ECZ 965

Farmasötik Ürünler İçin İyi İmalat Uygulamaları

2. HAFTA

Doç.Dr. Müge Kılıçarslan

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Child marriage divorces girls from opportunity

Joey O'Loughlin

11 October 2012—Today the world marks the first ever International Day of the Girl Child. The theme of the day is ending child marriage. The number one cause of death among girls aged 15-19 is death during pregnancy and childbirth. Early marriage also increases exposure to violence and abuse, and can increase the risk of HIV infection.

Read the fact sheet on adolescent pregnancy

Child marriage divorces girls from opportunity | Stopping the stigmatization of depression | More children immunized in Ethiopia | Kolkata India joins age-friendly cities network

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WHO reform
Addressing public health challenges in the 21st century

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Maternal and perinatal health

Family planning

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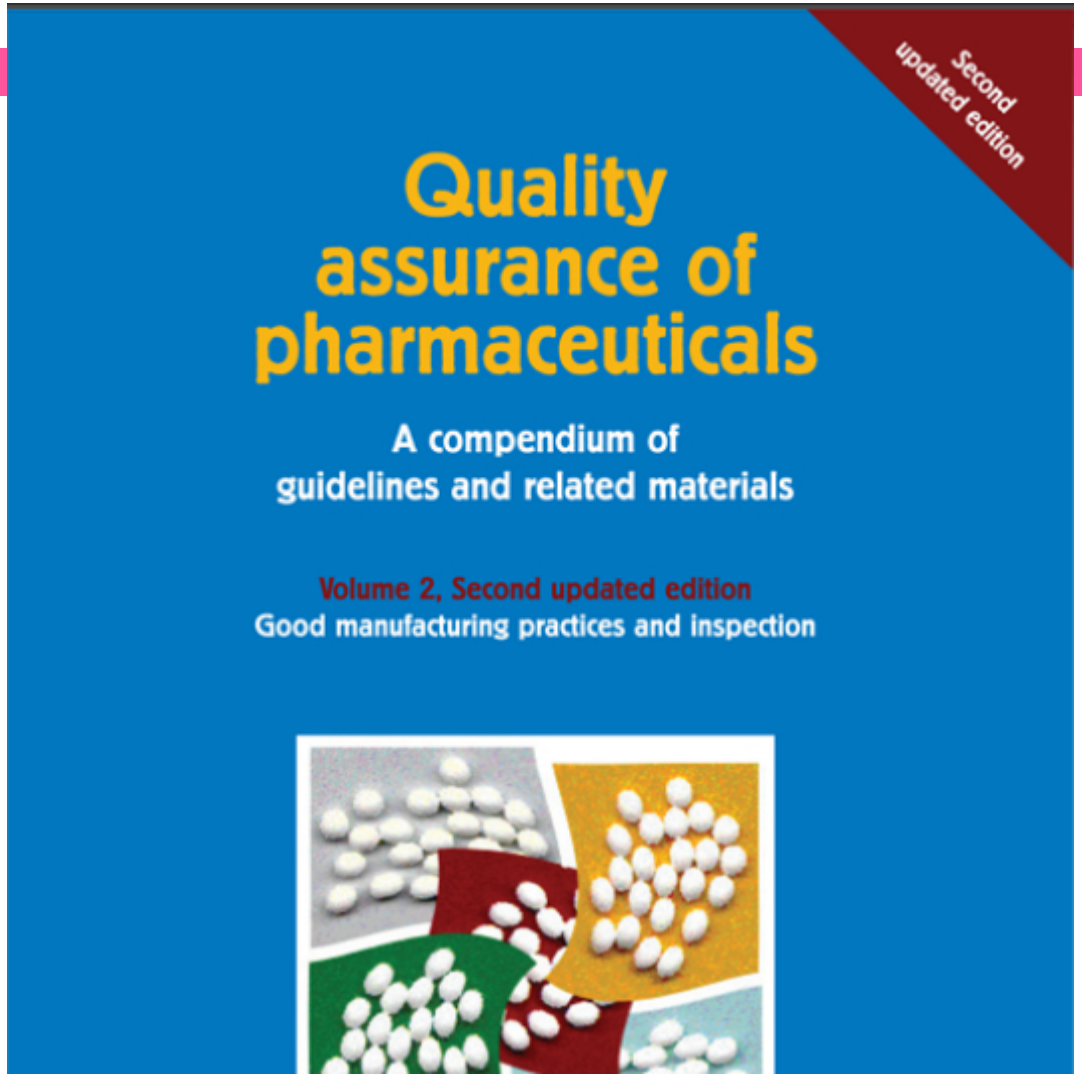
Second updated edition
Quality assurance of pharmaceuticals
A compendium of guidelines and related materials
Volume 2, Second updated edition
Good manufacturing practices and inspection

FDA


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Know Your Online Pharmacy
BeSafeRx Educates Public About Online Pharmacies
FDA is launching a national campaign to educate consumers about the dangers of buying medicines from fake pharmacies on the Internet.
1 2 3 4
For Consumers & Patients
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For Health Professionals
Medical product safety information, adverse event/problem reporting and more
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FDA

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C--DRUGS: GENERAL

PART 210 CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

§ 210.1 - Status of current good manufacturing practice regulations.

