Sistema de Gestão da Qualidade da Anvisa e o GBT – *WHO Global Benchmarking Tool*

Patricia Serpa

Coordenação do Sistema de Gestão da Qualidade da Anvisa

Gabinete do Diretor Presidente

CSGQA/GADIP/ANVISA

O que é GBT (WHO Global Benchmarking Tool)?

- 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)

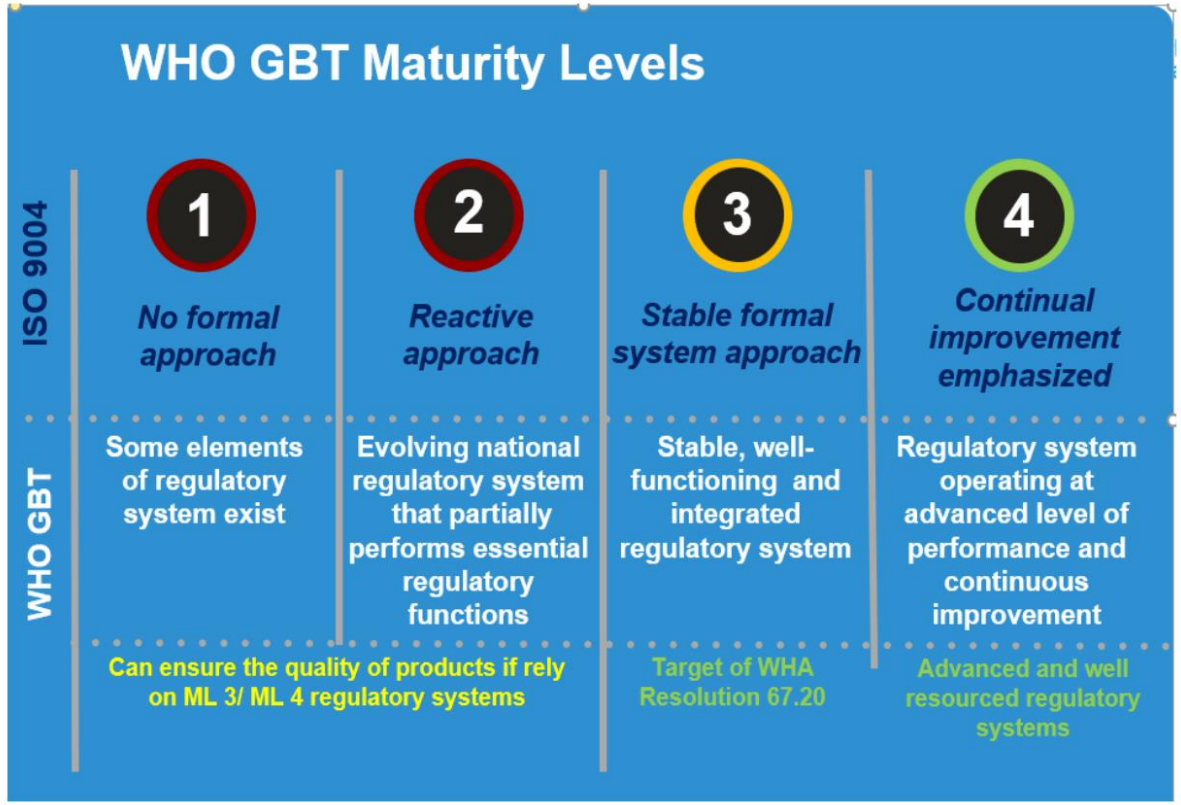
https://www.who.int/tools/global-benchmarking-tools/VI

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

CONCEPT NOTE: A FRAMEWORK FOR EVALUATING AND PUBLICLY DESIGNATING REGULATORY AUTHORITIES AS WHO-LISTED AUTHORITIES – May 2019 – Draft for comments

https://www.who.int/docs/default-source/medicines/norms-and-standards/current-projects/qas19-808-who-listed-authorities.pdf?sfvrsn=e5b350f3_2

INTERIM OPERATIONAL GUIDANCE

Version 1.0

EVALUATING AND PUBLICLY DESIGNATING REGULATORY AUTHORITIES AS WHO LISTED AUTHORITIES

Published on 31 March 2022

This document provides interim procedural guidance and general considerations related to the evaluation and listing of a regulatory authority as a WHO Listed Authority (WLA). WHO foresees further amendment of this guidance based on experience gained from the initial piloting of the WLA Framework in 2022.

