GBT/OMS e a interface com o SNVS

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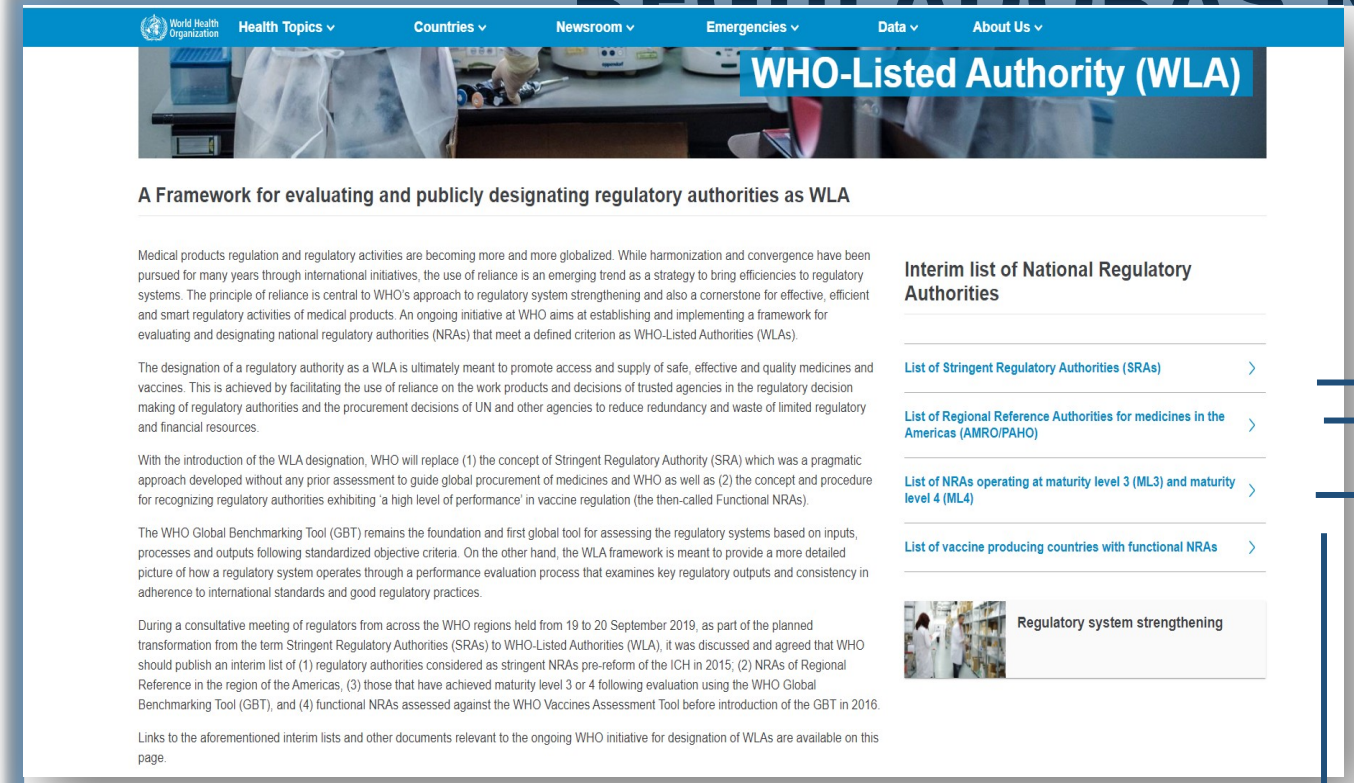
ORIGEM DO CONCEITO DE *WHO-LISTED AUTHORITIES (WLA)*

- Resolução WHA 67.20 de 2014.
- Substitui o conceito de “autoridades reguladoras estritas”.
- Resposta a demanda por um sistema mais transparente para reconhecimento das autoridades que operam em nível avançado.
- As autoridades serão avaliadas por meio de ferramenta específica (*Global Benchmarking Tool, GBT)* e terão atribuído um nível de maturidade,

