



ECZ 965

Farmasötik Ürünler İçin İyi İmalat Uygulamaları

1

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](#)

-  **Disease outbreak news**
Information about disease outbreaks
-  **Emergencies and disasters**
Humanitarian health action
-  **Director-General**
Director-General and senior management
-  **Governance**
Constitution, Executive Board and World Health Assembly
-  **WHO guidelines**
A selection of evidence-based guidelines
-  **WHO reform**
Addressing public health challenges in the 21st century

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

Sexual and reproductive health

Maternal and perinatal health | Family planning | Sexually transmitted infections

Quality assurance of pharmaceuticals

A compendium of guidelines and related materials

Volume 2, Second updated edition
Good manufacturing practices and inspection

Second updated edition



The image shows a screenshot of the FDA website homepage. At the top left, it says "U.S. Department of Health & Human Services". The main header features the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". On the right, there are links for "A to Z Index", "Follow FDA", and "FDA Voice Blog", along with a search bar and a "SEARCH" button. Below the search bar, it says "Most Popular Searches". A horizontal navigation menu includes links for "Home", "Food", "Drugs", "Medical Devices", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", "Radiation-Emitting Products", and "Tobacco Products".

The main content area features a large banner for the "BeSafeRx" campaign. The banner shows three pill bottles on a laptop. The text on the banner reads: "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." Below the text are four numbered navigation buttons (1, 2, 3, 4), with button 4 being highlighted.

To the right of the banner is a vertical list of four categories, each with an icon and a description:

- For Consumers & Patients**: Updates and information for staying safe and healthy.
- For Health Professionals**: Medical product safety information, adverse event/problem reporting and more.
- For Scientists & Researchers**: NCTR, pediatrics, clinical trials, critical path initiative and more.
- For Industry**: Guidance, registration and listing, import programs and more.

At the bottom of the page, there are three buttons: "Recalls & Alerts", "Approvals & Clearances", and "Report a Problem". On the far right, there is a section titled "FDA Initiatives".

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.

ITL 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

Subpart A--General Provisions

- § 211.1 - Scope.
- § 211.3 - Definitions.

Subpart B--Organization and Personnel

- § 211.22 - Responsibilities of quality control unit.
- § 211.25 - Personnel qualifications.
- § 211.28 - Personnel responsibilities.
- § 211.34 - Consultants.

Subpart C--Buildings and Facilities

- § 211.42 - Design and construction features.
- § 211.44 - Lighting.
- § 211.46 - Ventilation, air filtration, air heating and cooling.
- § 211.48 - Plumbing.
- § 211.50 - Sewage and refuse.
- § 211.52 - Washing and toilet facilities.
- § 211.56 - Sanitation.
- § 211.58 - Maintenance.



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SCIENCE MEDICINES HEALTH

An agency of the European Union



Text size: [A](#) [A](#) [A](#)

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Search for medicines

Search our database of medicines - including human medicines, veterinary medicines and herbal medicines.

Quick search



Or go to the [medicines](#) section for more options to help you find what you need.

World Mental Health Day

10 October 2012

Find out more about the Agency's activities in this field...



World Federation for Mental Health

Find information for...

▶ Patients and carers



▶ Healthcare professionals



▶ Animal health professionals



▶ Business



▶ Media professionals



Product emergency
HOTLINE
(Outside working hours)



Latest news

⚠ Patient safety

⚠ Veterinary alerts

New medicines

Public consultations

10/10/2012

European Medicines Agency on track to meet core business targets for 2012

The European Medicines Agency's Management Board discussed the Agency's annual mid-year report for 2012 at its meeting on 4 October. ... ▶ Read more

09/10/2012

European Medicines Agency releases guideline on medicinal products for the treatment of schizophrenia

The European Medicines Agency has updated its guidance for pharmaceutical companies developing medicinal products for the treatment of schizophrenia. ... ▶ Read more

09/10/2012



World Mental Health Day: 10 October 2012

The European Medicines Agency is supporting World Mental Health Day

What's New
on the website




[Human medicines](#)
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Quality guidelines

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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 must justify **deviations from guidelines** fully in their applications at the time of submission. The Agency advises applicants to discuss any proposed deviations with EU regulators during medicine development through [scientific advice](#).