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

World Health Organization

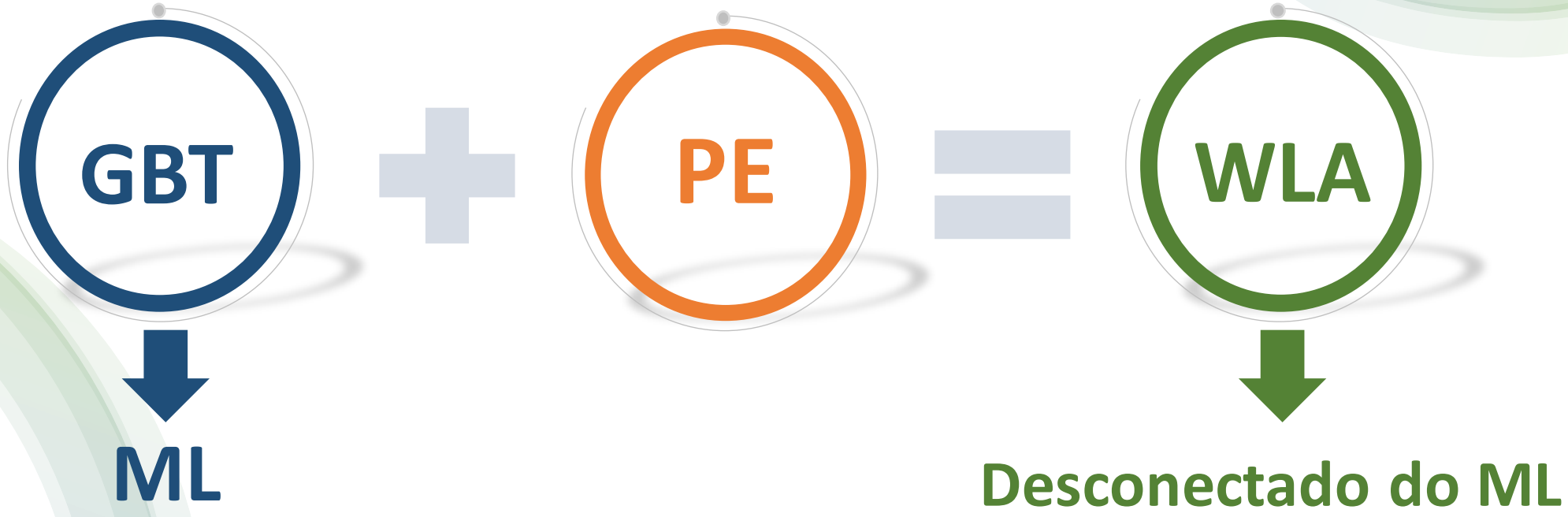
Evaluating and publicly designating a NRA/RRS as WHO Listed Authority

Interim manual for the performance evaluation of regulatory authorities seeking the designation as WHO listed authorities