OBJETIVOS E BENEFÍCIOS PRETENDIDOS PELA OMS

- Permitir o uso eficiente de recursos regulatórios, fornecendo uma estrutura robusta para promover a confiança entre os países
- Incentivar a melhoria contínua dos sistemas regulatórios e convergência regulatória
- Apoiar nas decisões de compras sobre produtos médicos pela ONU e outras agências, bem como por países (especialmente de baixa e média renda)
- Contribuir para o programa de pré-qualificação da OMS, expandindo o conjunto de autoridades reguladoras confiáveis
- Promover a equidade na saúde possibilitando um ambiente de inovação e produção local e acelerando o acesso a produtos médicos

LISTA PROVISÓRIA DE AUTORIDADES REGULADORAS NACIONAIS



- https://www.who.int/initiatives/who-listed-authority-reg-authorities

Stringent Regulatory Authorities (SRAs)

- Medicamentos
  - Membros fundadores do ICH (2015)
- Vacinas
  - Autoridades Regulatórias de alto desempenho

NRAs of regional reference (WHO/PAHO)

- Baseada na ferramenta da OPAS

NRAs at ML3 and ML4

- Baseada na ferramenta GBT (2016)

WHO functional NRAs (vaccines)

- Baseada na ferramenta de vacinas - OMS

COMO SER AUTORIDADE DE REFERÊNCIA

Nível de Maturidade
ML

Avaliação de performance

O que é GBT (WHO Global Benchmarking Tool)?

https://www.who.int/tools/global-benchmarking-tools/VI

- Ferramenta da OMS para avaliação dos sistemas regulatórios das Autoridades Sanitárias Nacionais;
- União de outras ferramentas utilizadas desde 1997 para vacinas e medicamentos
- Compreendido por 8 funções regulatórias + Sistema Regulatório (RS)
  - National Regulatory Systems (RS)
  - Registration and Marketing Authorization (MA)
  - Vigilance (VL)
  - Market Surveillance and Control (MC)
  - Licensing Establishments (LI)
  - Regulatory Inspection (RI)
  - Laboratory Testing (LT)
  - Clinical Trials Oversight (CT)
  - NRA Lot Release (LR)