§ 210.2 - Applicability of current good manufacturing practice regulations.

§ 210.3 - Definitions.

FDA

ITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C--DRUGS: GENERAL

PART 211 CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

EMA


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10 October 2012
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World Federation for Mental Health
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European Medicines Agency on track to meet core business targets for 2012
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European Medicines Agency releases guideline on medicinal products for the treatment of schizophrenia
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World Mental Health Day: 10 October 2012
The European Medicines Agency is supporting World Mental Health Day
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Quality
Active Substance
Manufacturing
Impurities

Quality guidelines

This section includes the European Medicines Agency's guidelines on the **quality of medicines**.

The Agency's Committee for Medicinal Products for Human Use (CHMP) prepares **scientific guidelines** in consultation with regulatory authorities in the European Union (EU) Member States, to help applicants prepare marketing-authorisation applications for human medicines.

Guidelines provide a basis for practical harmonisation of how the EU Member States and the Agency **interpret** and **apply** detailed requirements for the demonstration of quality, safety and efficacy that are in the **Community directives**.

The Agency strongly encourages applicants and marketing-authorisation holders to follow these guidelines. Applicants n justify **deviations from guidelines** fully in their applications at the time of submission. The Agency advises applicants to any proposed deviations with EU regulators during medicine development through scientific advice.

Quality guidelines are provided for:

- Active substance
- Manufacturing

ICH


ICH
harmonisation for better health
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The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has evolved, through its ICH Global Cooperation Group, to respond to the increasingly global face of drug development, so that the benefits of international harmonisation for better global health can be realised worldwide. ICH's mission is to achieve greater harmonisation to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Download the ICH 20th Anniversary Publication
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Quality Guidelines
Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities... (more)
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by responding to one of our consultations. Your contribution will then be considered by the relevant ICH Working Group.
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Q&A Documents
Recent News
3 July 2012
Press release from the ICH Steering Committee meeting in Fukuoka, 6-7 June 2012
The six official ICH parties have

PIC ve PIC/s


PIC/S
Pharmaceutical Inspection Co-operation Scheme
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PIC/S | Role | Benefits | Members & Partners | Activities | Training | Publications | Accession | Links | News
Welcome to the PIC/S Website!
The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.
PIC/S' mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products."
This is to be achieved by developing and promoting harmonised GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates; and facilitating the co-operation and networking for competent authorities and international
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PIC/S

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SITE MASTER FILE FOR PLASMA WAREHOUSES	PI 020-3			Download
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PIC/S GMP GUIDE (PART I: BASIC REQUIREMENTS FOR MEDICINAL PRODUCTS)	PE 009-10 (Part I)			Download
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EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, 14 February 2008

