Training on Good Regulatory Practices and their Implementation in the Medical Device Sector

Mexico

Session III

Pharmacopoeia of the United Mexican States Supplement for Medical Devices

SALUD
SECRETARÍA DE SALUD

COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

FEUM
FARMACOPEA
de los Estados Unidos Mexicanos

November 17th, 2021

Regulatory context in Mexico

It is a matter of general health

The **sanitary control** of the process, use, maintenance, import, export and final disposal of medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical materials, healing and hygienic products

Article 3, section XXIII of the General Health Law.

Regulatory context in Mexico

What is health control?

What

Who

How

"(...) health control is understood as the set of actions of orientation, education, sampling, verification and, where appropriate, application of security measures and sanctions, exercised by the Secretariat of Health with the participation of producers, marketers and consumers, based on what is established by Official Mexican Standards and **other applicable provisions**."

The exercise of health control shall be applicable to:

(...)

III. Process, use, maintenance, import, export, and final disposal of medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical materials, healing and hygienic products, and

(...)

What other provisions apply to the sanitary control of health supplies?

Article 194 of the General Health Law.

Regulatory context in Mexico

What other provisions apply to the health control of medicines and other health supplies?

The Secretariat of Health will issue the Official Mexican Standards to which the process and specifications of the products referred to in this Title must be subject. Medicines and other health supplies shall be regulated by the Pharmacopoeia of the United Mexican States.

Article 195 of the General Health Law.
TITLE TWELFTH
Sanitary Control of Products and Services of their Import and Export

Definition

The **Pharmacopoeia of the United Mexican States** is the regulatory document of health supplies established in the General Health Law and issued by the Secretariat of Health, which helps to guarantee public health through the consignment of:

- Methods of analysis and reference substances
- Requirements on the specifications of identity, purity and quality of health supplies and their raw materials.

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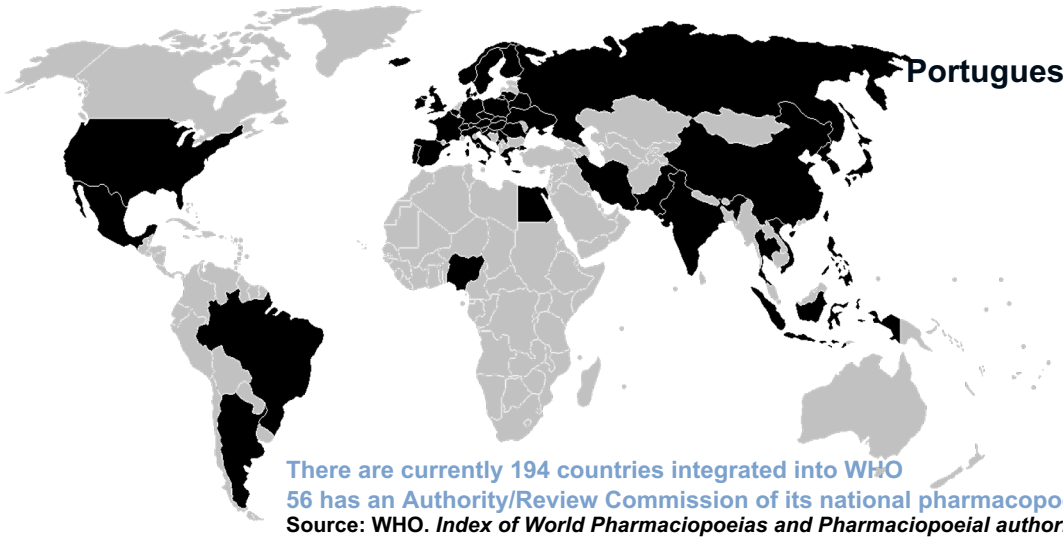
National pharmacopoeias over time