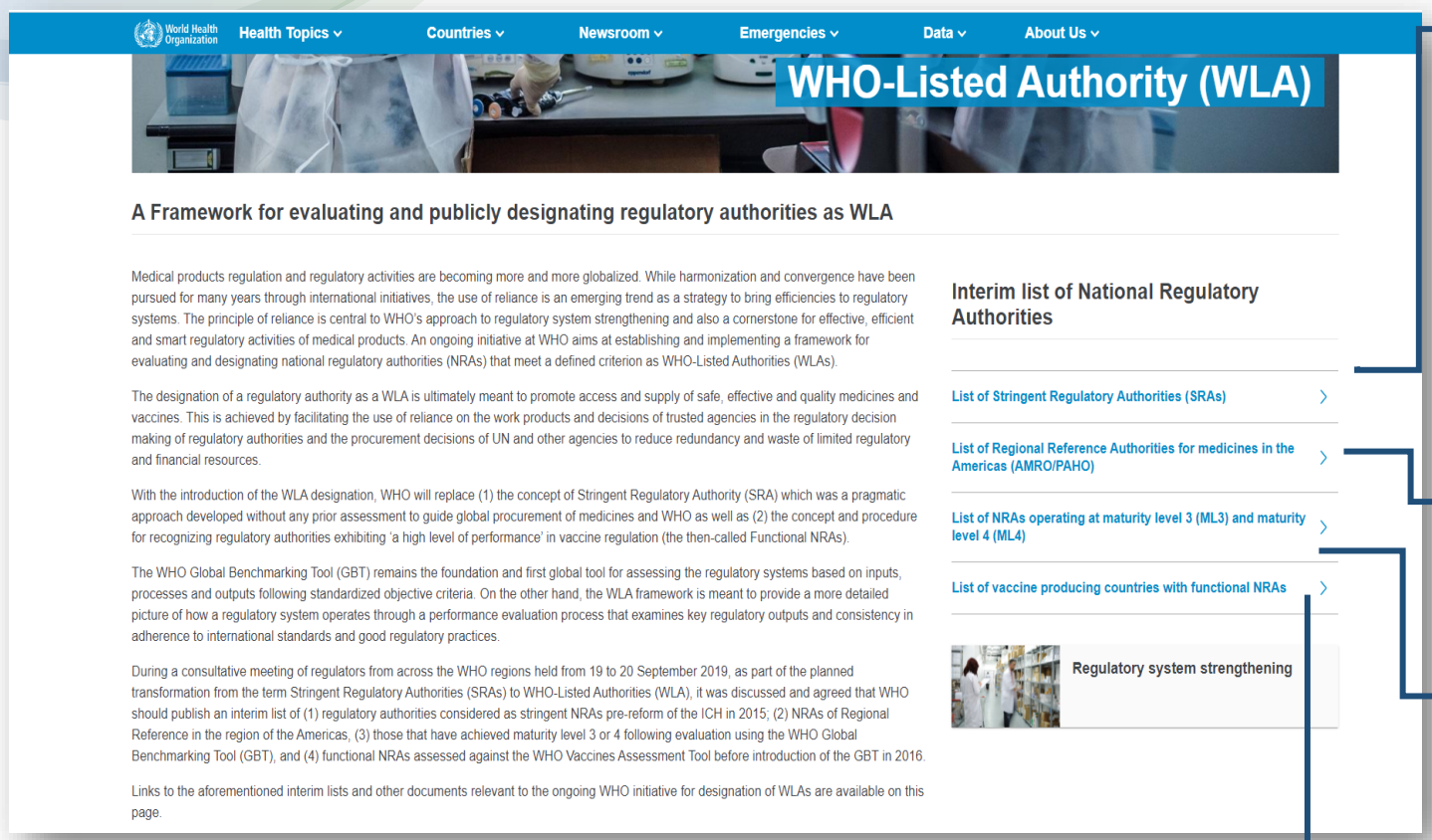
Published on 31 March 2022

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

Como ser autoridade referência?



Listas provisórias de Autoridades Reguladoras Nacionais



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WHO-Listed Authority (WLA)

A Framework for evaluating and publicly designating regulatory authorities as WLA

Medical products regulation and regulatory activities are becoming more and more globalized. While harmonization and convergence have been pursued for many years through international initiatives, the use of reliance is an emerging trend as a strategy to bring efficiencies to regulatory systems. The principle of reliance is central to WHO's approach to regulatory system strengthening and also a cornerstone for effective, efficient and smart regulatory activities of medical products. An ongoing initiative at WHO aims at establishing and implementing a framework for evaluating and designating national regulatory authorities (NRAs) that meet a defined criterion as WHO-Listed Authorities (WLAs).

The designation of a regulatory authority as a WLA is ultimately meant to promote access and supply of safe, effective and quality medicines and vaccines. This is achieved by facilitating the use of reliance on the work products and decisions of trusted agencies in the regulatory decision making of regulatory authorities and the procurement decisions of UN and other agencies to reduce redundancy and waste of limited regulatory and financial resources.