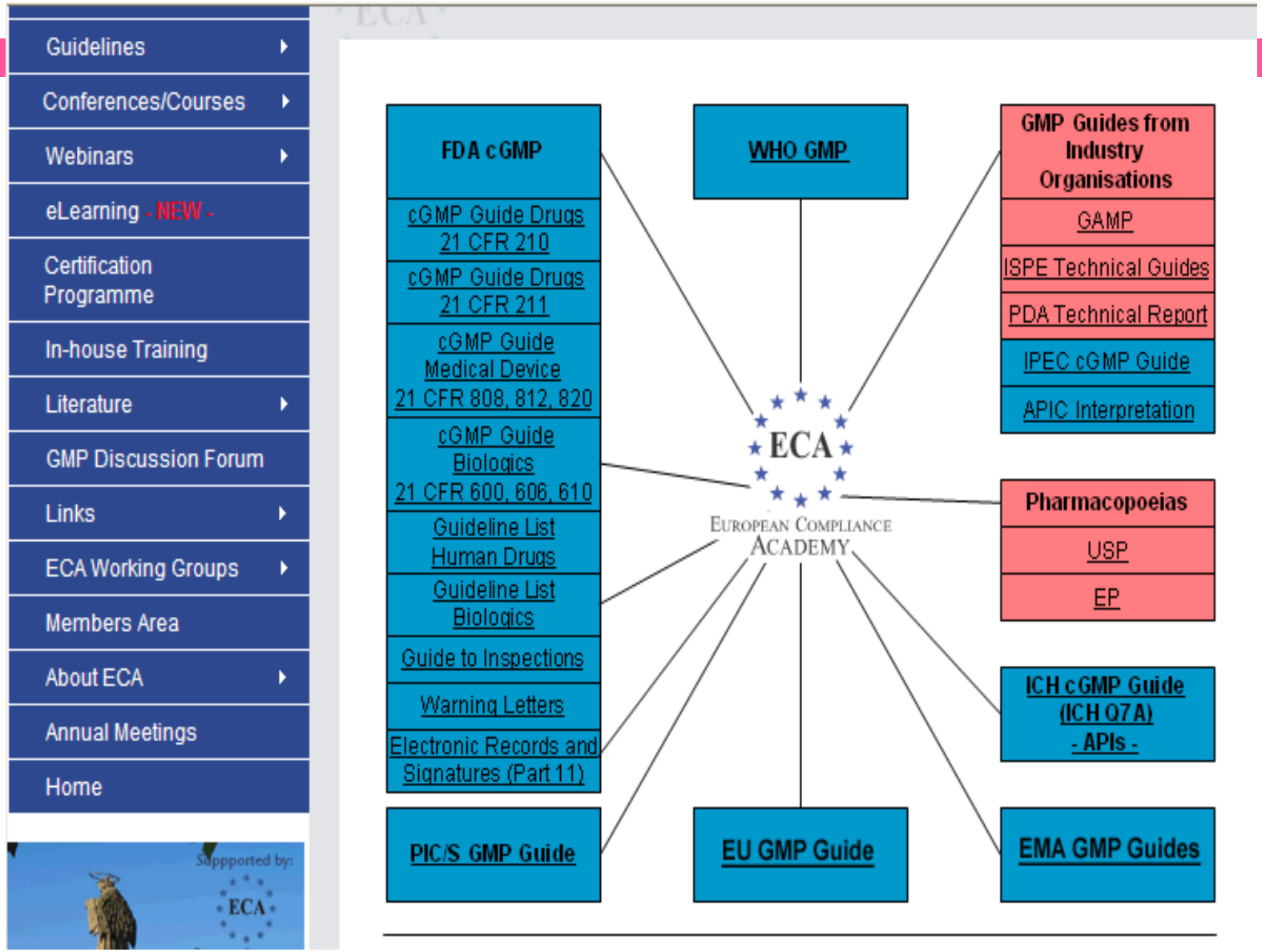
EudraLex
The Rules Governing Medicinal Products in the European Union

Volume 4
EU Guidelines to
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use

Part I
Chapter 1 Quality Management

Document History	
Revision to include concept of Product Quality Review	25 October 2005
Date of revised version coming into operation and superseding previous version dated 25 October 2005	01 July 2008

GMP Rehberleri



www.gmp-compliance.org/eca_link_navigator.html

Links - Link-Navigator

FDA cGMP
cGMP Guide Drugs 21 CFR 210
cGMP Guide Drugs 21 CFR 211
cGMP Guide Medical Device 21 CFR 808, 812, 820
cGMP Guide Biologics 21 CFR 600, 606, 610
Guideline List Human Drugs
Guideline List Biologics
Guide to Inspections
Warning Letters
Electronic Records and Signatures (Part 11)

WHO GMP

ECA
EUROPEAN COMPLIANCE ACADEMY

GMP Guides from Industry Organisations
GAMP
ISPE Technical Guides
PDA Technical Report
IPEC cGMP Guide
APIC Interpretation

Pharmacopoeias
USP
EP

ICH cGMP Guide (ICH Q7) APIs

FDA cGMP

- cGMP Guide Drugs 21 CFR 210
- cGMP Guide Drugs 21 CFR 211
- cGMP Guide Medical Device 21 CFR 808, 812, 820
- cGMP Guide Biologics 21 CFR 600, 606, 610
- Guideline List Human Drugs
- Guideline List Biologics
- Guide to Inspections
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PIC/S GMP Guide

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- ISPE Technical Guides
- PDA Technical Report
- IPEC cGMP Guide
- APIC Interpretation

Pharmacopoeias

- USP
- EP

ICH cGMP Guide (ICH Q7) APIs

EMA GMP Guides

EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines

Part I - Basic Requirements for Medicinal Products

- Chapter 1 Pharmaceutical Quality System (65 KB)into (into operation since 31 January 2013)
- Chapter 2 Personnel
  - Current (20 KB)
  - Deadline for coming into operation: 16 February 2014 (56 KB)*NEW*
- Chapter 3 Premise and Equipment (34 KB)
  - A revised version of Chapter 3 is in preparation. The public consultation on the proposed draft (53 KB)is currently closed.
- Chapter 4 Documentation (January 2011) (33 KB)
- Chapter 5 Production (50 KB)
  - A revised version of Chapter 5 is in preparation. The public consultation on the proposed draft (84 KB)is currently closed.
- Chapter 6 Quality Control (33 KB)
  - A revised version of Chapter 6 is in preparation. The public consultation on the proposed draft (62 KB)is currently closed.
- Chapter 7 on Outsourced activities (21 KB) (into operation since 31 January 2013)
  Chapter 7 Contract Manufacture and Analysis (22 KB)
- Chapter 8 Complaints and Product Recall (18 KB)
  - A revised version of Chapter 8 is in preparation. The public consultation on the proposed draft (79 KB)is currently closed
- Chapter 9 Self Inspection (11 KB)