1700 1720 1740 1760 1780 1800 1820 1840 1860 1880 1900 años

Matritense (1739)
Danic (1772)
Sweden (1775)
Portuguese (1794)
American (1820)
Mexican (1846)
Dutch (1851)
Belgian and Norway (1854)
Romanian (1862)
Briton (1864)
Helvetica (1865)
Russian (1866)
Hungarian (1871)
German (p.u. 1872)
Chilean (1882)
Italian (p.u.1892)
Argentina (1898)



There are currently 194 countries integrated into WHO
56 has an Authority/Review Commission of its national pharmacopoeia until 2021
Source: WHO. *Index of World Pharmaciopoeias and Pharmaciopoeial authorities* . February 2021

The Mexican Pharmacopoeia through time

MEDICAL DEVICES IN EDITIONS OF THE MX PHARMACOPOEIA:

Cotton: 1874, 1884, 1930, 1952 (2)

Gauze: 1896, 1930, 1952

Contrast media: 2000

Sutures: FNEUM 1952
USP XII (1942),
BPhC (1930)

Mexican Pharmacopoeia

Prepared by the Pharmaceutical Academy of the City of the Republic

1846

New Mexican Pharmacopoeia

1874 Primera edición
1884 Segunda edición
1896 Tercera edición
1904 Cuarta edición
1925 Quinta edición
1952 Sexta edición

Prepared by the Mexican Pharmaceutical Society

Oficial

National Pharmacopoeia of the United States of Mexico

Issued by the State

1930 Primera edición
1952 Segunda edición
1962 Tercera edición
1974 Cuarta edición

FEUM MEDICAL DEVICE SUPPLEMENT

2006

2011

2014

2017

2022

Supplement for Medical Devices

FEUM Annual Supplements with Medical Device Updates

2012

2013

2015

2016

2019

2020

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The Supplement for Medical Devices:

- It has the same level as a NOM.
- It is a document that is constantly updating its contents.
- It is the Secretariat of Health that monitors its compliance.
- May set monographs by product family.
- Establishes General Methods of Analysis, when these apply to more than two monographs, otherwise the specific method is included within the monograph of the device.

SUPPLEMENT FOR MEDICAL DEVICES, 4th EDITION

CONTENT

Chapter of Generalities

Chapter of (333) Solutions and Reagents

65 General Methods of Analysis

224 Product monographs

53 monographs of Radiopharmaceuticals

10 Appendices:

- Health regulation applicable to DM
- Criteria for MD classification
- Guidelines for obtaining sanitary registration
- MD grouping criteria for health registration purposes
- Application of MD Risk Management
- Preservation and management of reference microbial cultures
- Microbiological analysis of non-sterile products
- Glossary
- Technovigilance activities.
- Biocompatibility. A table for test selection harmonized with ISO 10993 is included.

Upgrade process

FEUM update process based on NOM-001-SSA1-2020

Annual Work Plan

Updates to monographs, new content, and deletions are included, based on user need.

Risk-based approach

Transparency

Draft

The Committee of Experts generates a draft

Qualitative data and sound science

Use of International Standards

Consultation with users

For 2 months individuals can download the drafts and send their comments

Transparency and stakeholder engagement

Public consultation

Final version

The Committees analyze the comments and obtain the final version of the monograph

Qualitative data and sound science

Consensus

Publishing and printing

The Executive Directorate is in charge of the process of editing and printing the FEUM copy

Central coordination

Formalization

The DE-CPFEUM manages the publication in the DOF of the Notice of Sale of the FEUM copy

Entry into force and monitoring

The Notice of Sale indicates the entry into force, and the monitoring of compliance lies with COFEPRIS

Consultas

Puedes consultar y hacer tus observaciones al material que se integrará en las próximas publicaciones de la FEUM de acuerdo al siguiente calendario:

Consulta a usuarios de la FEUM

Periodos de Consulta a los usuarios

El Objetivo es establecer una comunicación activa con la industria Farmacéutica y demás sectores involucrados, mediante el envio de sus comentarios para enriquecer su contenido y cubrir las necesidades de las autoridades sanitarias y de la Industria establecida en nuestro país.