With the introduction of the WLA designation, WHO will replace (1) the concept of Stringent Regulatory Authority (SRA) which was a pragmatic approach developed without any prior assessment to guide global procurement of medicines and WHO as well as (2) the concept and procedure for recognizing regulatory authorities exhibiting 'a high level of performance' in vaccine regulation (the then-called Functional NRAs).

The WHO Global Benchmarking Tool (GBT) remains the foundation and first global tool for assessing the regulatory systems based on inputs, processes and outputs following standardized objective criteria. On the other hand, the WLA framework is meant to provide a more detailed picture of how a regulatory system operates through a performance evaluation process that examines key regulatory outputs and consistency in adherence to international standards and good regulatory practices.

During a consultative meeting of regulators from across the WHO regions held from 19 to 20 September 2019, as part of the planned transformation from the term Stringent Regulatory Authorities (SRAs) to WHO-Listed Authorities (WLA), it was discussed and agreed that WHO should publish an interim list of (1) regulatory authorities considered as stringent NRAs pre-reform of the ICH in 2015; (2) NRAs of Regional Reference in the region of the Americas, (3) those that have achieved maturity level 3 or 4 following evaluation using the WHO Global Benchmarking Tool (GBT), and (4) functional NRAs assessed against the WHO Vaccines Assessment Tool before introduction of the GBT in 2016.

Links to the aforementioned interim lists and other documents relevant to the ongoing WHO initiative for designation of WLAs are available on this page.

Interim list of National Regulatory Authorities

List of Stringent Regulatory Authorities (SRAs)

List of Regional Reference Authorities for medicines in the Americas (AMRO/PAHO)

List of NRAs operating at maturity level 3 (ML3) and maturity level 4 (ML4)

List of vaccine producing countries with functional NRAs

Regulatory system strengthening

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

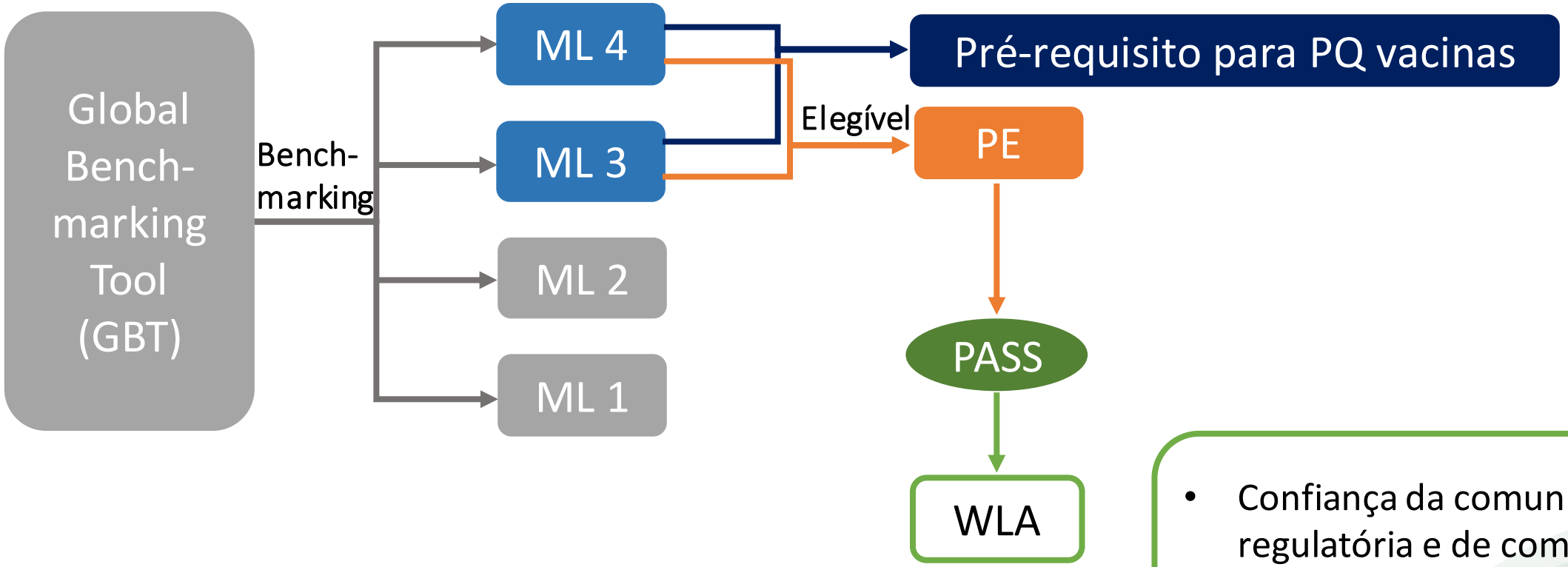
- Baseada na ferramenta GBT (2016)