Annexes

Table Eudralex	
Annex 1	Manufacture of Sterile Medicinal Products (122 KB)
Annex 2	Manufacture of Biological active substances and Medicinal Products for Human Use (171 KB) ((into operation since 31 January 2013)
Annex 3	Manufacture of Radiopharmaceuticals (68 KB)
Annex 4	Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products (14 KB)
Annex 5	Manufacture of Immunological Veterinary Medicinal Products (43 KB)
Annex 6	Manufacture of Medicinal Gases (48 KB)
Annex 7	Manufacture of Herbal Medicinal Products (23 KB)
Annex 8	Sampling of Starting and Packaging Materials (20 KB)

Annex 9	Manufacture of Liquids, Creams and Ointments (13 KB)
Annex 10	Manufacture of Pressurised Metered Dose Aerosol Preparations for Inhalation (17 KB)
Annex 11	Computerised Systems (revision January 2011) (22 KB)
Annex 12	Use of Ionising Radiation in the Manufacture of Medicinal Products (50 KB)
Annex 13	Manufacture of Investigational Medicinal Products (67 KB)
Annex 14	Manufacture of Products derived from Human Blood or Human Plasma (50 KB) - May 2011
Annex 15	Qualification and validation (136 KB)

Annex 16	Certification by a Qualified person and Batch Release (41 KB) A revised version of Annex 16 is in preparation. Stakeholders are invited to comment on this draft (150 KB) by 5 November 2013 at the latest. Comments should be sent by email to: ADM-GMDP@ema.europa.eu and SANCO-pharmaceuticals-D6@ec.europa.eu
Annex 17	Parametric Release (124 KB)
Annex 19	Reference and Retention Samples (24 KB)

Glossary

- Glossary (27 KB)

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Part II - Basic Requirements for Active Substances used as Starting Materials

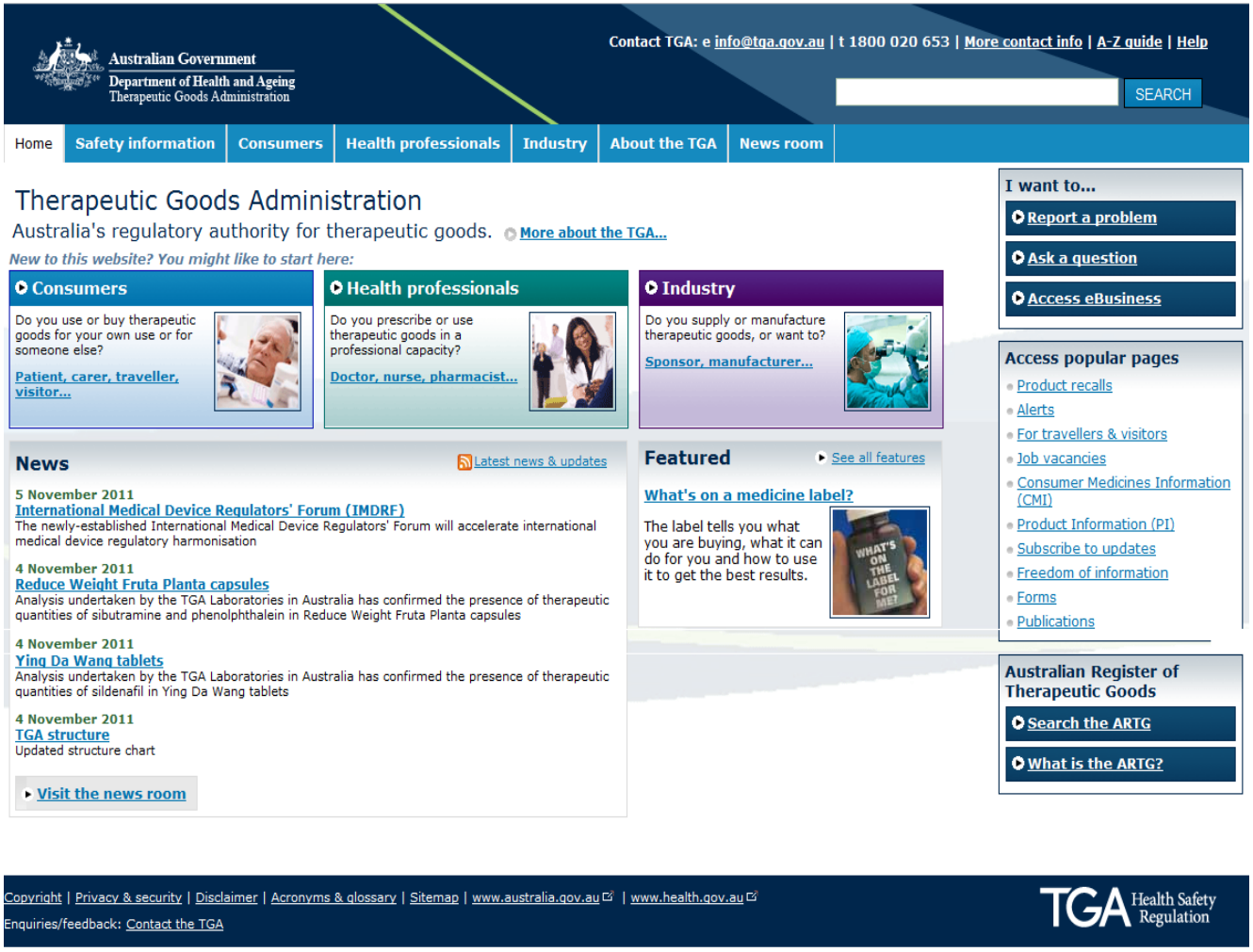
- Basic requirements for active substances used as starting materials (452 KB)

