

GMP MANUAL

Good Manufacturing Practice & Implementation



Maas & Peither
GMP PUBLISHING

Knowledge is Power.

With the GMP MANUAL, you have the information you need to make sure your GMP program in the best it can be.

www.gmp-manual.com

Best practices

Benchmarks

Industry perspectives

GMP
in Practice

Checklists

How-to-do



Examples

ICH

Japan

WHO

GMP
Regulations

PIC/S

US-FDA

EU

“ This is a great manual.

I wish we had access to this many years ago.

My favorite chapters were documentation, research and development (great information about **GLP vs. GMP vs. GCP**), risk management.

I could replace over 10 training books that I have in my office with just this one document.”

Customer

GMP in Practice

General Chapters

Technology Chapters

Validation Chapters

Manufacturing Chapters

Special Chapters

GMP Regulations

Valuable reasons to buy the GMP MANUAL

- 1 Benchmark your procedures**

It's important to know how other experts solved the quality challenge in their company. With that knowledge you can improve and fine-tune your procedures and processes.
- 2 Regulations and interpretations in one convenient source**

You need complete GMP information in one easy location. Are you wasting time looking at several websites to gather the information you need? We do that for you and cover regulations and the interpretations all at one source, with one search engine to save you time & money.
- 3 The only current GMP knowledge source**

As you know, only the most current information is good information. We update the GMP MANUAL on a regular basis. Our knowledge source remains up-to-date.
- 4 More than 10,000 satisfied professionals around the globe**

We realize that you are looking for a knowledge source that is accepted by the industry and regulators. The GMP MANUAL is used in more than 65 countries around the globe. More than 10,000 users must be right. They all save time & money by using the GMP MANUAL knowledge source.
- 5 Training Material**

If you have to prepare presentations and training programs, do you need training/reference material for new employees? The GMP MANUAL's 21 chapters cover nearly every topic in the area of GMP. Clear description – easy to understand – a must have for your business.
- 6 Global perspective of GMP**

You get information from the most important GMP regions: Europe, USA, Japan. We deliver information about globally implemented GMP procedures that will fulfil all requirements. Be sure to follow the best practices outlined in the GMP MANUAL.
- 7 It's easy to find the appropriate information when needed**

You will find it an easy and efficient way to retrieve the appropriate information needed. We implemented a powerful search engine, a comprehensive index and one table of contents. Don't spend time searching – find what you need quickly!

and there are more ...

GMP in Practice

General Chapters

Quality Management
Personnel
Risk Management
Quality Control
Documentation
Inspections

Technology Chapters

Facilities
Equipment
Premises
Pharmaceutical Water

Validation Chapters

Qualification
Process Validation
Cleaning Validation
Computer Validation

Manufacturing Chapters

Production
Sterile Manufacturing
Packaging

Special Chapters

R & D
Contracting
Quality Tools
API

GMP Regulations

US-FDA

Europe

Japan

ICH

PIC/S

WHO

Supported by experts and Advisory Board members from Europe, United States of America and Japan.

Recommended by Parenteral Drug Association (PDA) and Regulatory Affairs Professionals Society (RAPS).

“...The *GMP MANUAL* occupies a spot in my bookcase and I often have the occasion to refer to it. If you are a professional in the field of *GMP* and regulatory compliance, you may find it should be in your bookcase too.”

Bob Dana

*Senior Vice President,
Regulatory Affairs and
PDA Training and Research
Institute*

GMP MANUAL ONLINE CORPORATE LICENSE



GMP MANUAL Online

With nothing more than an internet connection, you can access the ONLINE version of the GMP MANUAL. Using either a corporate or a named-user license, you always have access to the current GMP MANUAL information.

General information and functionalities:

- Easy and direct access via your Internet browser
- More content than the paper version
- Comfortable and full text search
- Copy and paste
- Set-up bookmarks
- Print
- Includes checklists, templates and examples of SOPs
- Automatically updated
- No shipping costs

GMP MANUAL CD-ROM

The CD-ROM version works with every computer and is perfect when you are in the field or traveling. It is small enough to come along wherever you go.

Other great features:

- Easy to use
- Full text search
- Copy and paste
- Set up bookmarks
- Print

GMP MANUAL Paper and CD-ROM

The paper version of the GMP MANUAL is a convenient way to read entire chapters or to view multiple sections at once. Our five loose-leaf binders are a must for every pharmaceutical company library.

The CD-ROM comes along with the paper version to complement your collection. It contains the same information as found in the binders and enables a comfortable text search.

Table of Contents

GMP in Practice:

Written by internationally renowned industry experts.

1. Quality Management
2. Personnel
3. Premises
4. Facilities and Equipment
5. Pharmaceutical Water
6. Qualification
7. Process Validation
8. Cleaning Validation
9. Computer Validation
10. Risk Management
11. Production
12. Sterile Manufacturing
13. Packaging
14. Laboratory and Analytical Controls
15. Documentation
16. Research and Development
17. Contract Manufacturing and Analysis
18. Inspections
19. Quality Unit
20. Quality Tools
21. Active Pharmaceutical Ingredients

GMP Regulations:

Continuously updated

- A. Index
- B. Japan
- C. EU
- D. USA
- E. ICH
- F. PIC/S
- G. WHO
- H. Other Organizations

Important GMP Links

Europe

EU-GMP-Guidelines

<http://ec.europa.eu/enterprise/pharmaceuticals/eud>

European Commission Enterprise DG Pharmaceuticals

<http://ec.europa.eu/enterprise/pharmaceuticals/ind>

EMA NEWS

www.emea.europa.eu/whatsnewp.htm

USA

U.S. Food and Drug Administration (FDA) Home

www.fda.gov

21 CFR

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

FDA: Drug Newsletter, RSS, Podcasts

www.fda.gov/Drugs/ucm136245.htm

FDA Guidelines (CDER)

www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/default.htm

FDA: Warning letters

www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

FDA: Guides to Inspections

www.fda.gov/ICECI/Inspections/InspectionGuides/default.htm

Others

ICH

www.ich.org

PIC/S

www.picscheme.org

WHO

<http://www.who.int/medicines/publications/en/>

Associations

PDA – Parenteral Drug Association

www.pda.org

RAPS – Regulatory Affairs Professionals Society

www.raps.org

ISPE – International Society of Pharmaceutical Engineers

www.ispe.org

DIA – Drug Information Association

www.diahome.org

More Links: www.gmp-publishing.com



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