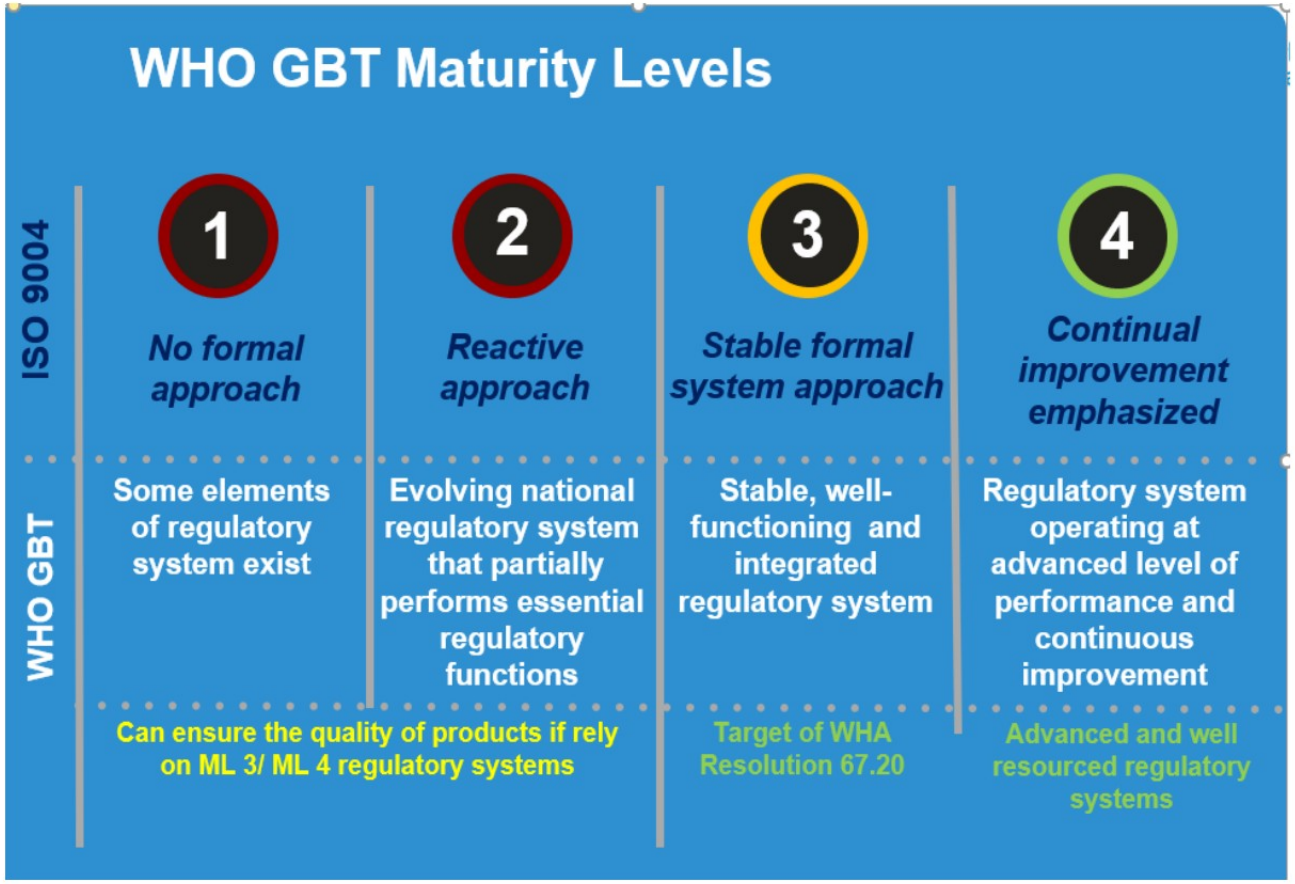
Estrutura do GBT

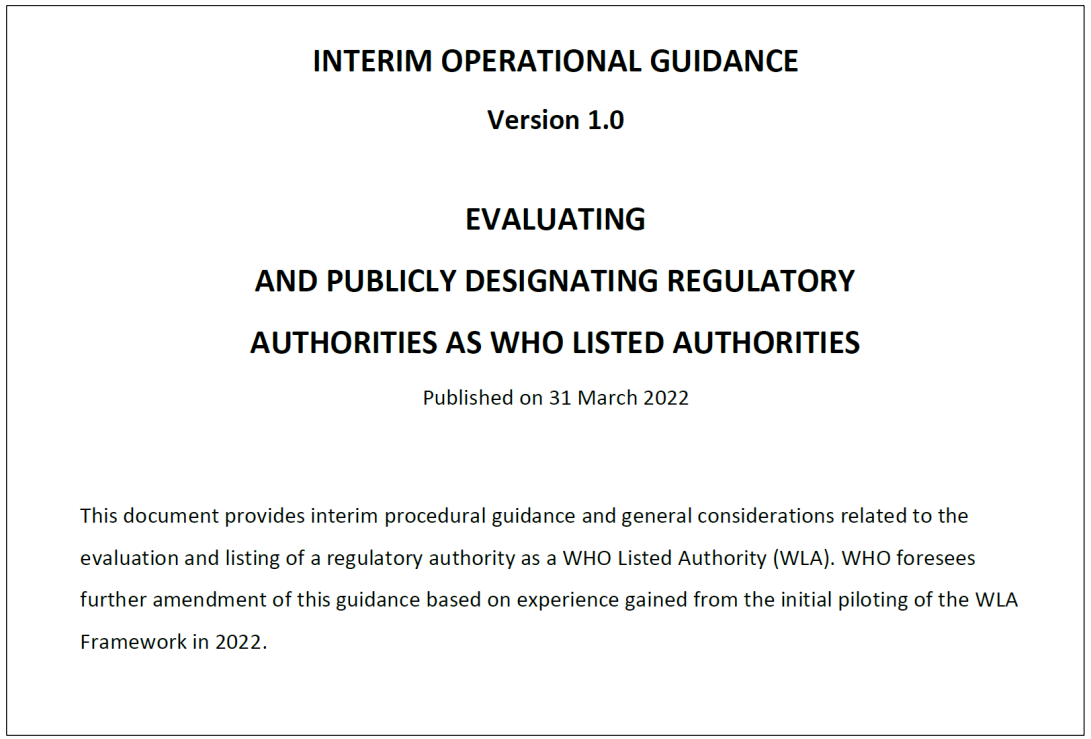
Function:	01- NATIONAL REGULATORY SYSTEM (RS)
Description:	The National Regulatory System provides the framework that supports the World Health Organization (WHO) recommended regulatory functions. The National Regulatory Authority (NRA) is the institution in charge of assuring the quality, safety, and efficacy of medical products as well as ensuring the relevance and accuracy of product information. A sustainable, well-functioning regulatory system will ensure an independent and competent oversight of medical products.
Indicator:	**RS01 Legal provisions, regulations and guidelines required to define regulatory framework of national regulatory system (RS)**
Objective:	The objective of this indicator is to ensure that the legal basis defining the regulatory framework for the national regulatory system exists. The assessor should identify how the different pieces of the legislation are drafted and to know which organizations and institutions are consulted during this process, including the public, industry, non-governmental organizations and other interested parties. The assessor should identify the cases where the relevant legal provisions have been defined but the regulations have not been enacted and published, which may lead to legal uncertainty, misunderstanding or misinterpretation. The regulatory system functions should be supported by appropriate and promulgated legislation.
Category:	01. Legal provisions, regulations and guidelines
Sub Indicator:	**RS01.01: Legal provision and regulations define the medical products that should be regulated.**
Maturity Level:	1

Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and plasma derived medicinal products (PDMPs))
Description:	The assessor should identify within the existing legislation and institutional regulations, the scope of regulatory activities and products that should be regulated. Existing definitions for regulated medical products (e.g., medicines, biological products, and medical devices) should be used. It is not necessary to have a single (standalone) drug law; however, a promulgated and enforced law should exist. If the base laws and regulations refer to the need for complementary regulation, it is important to access that information.
Objective:	The objective of this sub-indicator is to ensure the existence of legislation and institutional regulations that define the products that should be regulated. It is important to set up the scope and mandate of the regulatory agency in charge of regulating medical products in the country.
Requirement:	Scope of regulated medical products
Evidence to review:	The assessor should request for and review: 1. Promulgated legal provisions and regulations that define the medical products that should be regulated.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885)., (1), (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf)
Framework:	Structure/Foundation/Input

Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions or regulations defining the medical products that should be regulated. ⇒ ONGOING IMPLEMENTATION (OI): There are some legal provisions and regulations or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations defining the medical products that should be regulated were recently developed as draft but not yet promulgated and enforced. ⇒ IMPLEMENTED (I): The legal provisions and regulations defining the medical products are promulgated and enforced.
Limitations and remarks:	▪ In a short time, it may not be possible for the assessor to review all aspects that this indicator includes. Preferably the country profile or other documents that provide a good description of the regulatory landscape in the country should be studied beforehand. ▪ For blood and blood products, it is important that standards for preparation of blood for transfusion (e.g., collection of blood, donor selection, donor deferral and transfusion transmitted infection testing) should be referenced in legislation. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

Níveis de Maturidade





https://www.who.int/publications/m/item/wla-interim-operational-guide-combined

https://www.who.int/publications/m/item/a-framework-for-evaluating-and-publicly-designating-regulatory-authorities-as-who-listed-authorities-wla