_Part III - GMP related documents

- Site Master File (33 KB)
- Q9 Quality Risk Management
- Q10 Note for Guidance on Pharmaceutical Quality System
- MRA Batch Certificate (101 KB)
- Template for the 'written confirmation' for active substances exported to the European Union for medicinal products for human use (487 KB)(Version 2, January 2013)

Avustralya

- Therapeutic Goods Administration (Terapötik Ürünler Dairesi) Avustralya'daki terapötik ürünlerden sorumlu otoritedir.
- 1989 yılında "Therapeutic Goods Act" yasası ile kurulmuştur.



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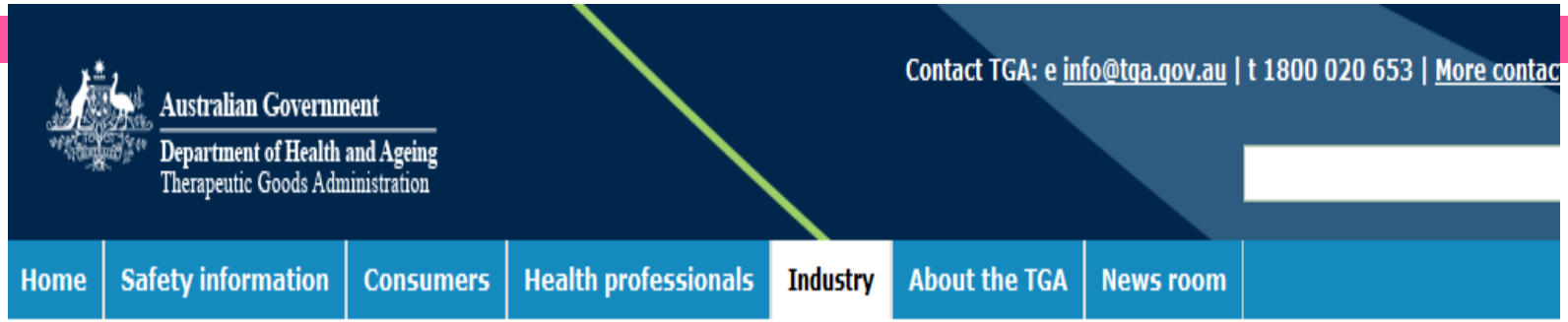

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PIC/S guide for good manufacturing practice for medicinal products

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2009 adopts the *PIC/S Guide to Good Man*
for Medicinal Products, PE 009-8, published by the Pharmaceutical Inspection Convention and Pharmaceutical Insp
Scheme (jointly referred to as PIC/S), dated 15 January 2009. The Guide is reproduced in its entirety with the per