Quality guidelines are provided for:

▶ [Active substance](#)

▶ [Manufacturing](#)

The screenshot shows the ICH official website homepage. At the top left is the ICH logo with the tagline "ICH harmonisation for better health". To the right are links for "Contact", "Glossary", "FAQs", and "Log In". Below the logo is a navigation bar with buttons for "About ICH", "Work Products", "Meetings", "Training", "Newsroom", and social media icons. A search bar labeled "Search Our Site" is on the right. The main content area features a "Welcome to the ICH official website" section with a paragraph about ICH's mission and a link to the "ICH 20th Anniversary Publication". Below this is a "Discover ICH Products" section with a large "Q" graphic and a "Quality Guidelines" sub-section, including a "View All Quality Guidelines" button. On the right side, there are two sidebars: "Help to Shape the ICH Guidelines" with a link to "Draft Guidelines Q&A Documents" and a 3D character illustration, and "Recent News" with a link to a "Press release from the ICH Steering Committee meeting in Fukuoka, 6-7 June 2012".

Contact Glossary FAQs Log In

Q S E M

Home About ICH Work Products Meetings Training Newsroom RSS +

Search Our Site

Welcome to the ICH official website

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](#)

Discover ICH Products

Quality Guidelines

Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities... [\(more\)](#)

[View All Quality Guidelines](#)

Help to Shape the ICH Guidelines

by responding to one of our consultations. Your contribution will then be considered by the relevant ICH Working Group.

[Draft Guidelines 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



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The screenshot shows the homepage of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). At the top, there is a navigation bar with the following items: PIC/S, Role, Benefits, Members & Partners, Activities, Training, Publications, Accession, Links, and News. The main content area is divided into several sections:

- 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 organisations.
- Members area**

Username

Enter

This area is reserved to PIC/S Members only

Last update 30 September 2012.
- Training**

Expert Circle on Blood & Tissue [Read more](#)
< Expert Circle on Computerised Systems [Read more](#)
- All the Publications**

Most PIC/S publications can be downloaded for free

 - Q&A Documents
 - PIC/S GMP Guide
 - Site Master Files
 - Inspectorates
 - Aide-Memoires
 - Guidance documents
- News**

Registrations open
2012 PIC/S SEMINAR, UKRAINE (3-5 OCTOBER)
>Read more

PIC/S EVENTS IN GENEVA, SWITZERLAND, 7-11 MAY 2012
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KOREA APPLIES FOR PIC/S MEMBERSHIP
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Pharmaceutical Inspection Co-operation Scheme

Last update 20 September 201

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[Home](#) > [Publication](#) > [PIC/S GMP Guide](#)

PIC/S

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Document	Reference	Category	Section	
SITE MASTER FILE FOR PLASMA WAREHOUSES	PI 020-3			Download
PIC/S GMP GUIDE (INTRODUCTION)	PE 009-10 (Intro)			Download
PIC/S GMP GUIDE (PART I: BASIC REQUIREMENTS FOR MEDICINAL PRODUCTS)	PE 009-10 (Part I)			Download
PIC/S GMP GUIDE (PART II: BASIC REQUIREMENTS FOR ACTIVE PHARMACEUTICAL INGREDIENTS)	PE 009-10 (Part II)			Download
PIC/S GMP GUIDE (ANNEXES)	PE 009-10 (Annexes)			Download

Eudralex

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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