Interface com o SNVS

https://www.who.int/tools/global-benchmarking-tools/VI

- 8 funções regulatórias + Sistema Regulatório (RS)
  - National Regulatory Systems (RS)
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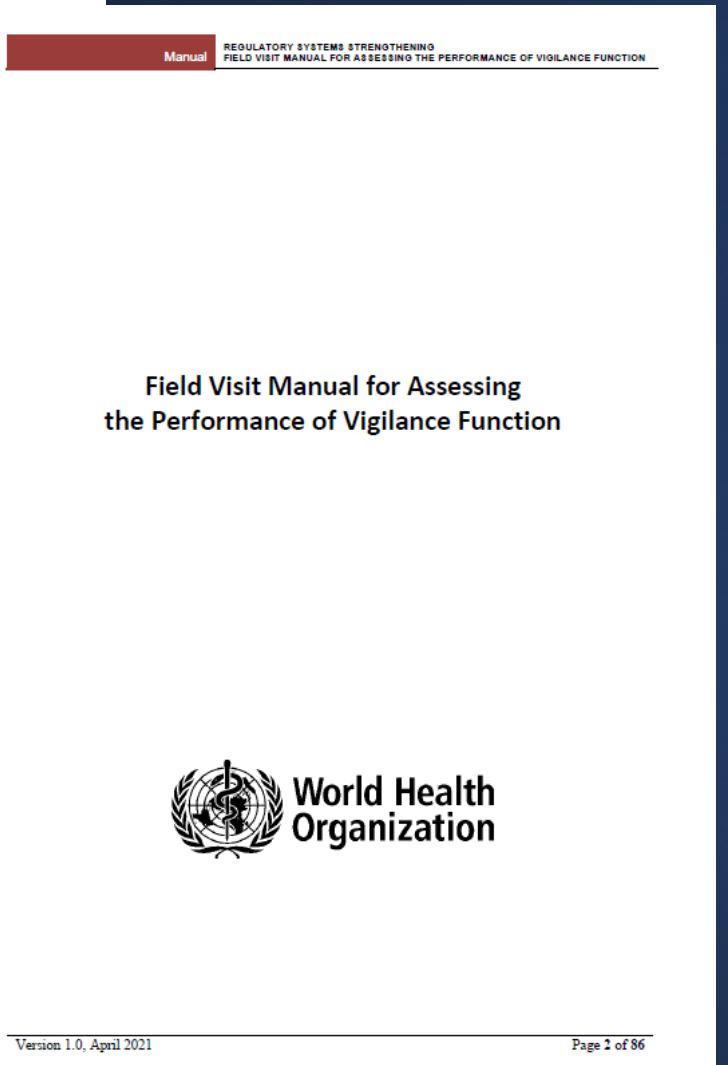
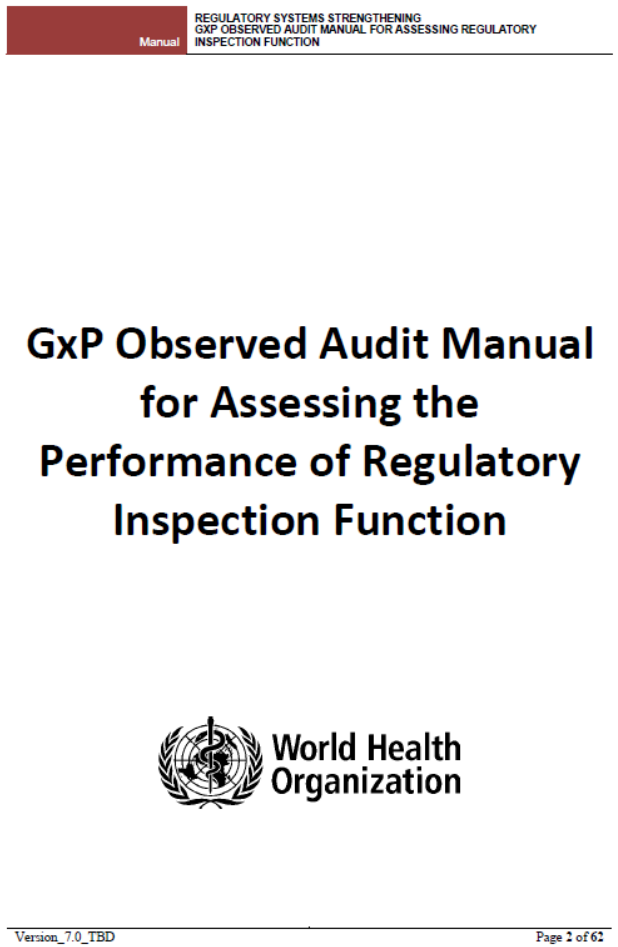
Farmacovigilância Ferramenta de avaliação