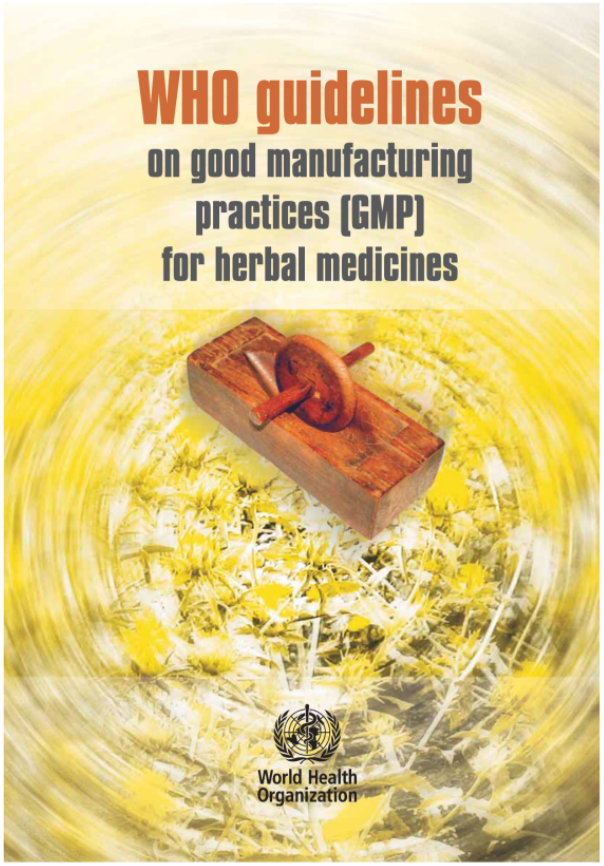
The PIC/S provide an active and constructive co-operation in the field of GMP (Good Manufacturing Practice). Th
to facilitate the networking between participating authorities and the maintenance of mutual confidence, the excl
and experience in the field of GMP and related areas, and the mutual training of GMP inspectors. Australia is a mer

- Guide to Good Manufacturing Practice for Medicinal Products - Introduction
- Guide to Good Manufacturing Practice for Medicinal Products - Part I
- Guide to Good Manufacturing Practice for Medicinal Products - Part II
- Guide to Good Manufacturing Practice for Medicinal Products - Annexes

Avustralya

- Şu an Avustralya'da geçerli olan GMP rehberi PIC/S tarafından yayımlanan "Guide to Good Manufacturing Practices for Medicinal Products, PE 009-8, 15 January 2009" dur. Bu rehberin 01.07.2010 tarihinden beri yasal yaptırımı vardır.
- Kabul edilen bu rehber "Australian Code of Good Manufacturing Practice for Medicinal Products (2002)" ve "Australian Code of Good Manufacturing Practice for Sunscreen Products (1994)" yasaları yerine geçmiştir.

Herbal Drug


WHO guidelines
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practices (GMP)
for herbal medicines
World Health
Organization

Medical Devices

7 Haziran 2011 SALI Resmî Gazete Sayı : 27957

YÖNETMELİK

Sağlık Bakanlığından:

TIBBİ CİHAZ YÖNETMELİĞİ

BİRİNCİ BÖLÜM

Amaç, Kapsam, Dayanak ve Tanımlar

Amaç ve kapsam

MADDE 1 –(1) Bu Yönetmeliğin amacı; tıbbi cihaz ve aksesuarlarının taşıması gereken temel gerekleri belirlemek ve bu cihazlar ile aksesuarlarının kullanımı sırasında hastaların, uygulayıcıların, kullanıcıların ve üçüncü şahısların sağlık ve güvenliği açısından ortaya çıkabilecek tehlikelere karşı korunmalarını sağlamak amacıyla tasarımına, sınıflandırılmasına, üretimine, piyasaya arzına, hizmete sunulmasına ve denetlenmesine ilişkin usul ve esasları düzenlemektir.

(2) Bu Yönetmelik; kamu kurum ve kuruluşları ile gerçek ve tüzel kişilerin, tıbbi cihaz ve aksesuarlarının tasarımı, imalatı, piyasaya arzı, hizmete sunulması, kullanımı ve denetimi ile ilgili bütün faaliyetlerini kapsar.

(3) Bir cihaz 19/1/2005 tarihli ve 25705 sayılı Resmî Gazete'de yayımlanan Beşeri Tıbbi Ürünler Ruhsatlandırma Yönetmeliği kapsamına giren bir tıbbi ürünün uygulanması amacıyla üretilmiş ise, anılan cihaz bu Yönetmelik kapsamında değerlendirilir. Bu durum, tıbbi ürüne Beşeri Tıbbi Ürünler Ruhsatlandırma Yönetmeliği hükümlerinin uygulanmasını engellemez.