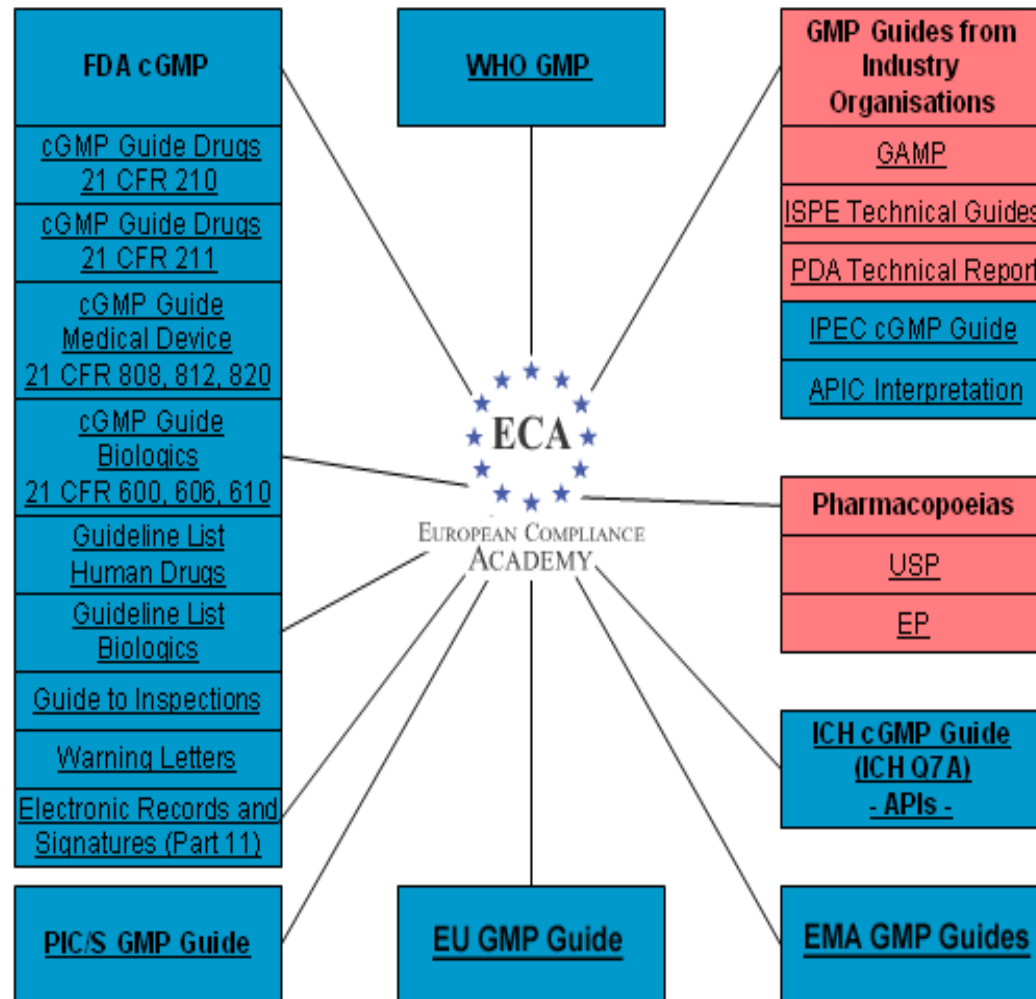
Part I
Chapter 1 Quality Management

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

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- Guidelines ▶
- Conferences/Courses ▶
- Webinars ▶
- eLearning - NEW -
- Certification Programme
- In-house Training
- Literature ▶
- GMP Discussion Forum
- Links ▶
- ECA Working Groups ▶
- Members Area
- About ECA ▶
- Annual Meetings
- Home



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)