WHO functional NRAs (vaccines)

- Baseada na ferramenta de vacinas -OMS

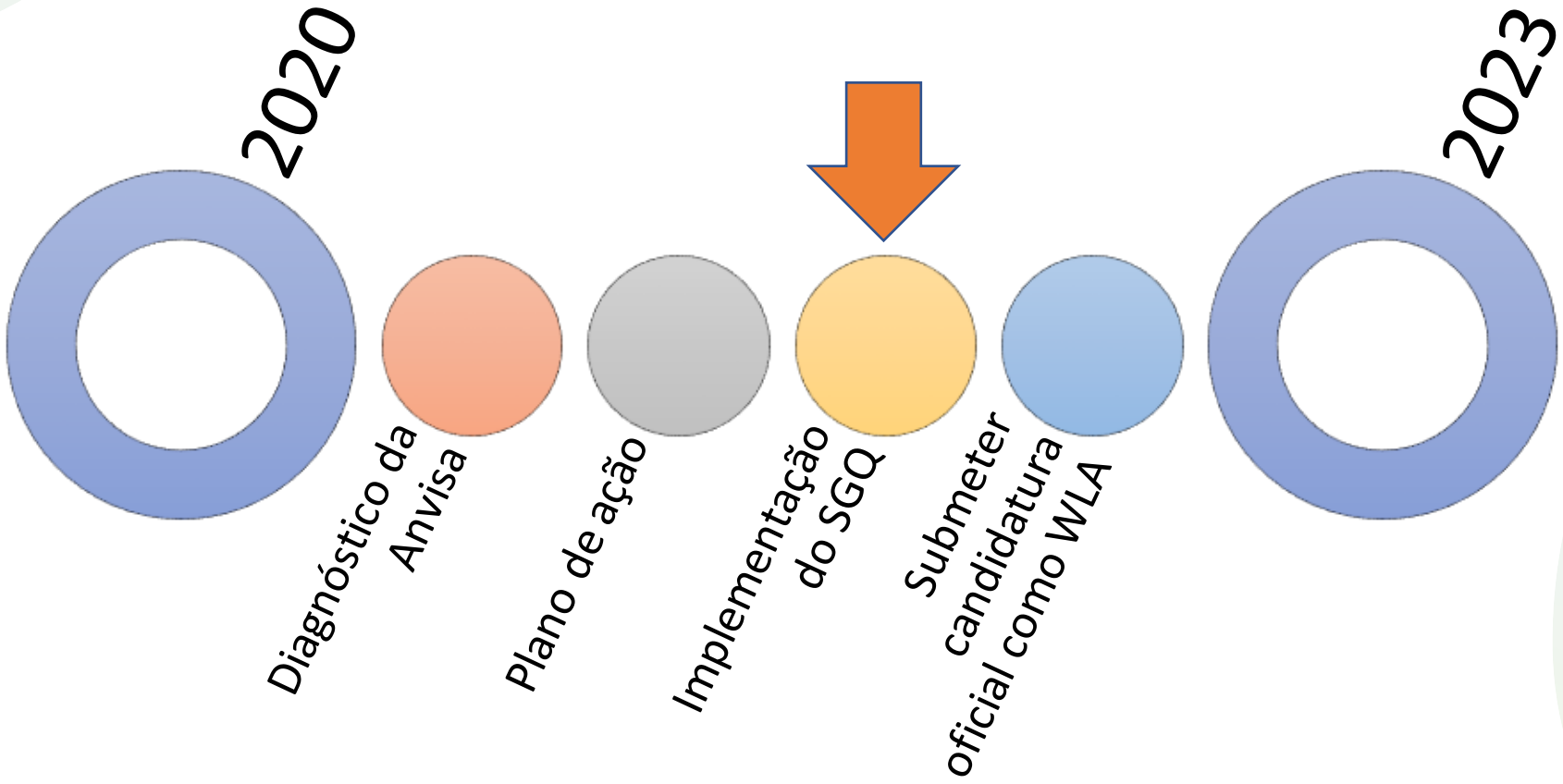
- https://www.who.int/initiatives/who-listed-authority-reg-authorities