(4) Bir cihaz, tıbbi ürün ile kombine halde tek bir ürün olarak piyasaya sürülüyorsa ve tek kullanımlık ise, bu tek ürün Beşeri Tıbbi Ürünler Ruhsatlandırma Yönetmeliği hükümlerine tabidir. Bu durumda, tıbbi cihazın güvenlik

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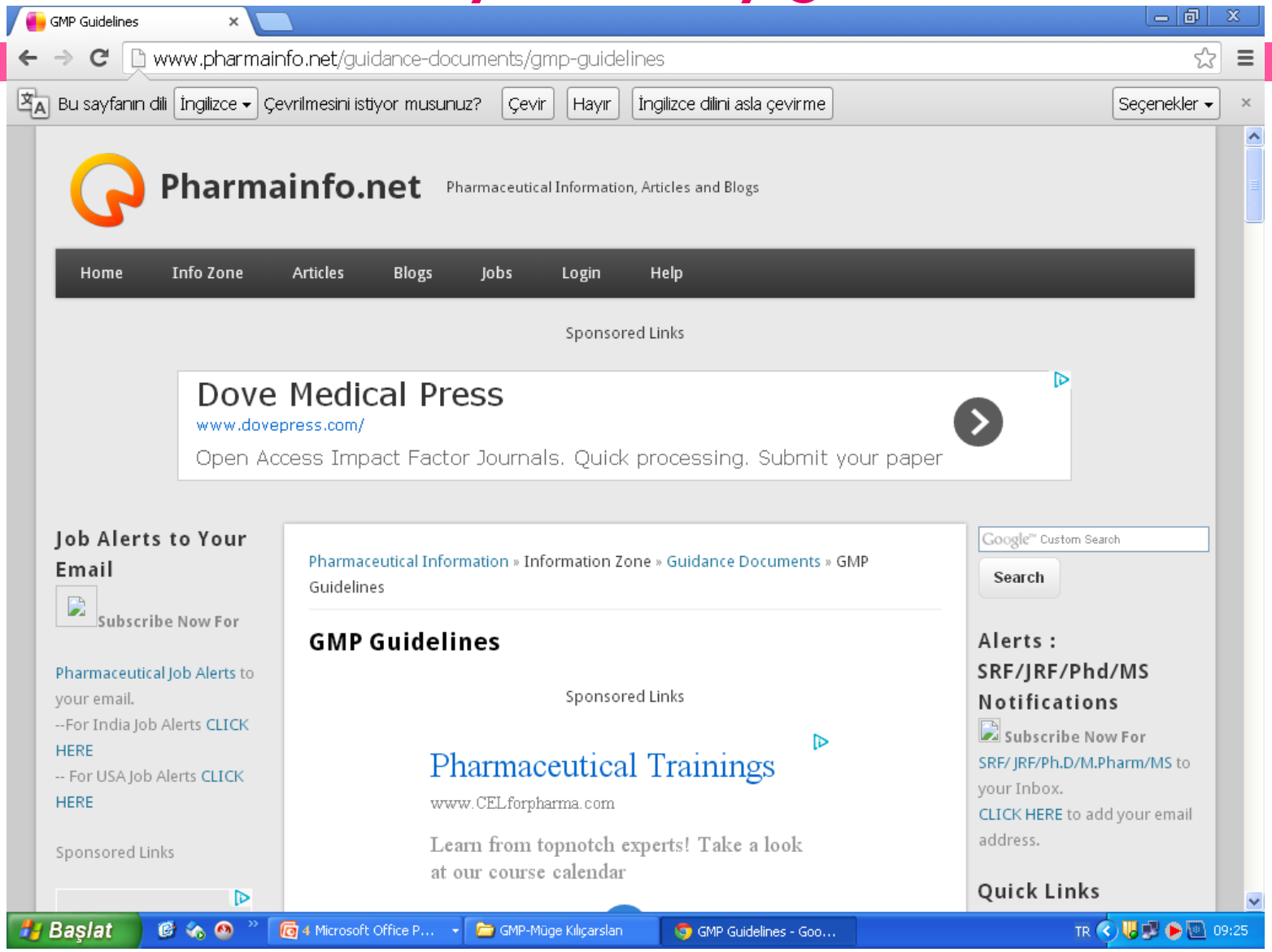

