Drug Development.
- Generic Drug Manufacturing.
- Quality Control /Assurance
- PAI Know How
 - Microbiology Control
- BA/BE Food-Effect Studies
 - Pharmaceutical Stability
 - Regulatory Affairs
 - Global Product Registration
 - Bulk Pharmaceutical Chemical GMP/validation
- Features the *Ins-and-Outs* of **NDA** CMC sections.
- Dissolution Similarity Testing
 - IVIVC Development
- New Assays & Impurity Profiles
- Innovative Drug Development

THE INTERNATIONAL JOURNAL OF ENETIC

International Journal of Generic Drugs

Development and Manufacture of Generics and NDA CMC sections for the Pharmaceutical Scientist

LOCUM Int. Publishing House



Drug Development & Manufacture for Pharmaceutical Technology Profession:

Journal of Generic Drugs

Electronic < Journal on Disk

Journal on: the Web

e-- Journal

(Representative list of the current 2001/2002 Table of Contents in Summary Form)

♦ Material Selection

- ♦ Choosing the right active
- ♦ Choosing the right excipient
- ♦ Choosing the right dyes and colors
- ♦ DMF's Do's and Don'ts
- ♦ The Development Notebook

♦ Generic Drug Manufacture

- ♦ Preparing the *right* documentation
- ♦ Manufacturing Instructions Do's and Don'ts
- ♦ Developing the Formula from A Z
- ♦ Developing CR / MR/ ER and DR forms
- ♦ Development Checklist Step by Step.
- ♦ Individual and Population Bioequivalence
- ♦ Bioequivalence and IVIVC, & CDP's

◆ Setting the correct specifications

- ♦ In-process, Release and Check Specifications
- ♦ Decision trees (Polymorphism, Impurities etc.)
- ♦ 10 key Decision Trees in SOPs

◆ Process validation and protocols

- ♦ Scale-up for specific dosage forms
- ♦ Cleaning validation requirements
- ♦ PAIs and Post approval Inspections
- ♦ Tablet Hardness Qualification / LOD
- ♦ Sampling and Testing the Pivotal Batch

♦ Container-closure Systems

- ♦ Closure DMF's vendors obligations
- ♦ ANDA container-closure requirements
- ♦ EC and ANDA comparisons
- ♦ Getting the *paper work* right-first time
- ♦ New guidelines / New DMF obligations
- ♦ USP / 21 CFR / Indirect Food Regulations

♦ Biostudies

♦ Food/Fasting Studies, BCS, WaiversABE, IBE, IVIVC, CDP Bio Conferences

♦ Quality Control and Assurance

- ♦ Audits and vendor inspections
- ♦ Vendor audits by mail/fax

♦ Microbiological Controls

- ♦ Purified Water USP when to use it
- ♦ Topicals and their controls
- ♦ Cleaning Limits

♦ Pharmaceutical Stability

- ♦ Auditing your Stability Department
- ♦ Time limitations in the stability protocols
- ♦ Checking the Reference Listed Drug
- ♦ Reduced Testing Plans Bracketing / Matrixing

♦ Analytical Aspects

- ♦ Auditing Raw Data / Impurities / Limits
- ♦ Handling graphs and print-outs
- ♦ High Speed stability assay validations
- ♦ Model validation protocols /Assay /Dissolution
- ♦ Residual Solvents, OVI's & Limits/Regulations
- ♦ Ruggedness and Robustness / FDA vs.ICH

◆ Auditing your firm

- Spotting Deficiencies before PAI inspections
- ♦ Building in success for PAIs & File Reviews

♦ Regulatory Affairs

- ♦ ANDA & Global Generic Development
- ♦ Global Product Registration made simple
- ♦ ANDA Templates for any Documentation System
- ♦ All ANDAs made simple / EU interfacing

♦ Regulatory Do's and Don'ts

- ♦ Tips and traps to consider
- ♦ Annual Reports made simple

♦ Bulk Pharmaceutical Chemicals

- ♦ Actives for Generic Drugs
- ♦ Drug Master Files Actives
- ♦ How and What to Validate

♦ New Regulations

- ♦ Bioequivalent Food/Fasting Studies, BCS, Waivers
- ♦ How to handle *New OGD's Regulations*.
- ♦ OGD Regulations Made Simple
- ♦ Converting FDA speak into Plain English

♦ Current Checklists

- ♦ Generic Development Checklists
- ♦ Analytical checklists, Protocols, Validation
- ♦ Stability Indicating System checklists
- ♦ PAI Approvals All that's necessary
- ♦ Drug Development Checklist Solid Oral Dosages
- ♦ Drug Development Checklist Liquid & Suspensions

♦ SOPs of the Month

- ♦ New SOPs for generic firms
- ♦ Ten Major Decision Trees
- ♦ Current SOPs you should have
- ♦ SOPs for your firms security.

◆ Regulatory and Patents Info

- ♦ The Generic Drug Enforcement Act
- ♦ Seminar/Conference Summaries
- ♦ Drugs Off-Patents to the year 2016
- ♦ Drugs coming Off-Patent (annually).