



# The Regulatory Compliance Almanac: A Guide to Good Manufacturing, Clinical, and Laboratory Practices

*Les Schnoll*

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## **The Regulatory Compliance Almanac: A Guide to Good Manufacturing, Clinical, and Laboratory Practices** Les Schnoll

At last! A comprehensive guide to the myriad regulations governing good manufacturing, clinical, and laboratory practices from the FDA, EPA, and European Union. The second edition of The Regulatory Compliance Almanac contains updated, in-depth information on:

- \* Good Laboratory Practices
- \* Pharmaceutical Good Laboratory Practices
- \* Process Validation
- \* Documentation Requirements
- \* Complaint Investigation
- \* Good Manufacturing Practices
- \* Sanitation Compliance
- \* Medical Device Good Manufacturing Practices
- \* Medical Device Reporting
- \* The Medical Device Directive
- \* The Active Implantable Medical Device Directive
- \* The In-Vitro Diagnostic Device Directive
- \* The CE Mark
- \* Animal Welfare
- \* Good Clinical Practices
- \* Milestones in U.S. Food and Drug Law
- \* Complaint Investigation
- \* Consequences of Misconduct in FDA-Regulated Industries

Plus, the complete text of many acts, including:

- \* Federal Food and Drug Act of 1906
- \* GLP for Nonclinical Laboratory Studies
- \* Good Laboratory Practices Standards
- \* OECD Principles of Good Laboratory Practices
- \* Current Good Manufacturing Practices
- \* Animal Welfare Act
- \* Medical Device Directive--Annex I
- \* MEDWATCH Form FDA 3500A
- \* And many more!

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