Primer Periodo
Inicia el periodo: 01/02/2021
Termina el periodo: 31/03/2021

Segundo Periodo
Inicia el periodo: 01/05/2021
Termina el periodo: 30/06/2021

Tercer Periodo
Inicia el periodo: 01/08/2021
Termina el periodo: 30/09/2021

Cuarto Periodo
Inicia el periodo: 01/11/2021
Termina el periodo: 31/12/2021

Sistemas críticos +

Buenas prácticas de laboratorio +

Dispositivos médicos −

MGA-DM 1712. Resistencia a la corrosión

Agujas para toma y recolección de sangre, sencilla y/o múltiple, estériles, desechables

Catéter para cateterismo venoso central con equipo de inserción por técnica Seldinger, adulto

Catéter pediátrico para cateterismo venoso central con equipo de inserción por técnica Seldinger

Concentrador de oxígeno

Equipo para drenaje por aspiración para uso postquirúrgico

Jeringas de vidrio

MGA-DM 0352. Dureza para aceros inoxidables

MGA-DM 10993-3 Pruebas de biocompatibilidad. Pruebas para genotoxicidad, carcinogenicidad y toxicidad reproductiva (Informativo)

MGA-DM 10993-7 Pruebas de biocompatibilidad. Residuos de esterilización por óxido de etileno (Informativo)

Termómetro clínico

Envases primarios +

Estadística para ensayos biológicos +

"2021, Año de la Independencia"

COMENTARIOS

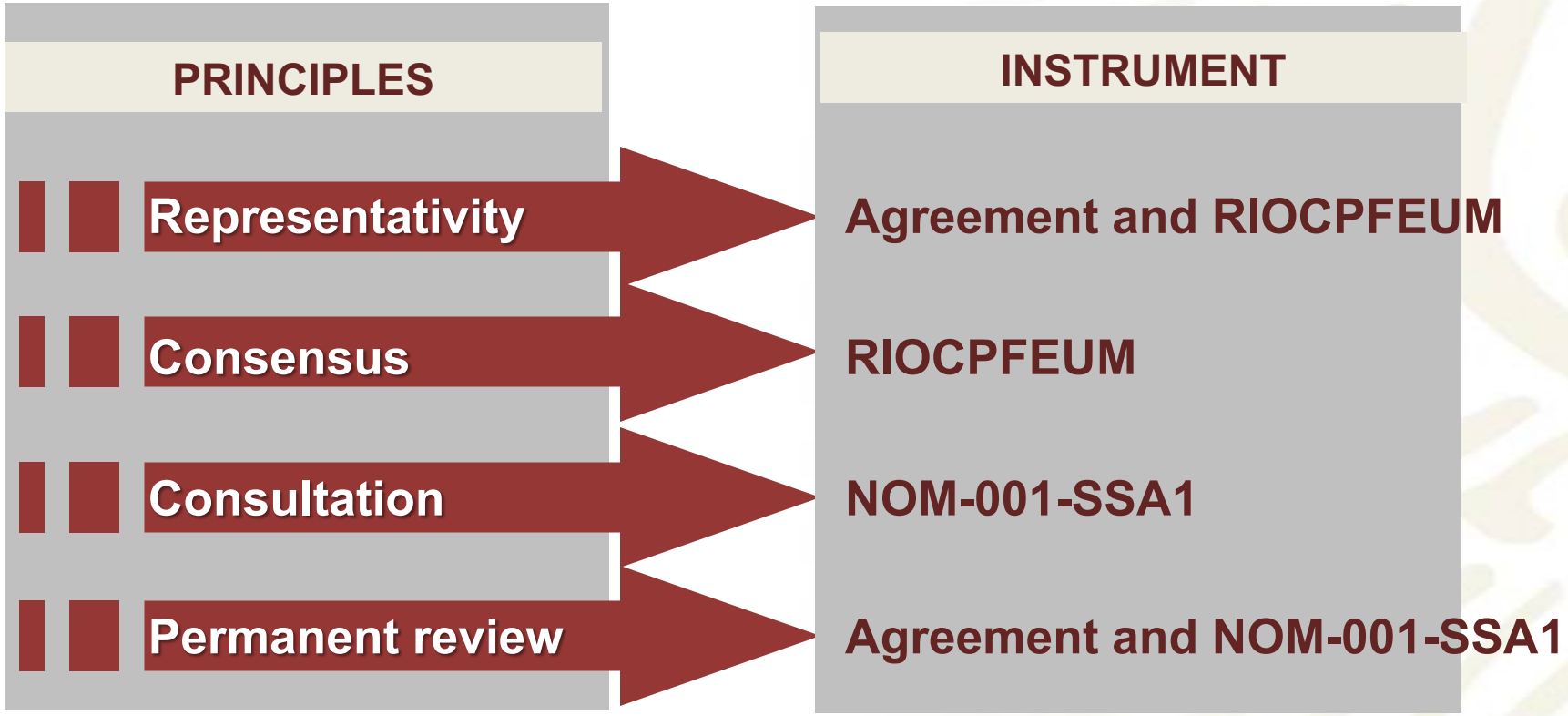
Con fundamento en el numeral 6.3.3.1 de la Norma Oficial Mexicana NOM-001-SSA1-2020, se publica el presente proyecto a efecto de que los interesados, a partir del 1º de noviembre y hasta el 31 de diciembre de 2021, lo analicen, evalúen y envíen sus observaciones o comentarios en idioma español y con el sustento técnico suficiente ante la CPFEUM, sito en Río Rhin número 57, colonia Cuauhtémoc, código postal 06500, Ciudad de México.
Correo electrónico: consultas@farmacopea.org.mx.