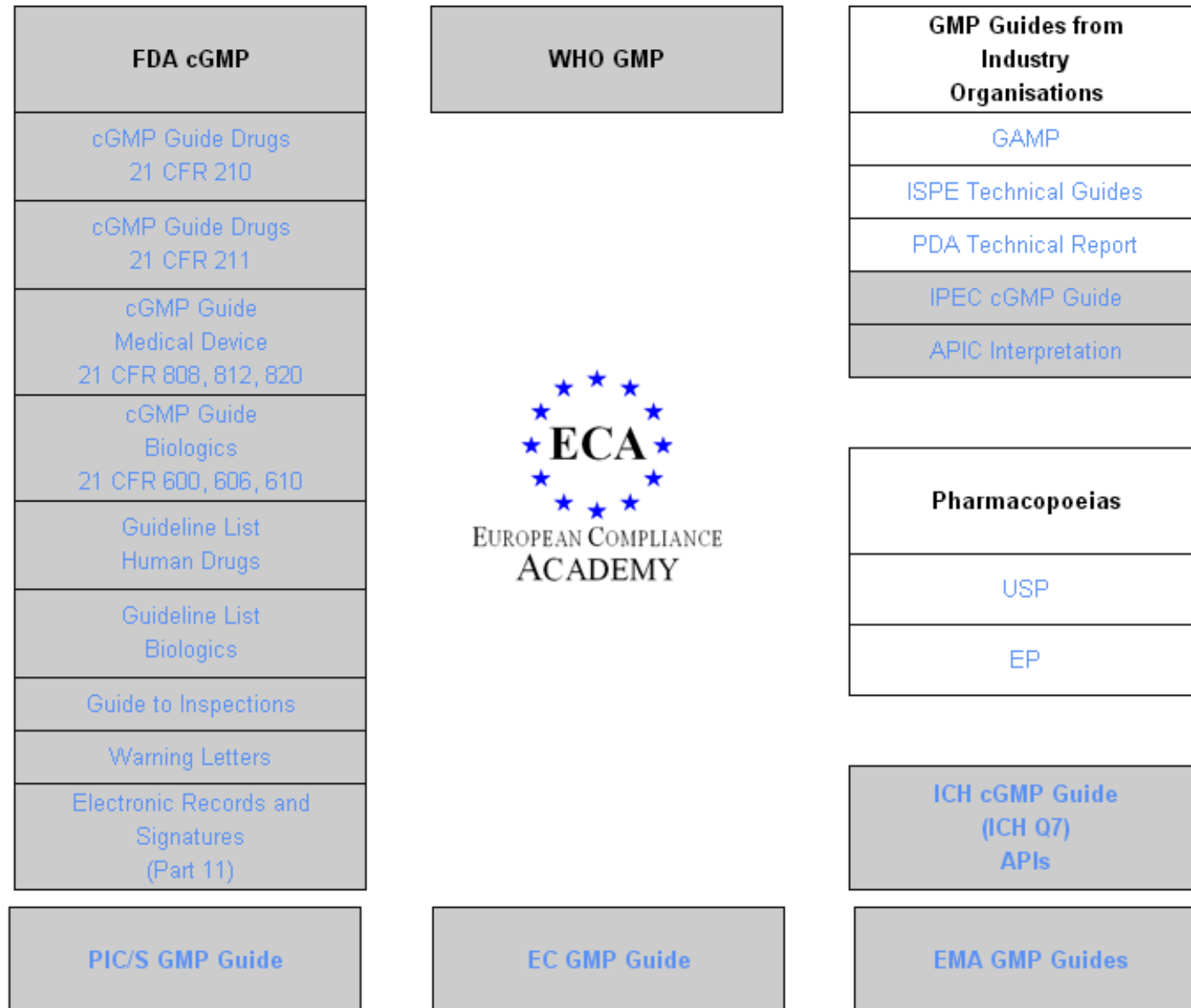
WHO GMP



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
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EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines

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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)






EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines.

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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

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

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Contact TGA: e info@tga.gov.au | t 1800 020 653 | [More contact info](#) | [A-Z guide](#) | [Help](#)

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Therapeutic Goods Administration

Australia's regulatory authority for therapeutic goods. [More about the TGA...](#)

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Industry

Do you supply or manufacture therapeutic goods, or want to?



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5 November 2011
[International Medical Device Regulators' Forum \(IMDRF\)](#)
The newly-established International Medical Device Regulators' Forum will accelerate international medical device regulatory harmonisation

4 November 2011
[Reduce Weight Fruta Planta capsules](#)
Analysis undertaken by the TGA Laboratories in Australia has confirmed the presence of therapeutic quantities of sibutramine and phenolphthalein in Reduce Weight Fruta Planta capsules

4 November 2011
[Ying Da Wang tablets](#)
Analysis undertaken by the TGA Laboratories in Australia has confirmed the presence of therapeutic quantities of sildenafil in Ying Da Wang tablets

4 November 2011
[TGA structure](#)
Updated structure chart


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What's on a medicine label?

The label tells you what you are buying, what it can do for you and how to use it to get the best results.



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Australian Register of Therapeutic Goods

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TGA Health Safety Regulation

Avustralia

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Australian Government
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Industry

- › Regulation basics
- › Prescription medicines
- › Over-the-counter medicines
- › Complementary medicines
- › Medical devices & IVDs
- › Blood, tissues & biologicals
- › Other therapeutic goods
- ▼ Manufacturing therapeutic goods

Manufacturing basics

Manufacturing medicines

Manufacturing medical devices & IVDs

[Home](#) > [Industry](#) > [Manufacturing therapeutic goods](#) > >

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](#) ^{PDF} adopts the *PIC/S Guide to Good Manufacturing Practice for Medicinal Products*, PE 009-8, published by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Scheme (jointly referred to as PIC/S), dated 15 January 2009. The Guide is reproduced in its entirety with the permission of the PIC/S.

