

Volume 07 2002 **US & Canada Edition**

Features reviews and articles on Development for the Drug 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

International



International Journal of Generic Drugs

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

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T A B L E O F C O N T E N T S 2001-2002 Issues

(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
- \Diamond 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, Waivers
- ABE, 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).