DATOS DEL PROMOVENTE

Nombre: _____ **Cargo:** _____
Institución o empresa: _____ **Dirección:** _____
Teléfono: _____ **Correo electrónico:** _____

Dice	Debe decir	Justificación*
MGA-DM 10993-7 PRUEBAS DE BIOCOMPATIBILIDAD. Residuos de esterilización por óxido de etileno (Informativo)		
INTRODUCCION		
Como se indica en la introducción de la norma ISO 11135-1, al determinar la idoneidad del óxido de etileno (OE) para la esterilización de dispositivos médicos, es importante asegurarse de que los niveles de OE residual, etilenclorhidrina (ECH) y Etilenglicol (EG) suponen un riesgo mínimo para el paciente con el uso normal del producto. Por lo tanto, es importante que se considere el uso de materiales alternativos y procesos de esterilización durante el diseño y desarrollo del producto. Se sabe que el OE exhibe una serie de efectos biológicos. En el desarrollo de esta parte de la Norma ISO 10993, se consideraron estos efectos, que incluyen irritación, daño orgánico, mutagenicidad y carcinogenicidad en		

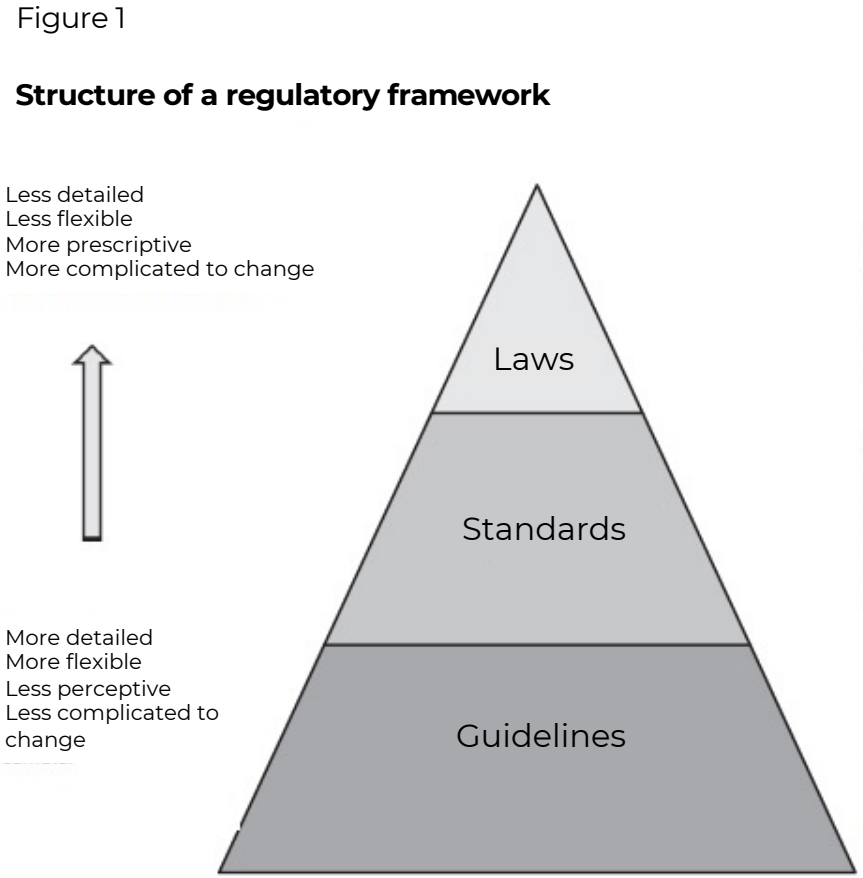
Principles at CPFEUM

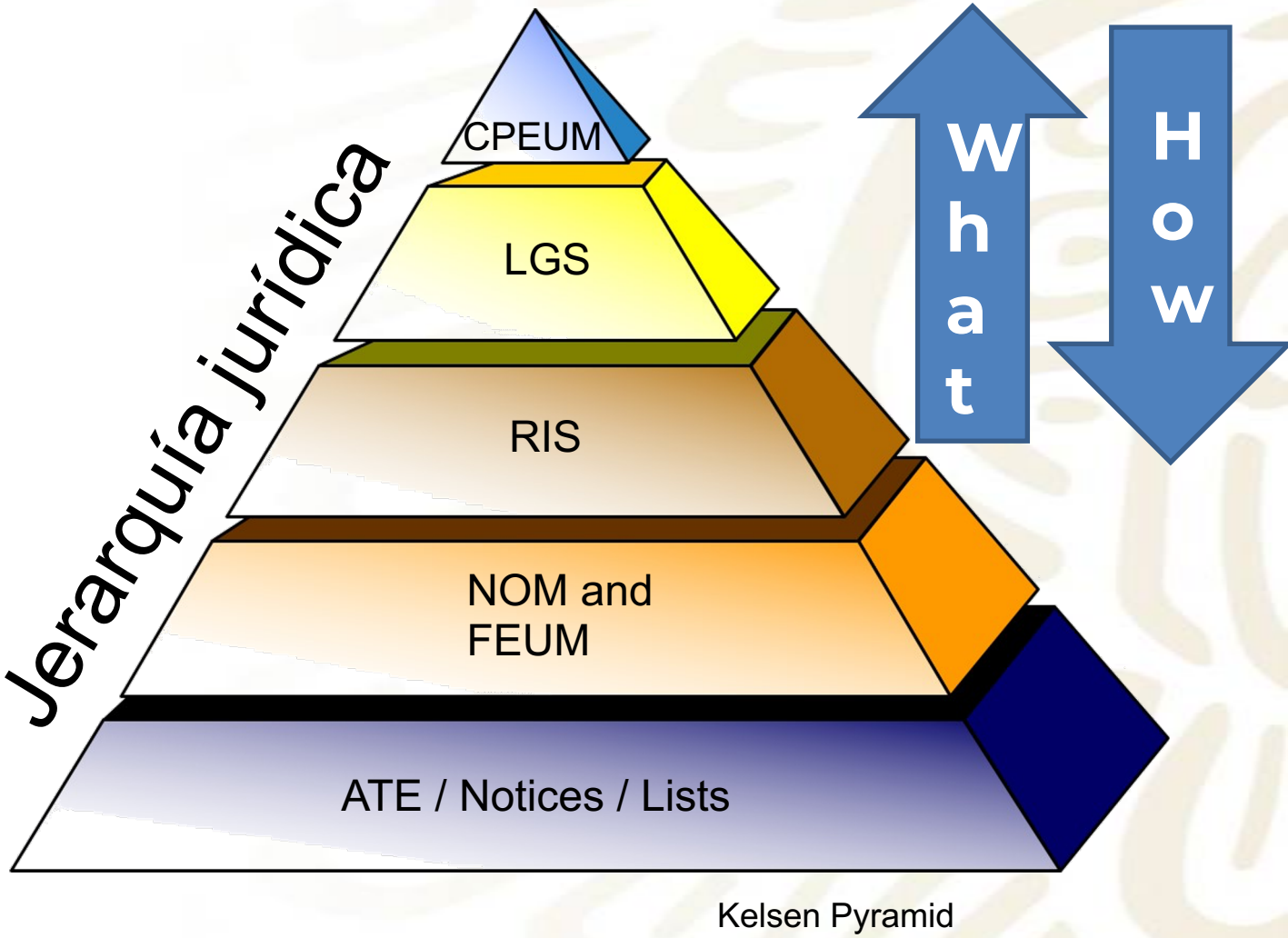


In the Context of BPR
Components of the regulatory framework

