Áreas Limpias: Sistemas de HVAC Farmacéutico

Capítulo Nº 1: Exigencia Regulatoria

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“El control de la calidad empieza con educación y termina con educación, hay que dar educación a todo el personal, desde el presidente hasta los operarios”

Kaoru Ishikawa

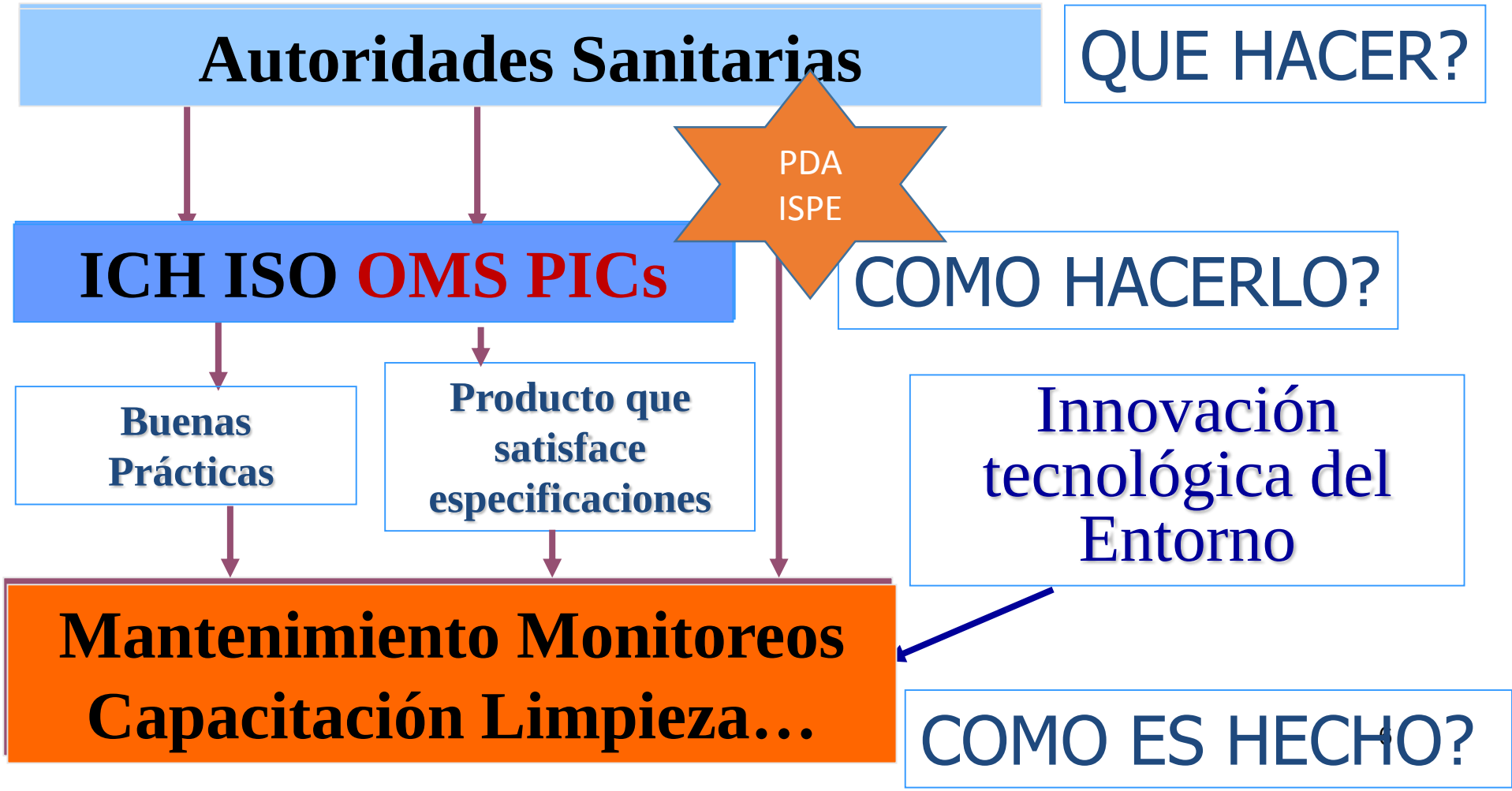
Temario:

1. **Exigencia Regulatoria**
2. Introducción a las áreas limpias
3. Diseño y Requerimientos de Usuario (URS)
4. Filtrado del Aire
5. Tipos de Flujo de Aire
6. Sistemas de HVAC
7. Validación de un Sistema de HVAC
8. Pruebas de Sala Limpia

Exigencia Regulatoria

[redacted]

Criterio de Armonización



Evolución en los Requerimientos Regulatorios: OMS

TRS 823 R32 (1992)	TRS 908 R37 (2003)	TRS 961 R45 (2011)
GMP Pharmaceutical Products	GMP Pharmaceutical Products	GMP Pharmaceutical Products Productos esteriles Documenta
	HACCP	
Validación métodos analíticos APIs		
Preparación guías de inspección	Reporte de inspección/ Pre qualification conce	Procedimiento pre ción
	GSP	GSP & GDP TTSP

Trs-957-Annex 4 WHO GMP for sterile pharmaceutical products (2010)

trs957_GLP annex1 2010

TRS-981 WHO QRM guidelines 2013

trs957_WHO good distribution practices for pharmaceutical products 2010

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Instituto Nacional de Vigilancia de Medicamentos y Alimentos.

Agencia Nacional de Regulación, Control y Vigilancia Sanitaria

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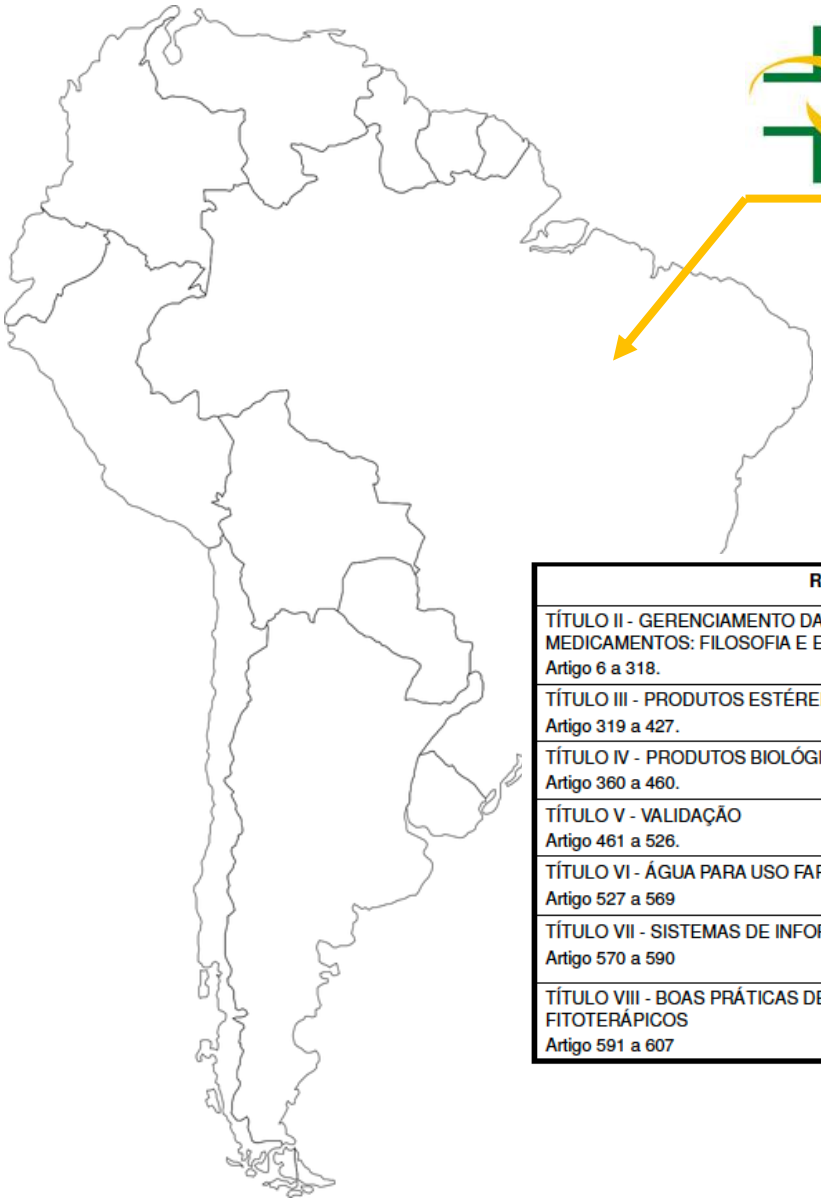
DIRECCIÓN GENERAL DE MEDICAMENTOS INSUMOS Y DROGAS