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

- [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](#)

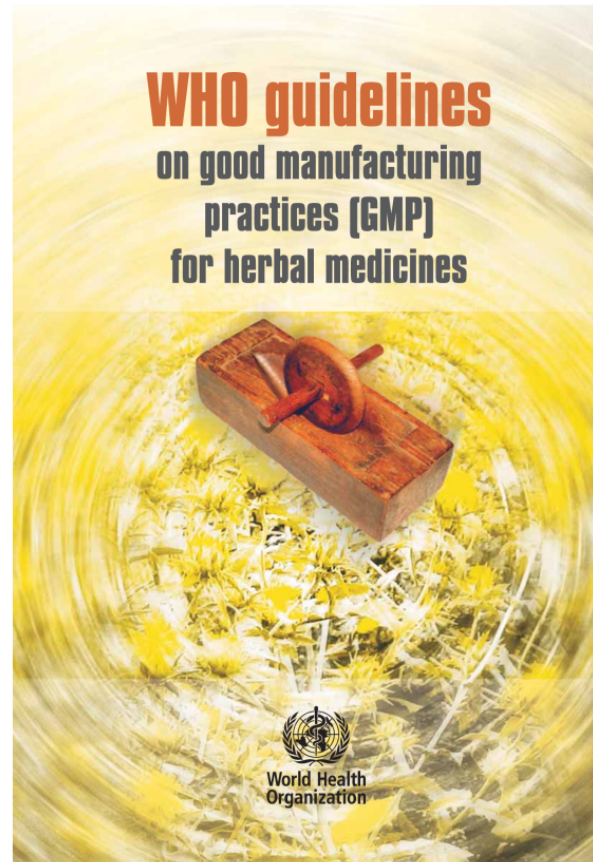
Avustralya

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- 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

24



Medical Devices

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7 Haziran 2011 SALI

Resmî Gazete

Sayı : 27957

YÖNETMELİK

Sağlık Bakanlığında:

TIBBİ CİHAZ YÖNETMELİĞİ BİRİNCİ BÖLÜM

Amaç, Kapsam, Dayanak ve Tanımlar

Amaç ve kapsam

MADDE 1 –(1) Bu Yönetmeliğin amacı; tıbbi cihaz ve aksesuarlarının taşınması 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

-GMP ve Dünyada uygulamalar

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The screenshot shows a web browser window displaying the Pharmainfo.net website. The address bar shows the URL www.pharmainfo.net/guidance-documents/gmp-guidelines. The page features a navigation menu with links for Home, Info Zone, Articles, Blogs, Jobs, Login, and Help. A sponsored link for Dove Medical Press is prominently displayed, advertising Open Access Impact Factor Journals. The main content area is titled "GMP Guidelines" and includes a sponsored link for Pharmaceutical Trainings. The sidebar on the left offers job alerts to email, and the right sidebar contains a search bar, alerts for SRF/JRF/Phd/MS, and quick links. The Windows taskbar at the bottom shows the system tray with the time 09:25 and the language TR.

Ödev

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gmp - Google'da Ara x ISPE GMP Guidelines | ISPE x

← → ↻ www.ispe.org/gmp-resources/gmp-guidelines

🗣️ Bu sayfanın dili İngilizce ▾ Çevrilmesini istiyor musunuz? Çevir Hayır İngilizce dilini asla çevirme



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[GMP Audits](#)

Australian GMP Guidelines

- ▶ [Questions & answers on the code of good manufacturing practice for medicinal products](#)
- ▶ [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 \(POL-0004\)](#)
- ▶ [GMP Inspection Policy for Canadian Drug Establishments \(POL-0011\)](#)

FARMASÖTİK ÜRÜNLERİN İYİ İMALAT UYGULAMALARINA İLİŞKİN KILAVUZ

T.C.
SAGLIK BAKANLIĞI
İlaç ve Eczacılık Genel Müdürlüğü

Sayı: 1505ANKARA
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