Figure 1

Structure of a regulatory framework





Kelsen Pyramid

FEUM Process in the Context of GRP

GRP

Principles:

Legality
Coherence
Independence
Impartiality
Proportionality
Flexibility
Clarity
Efficiency
Transparency

NOM-001-SSA1-2020

Principles:

Representativity
Consensus
Public consultation
Permanent review
Openess
Harmonization
Ethics
Social responsibility

The structure of CPFEUM in the context of RPG facilitators

- Political and government-wide support
- Effective organization and good governance supported by leadership
- Inter- and intra-organizational communication, collaboration and coordination
- A robust and well-functioning quality management system
- Sufficient and sustainable financial resources
- Competent human resources
- Ethics and organizational values
- Decision-making process based on data and science
- Excellent linkage and cooperation with NRA
- The structure of the CPFEUM has allowed consistency over 37 years
- There is collaboration with about 50 local institutions and organizations and with the Pharmacopoeias of the world
- There is a QMS
- It is a self-sustaining project, based on the sale of the SRef and publications and trainings.
- There is a young but mature team
- There is a living Code of Ethics
- Agreements by consensus, with objectivity and impartiallity based on science and taking up international standards

Cooperation and Convergence between Pharmacopoeias

USP Convention

The Executive Director is a voting delegate

Memorandum of Understanding 1999, 2009, 2018

FEUM-USP Scientific Meeting, every 2 years in CDMX
Exchange of publications, work plans and technical consultations
Mutual invitations to symposia or activities.
Stays for training or understanding of our processes.

Observer member, 2020

Participation in a working group with access and influence in the drafts of new pharmacopeial contents

Collaboration at IMWP

Participation in the 12 International Meetings of the World Pharmacopoeias led by WHO since 2012.
The 2022 meeting will be hosted by the CDMX.
Participation in monographic drafts of inputs for COVID-19
Participation in *55 Meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations*

Pacific Alliance

Recognition of the FEUM as a regional Pharmacopoeia

THANK YOU

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