- **Inclui visita de campo com aplicação de questionário em:**
  - Autoridade Sanitária Nacional e local
  - Programa Nacional e Regional de Imunização
  - Centros de vacinação, hospitais e clínicas
  - Programas Nacionais e Regionais de Saúde (p.ex. HIV, malaria, TB)



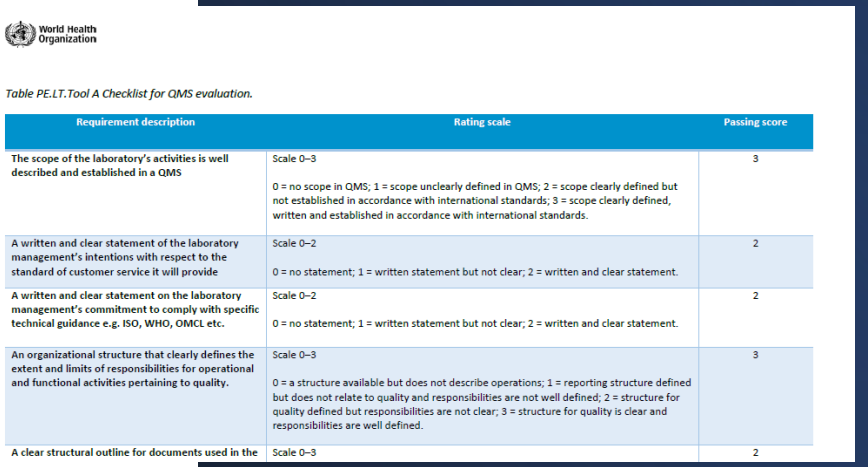
Inspeção observada Ferramenta de avaliação

- **Inspeção observada de BPDA e BPC**
  - BPF excluída pois o Brasil foi auditado pelo PIC/S há menos de 5 anos



Laboratórios Ferramenta de avaliação

- **Aplicada em auditoria nos laboratórios**
  - Não auditados laboratórios pré-qualificados para medicamentos (INCQS para medicamentos, Funed/MG e LACEN GO)
  - Avalia aspectos de SGQ (*Tool A*), competência do pessoal (*Tool B*), BPL (*Tool C*)



World Health Organization

Table PE.LT.Tool A Checklist for QMS evaluation.

Requirement description	Rating scale	Passing score
The scope of the laboratory's activities is well described and established in a QMS	Scale 0–3 0 = no scope in QMS; 1 = scope unclearly defined in QMS; 2 = scope clearly defined but not established in accordance with international standards; 3 = scope clearly defined, written and established in accordance with international standards.	3
A written and clear statement of the laboratory management's intentions with respect to the standard of customer service it will provide	Scale 0–2 0 = no statement; 1 = written statement but not clear; 2 = written and clear statement.	2
A written and clear statement on the laboratory management's commitment to comply with specific technical guidance e.g. ISO, WHO, OMCL etc.	Scale 0–2 0 = no statement; 1 = written statement but not clear; 2 = written and clear statement.	2
An organizational structure that clearly defines the extent and limits of responsibilities for operational and functional activities pertaining to quality.	Scale 0–3 0 = a structure available but does not describe operations; 1 = reporting structure defined but does not relate to quality and responsibilities are not well defined; 2 = structure for quality defined but responsibilities are not clear; 3 = structure for quality is clear and responsibilities are well defined.	3
A clear structural outline for documents used in the	Scale 0–3	2

Dúvidas?