SHAPA

SHAPA TECHNICAL PAPER 9

Introduction
To
Good Manufacturing Practice (GMP)

Introduction to Good Manufacturing Practice

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1) Objective.

The object of this paper is to provide a brief introduction to the topic of GMP and more importantly give references where the subject and it's many related disciplines can be researched more thoroughly.

2) Overview

GMP - Good Manufacturing Practice, originated in the USA to assist in meeting the quality and hygiene requirements of the Pharmaceutical Industry and is still today very much based upon the needs of that industry.

The phrase has however spread to many non-pharmaceutical situations and become an all-embracing term to convey a conceptual requirement, often with no specific guidelines or references with which to define what GMP means.

Within the pharmaceutical context GMP, is applicable to all aspects of the manufacturing process including buildings, facilities, water treatment, process equipment, and the manufacture of the drug itself, in fact by far the main emphasis is on GMP as applied to the drug manufacturing process.

Unfortunately no single reference source or document completely defines GMP even when looking at sub sectors such as process equipment or facilities design, therefore reference has to be made to many different sources.

This situation is further complicated by the fact that the Pharmaceutical Industry is heavily regulated by many bodies in various countries or regions of the World and each tends to have their own variation on the theme.

By far the most well known and arguably most important body is the United States FDA (Food & Drug Administration) closely followed by the equivalent European Union and Japanese authorities; these together with countries such as Australia and Canada form the front rank of the regulatory authorities.

Outside the USA and EU etc, many other countries either adopt the regulations of say the FDA, or produce their own, less exacting standard, which meets their local requirements, but does not allow them to export to Europe or the USA.

However some co-operation and standardization of approach between the major parties such as the FDA and European Council is underway and overall the situation with regard to having recognized and widely accepted guidelines is improving.

An organization, which has played a large part in facilitating this process, is the International Society for Pharmaceutical Engineering (ISPE) which although formed in the USA is now a world wide organization that acts to promote awareness of such issues and acts as a forum where industry and regulators can exchange views.

For members of the ISPE there is access to a large body of information relating to the subject of Pharmaceutical Engineering including GMP, they produce many publications on a wide variety of issues and have a very useful web site with information such as Glossaries of Industrial terms and Acronyms etc.

Of particular note are the "Baseline Guides" series produced as a partnership between the FDA, ISPE and a broad spectrum of the pharmaceutical industry.

> The aim of these guides is to provide engineers and other professionals, within the pharmaceutical industry, with baseline information on the design, construction and commissioning of new and renovated facilities, equipment and systems to achieve regulatory compliance.
>
> So far there are nine Baseline guides either published, or in development, these are listed in the references section, it should be noted that these guides are not regulatory documents in themselves, but do have a widely recognized status within the industry.

From an equipment supplier's viewpoint another interesting development is the proposal to use the United States Department of Agriculture (USDA) acceptance criteria as a basis for general design compliance, although this is still in the discussion stage.

The great benefit of this is that the USDA do publish meaningful criteria against which one can measure a design and rate it's suitability, it should be noted that in it's self compliance with USDA will not necessarily be sufficient to meet "fit for purpose" requirements on all occasions.

For non-pharmaceutical users and suppliers who still have a requirement for hygiene there are several relevant organizations that provide guidance and codes of practice etc, particularly for the food and dairy industries.

In the USA there are bodies such as 3A's, which covers Dairy, USDA for Meat, Poultry, general prepared foodstuffs, and of course the FDA. In the EU there are equivalent bodies such as the European Hygienic Engineering and Design Group.

3) Related GMP terms.

GAMP	Good Automated Manufacturing Practice
GCLP	Good Control Laboratory Practice
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GEP	Good Engineering practice
GILSP	Good Industrial Large Scale Practice
GLSP	Good Large Scale Practice
GMP	Good Manufacturing Practice

4) Relevant Organizations.

3-A SSI	3-A Sanitary Standards Inc
ECA	European Compliance Academy
EHEDC	European Hygienic Engineering and Design Group.
FDA	United States Food and Drug Administration
GMP Institute	Now a division of the ISPE.
MCA	UK Medicines Control Agency
I.S.P.E	International Society for Pharmaceutical Engineering
USDA	United States Department of Agriculture
ECA	European Compliance Academy

5) References and web sites.

i) Baseline Guides (available from ISPE)

Volume 1	Bulk Pharmaceutical Chemical Facilities	1996
Volume 2	Oral solid Dosage Forms	1998
Volume 3	Sterile Manufacturing Facilities	1999
Volume 4	Water and Steam Systems	2001
Volume 5	Commissioning and qualification	2001
Volume 6	Biopharmaceutical Manufacturing Facilities	Under Development
Volume 7	Packaging, Labelling and Warehousing Operations	Under Development
Volume 8	Maintenance	Under Development
Volume 9	Laboratories	Under Development

ii) Pharmaceutical Engineering Series (available from Arnold)

iii) www.ispe.org

iv) www.fda.gov

v) www.gmp-compliance.com

vi) www.usda.gov

vii) www.gmppublications.com

viii) www.ehedc.org

ix) www.gmp-navigator.com

x) www.3-a.org