Resultado da avaliação

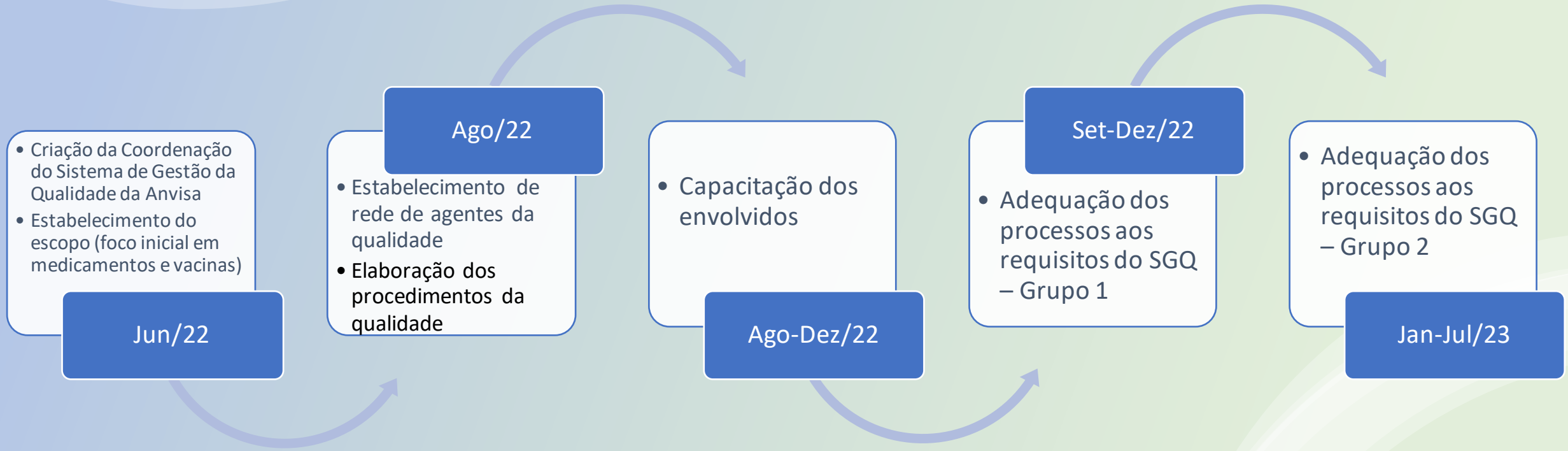


- Confiança da comunidade regulatória e de compras global
- Procedimento abreviado para PQ de medicamentos e vacinas