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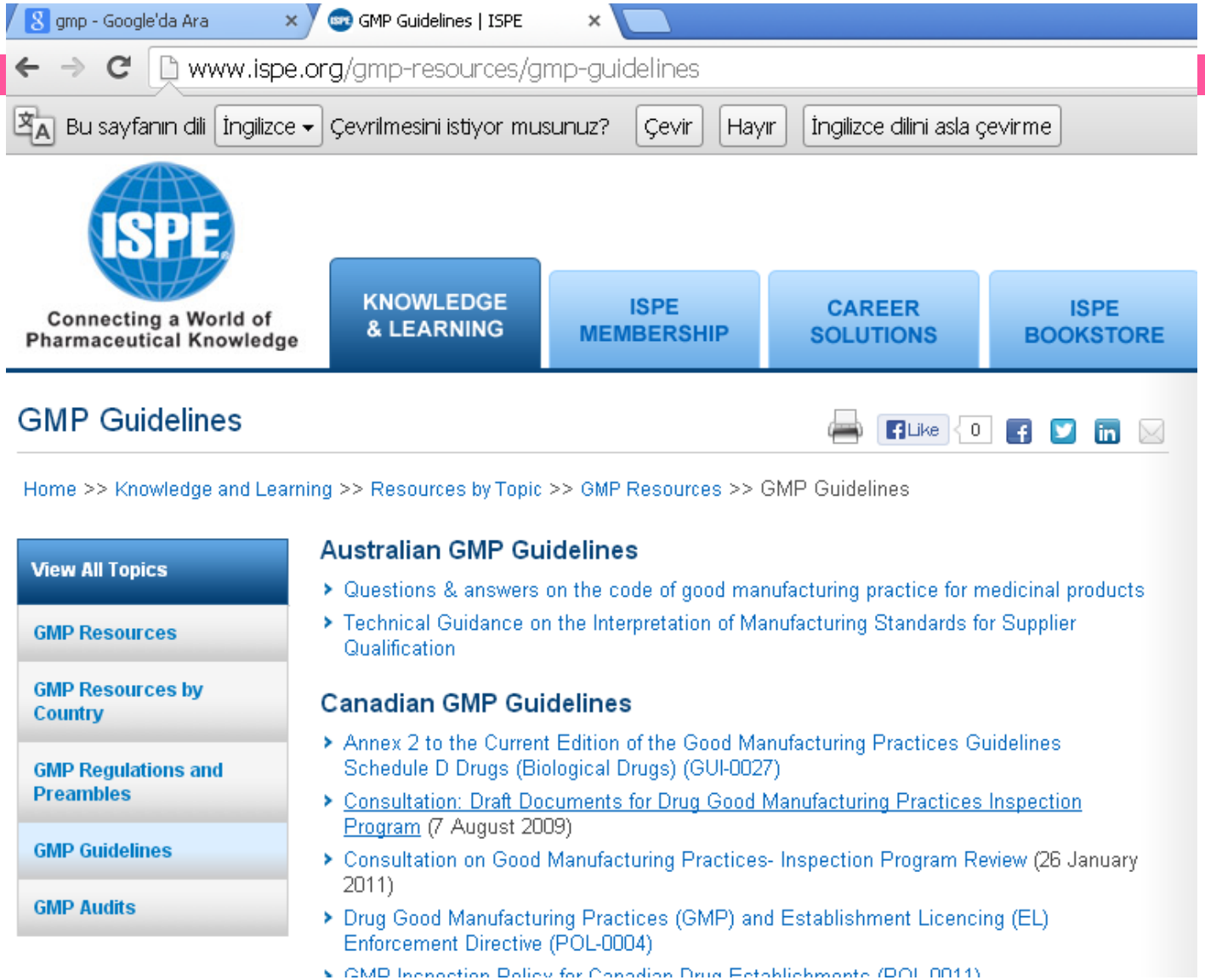
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Technical Guidance on the Interpretation of Manufacturing Standards for Supplier Qualification
Canadian GMP Guidelines
Annex 2 to the Current Edition of the Good Manufacturing Practices Guidelines Schedule D Drugs (Biological Drugs) (GUI-0027)
Consultation: Draft Documents for Drug Good Manufacturing Practices Inspection Program (7 August 2009)
Consultation on Good Manufacturing Practices- Inspection Program Review (26 January 2011)
Drug Good Manufacturing Practices (GMP) and Establishment Licencing (EL) Enforcement Directive (POL-0004)

FARMASÖTİK ÜRÜNLERİN İYİ İMALAT UYGULAMALARINA İLİŞKİN KILAVUZ

T.C.
SAGLIK BAKANLIĞI
İlaç ve Eczacılık Genel Müdürlüğü

Sayı: 15O5ANKARA
Konu:3.03. 1994

BAKANLIK MAKAMINA

Farmasötik müstahzar üreticilerinin, ürettikleri ürünün istenen etki, emniyet ve kalitede olmasını garanti etmelerini öngören hükümleri kapsayan 'İspençiyari ve Tıbbi Müstahzar İmalathaneleri Yönetmeliği", yayımlandığı 1 Kasım 1984 tarihinden itibaren gerek Bakanlığımız ve gerekse üreticiler tarafından ciddi şekilde uygulanmaya devam etmektedir. Üretimde uyulması gereken kurallar, o günün şartları ve Dünya Sağlık Örgütü'nün tavsiyeleri dikkate alınarak, bu Yönetmelikte kısa, öz ancak kesin bir ifade ile yer almıştır. GMP olarak tanımlanan bu kuralları yasal bir yükümlülük olarak uygulamaya koyan ilk ülkeler arasında yer alan Türkiye, geçen zaman içinde teknolojik gelişmeler ve yenilikler ile farmasötik müstahzarlarda görülen çeşitliliği de dikkate alarak, yürürlükte olan Yönetmeliğin uygulayıcılar