Instituto de Salud Pública
Ministerio de Salud
Gobierno de Chile

Agência Nacional de Vigilância Sanitária

anmat
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica



Agência Nacional de Vigilância Sanitária

PIC/S

RDC 17/2010	REFERÊNCIA INTERNACIONAL
TÍTULO II - GERENCIAMENTO DA QUALIDADE NA INDÚSTRIA DE MEDICAMENTOS: FILOSOFIA E ELEMENTOS ESSENCIAIS Artigo 6 a 318.	WHO TRS 961, 2011 - Annex 3 WHO TRS 986, 2014 - Annex 2
TÍTULO III - PRODUTOS ESTÉREIS Artigo 319 a 427.	WHO Technical Report Series 961, 2011 - Annex 6
TÍTULO IV - PRODUTOS BIOLÓGICOS Artigo 360 a 460.	WHO Technical Report Series 996, 2016 - Annex 3
TÍTULO V - VALIDAÇÃO Artigo 461 a 526.	WHO Technical Report Series 992, 2015 - Annex 3 Appendice 7 - Non-sterile process validation
TÍTULO VI - ÁGUA PARA USO FARMACÊUTICO Artigo 527 a 569	WHO Technical Report Series 970, 2012 - Annex 2
TÍTULO VII - SISTEMAS DE INFORMAÇÃO COMPUTADORIZADOS Artigo 570 a 590	EMA - Good Manufacturing Practice Medicinal Products for Human and Veterinary Use - Annex 11: Computerised Systems, 2011
TÍTULO VIII - BOAS PRÁTICAS DE FABRICAÇÃODE MEDICAMENTOS FITOTERÁPICOS Artigo 591 a 607	WHO Technical Report Series 937, 2006 - Annex 3

¿Comparativo Regulatorio?

Tipo	TRS 823 R32 (1992)	TRS 908 R37 (2003)	TRS 961 R45 (2011)
Colombia	✓	2020 (No Estériles)	2021 (Estériles)
Ecuador		✓	
Perú		✓	
Chile		✓	
Brasil			✓
Argentina			✓

Serie de normas ISO 14.644

ISO TC-209: Cleanrooms and associated controlled environments

Norma	Título	WG
14644-1:2015	Part 1: Classification of air cleanliness by particle concentration	01
14644-2:2015	Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	01
14644-3:2019	Part 3: Test methods	03
14644-4:2001	Part 4: Design, construction and start-up	04
14644-5:2004	Part 5: Operations	05
14644-7:2004	Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)	07
14644-8:2013	Part 8: Classification of air cleanliness by chemical concentration (ACC)	08
14644-9:2012	Part 9: Classification of surface cleanliness by particle concentration	09
14644-10:2013	Part 10: Classification of surface cleanliness by chemical concentration	08

ISO TC-209: Cleanrooms and associated controlled environments

14644-12	Part 12: Specification of air cleanliness by nanoscale particle concentration	10
14644-13	Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications	12
14644-14	Part 14: Assessment of suitability for use of equipment by airborne particle concentration	11
14644-15	Part 15: Assessment of suitability for use of equipment and materials by airborne chemical and surface chemical concentration	11
14644-16	Part 16: Code of practice for improving energy efficiency in cleanrooms and clean air devices	13
14698-1:2003	Biocontamination control - Part 1: General principles and methods	02
14698-2:2003	Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data	02

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