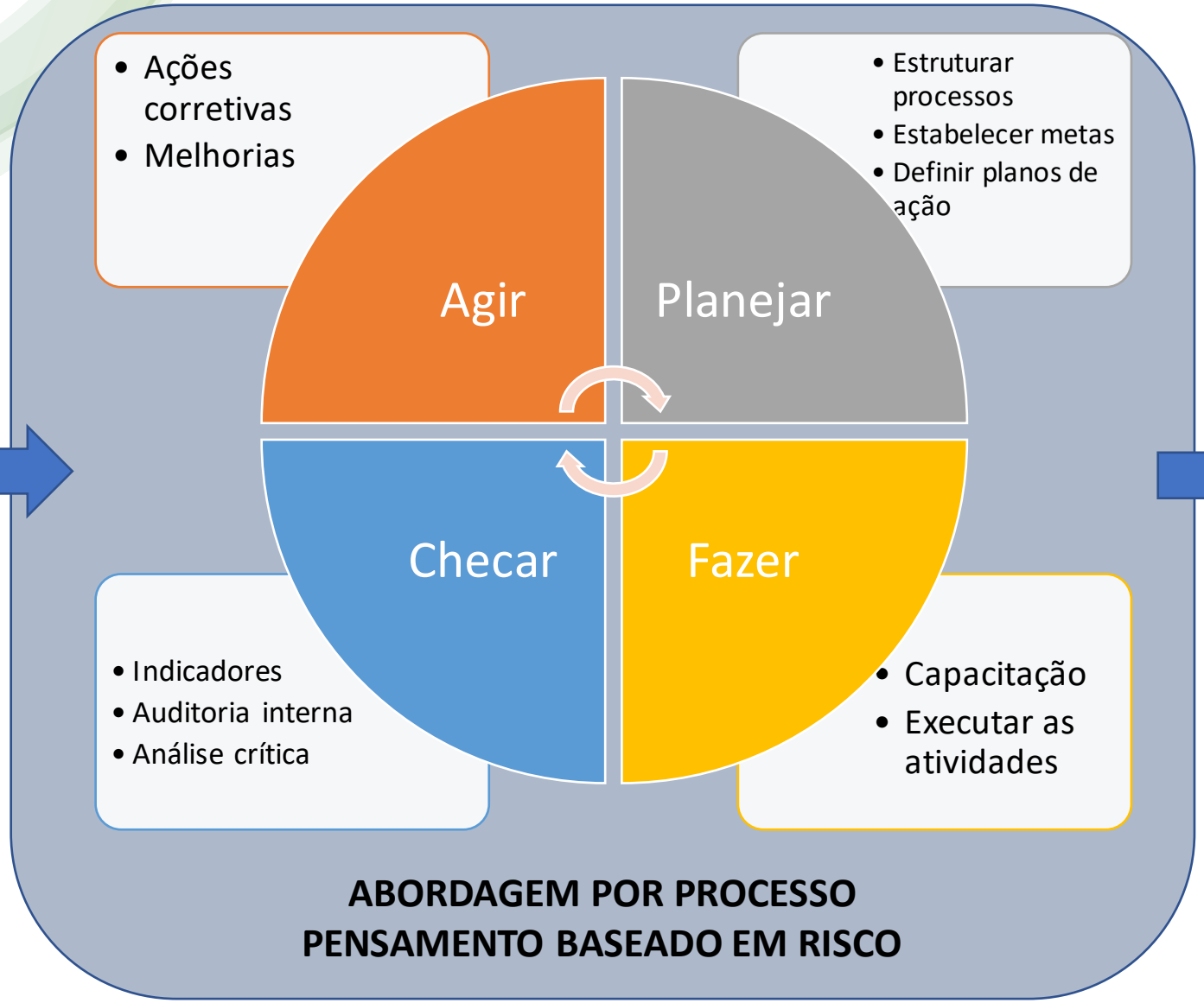
Projeto Estratégico - Avaliação da Anvisa como WHO Listed Authority (WLA)



Implantação do SGQ



Modelo do SGQ Anvisa



Necessidade dos cidadãos e partes interessadas

Produtos e serviços

Satisfação dos cidadãos e partes interessadas

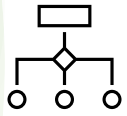
- ISO 9001:2015
- Guia OMS – Implementação de SGQ em Autoridade Sanitária Nacional
- Guia para Implantação de SGQ em unidades do SNVS
- Requisitos do GBT e PE

Critérios do GBT e PE para Farmacovigilância

Critérios do GBT para Farmacovigilância

6 indicadores divididos em 26 subindicadores:

1. Disposições legais, regulamentos e diretrizes necessárias para definir o marco regulatório da vigilância.



2. Arranjo para uma organização eficaz e boa governança.

3. Recursos humanos para realizar atividades de vigilância.

4. Procedimentos estabelecidos e implementados para realizar atividades de vigilância.

5. Mecanismo implementado para monitorar o desempenho e a produção regulatória.

6. Existe mecanismo para promover transparência, prestação de contas e comunicação

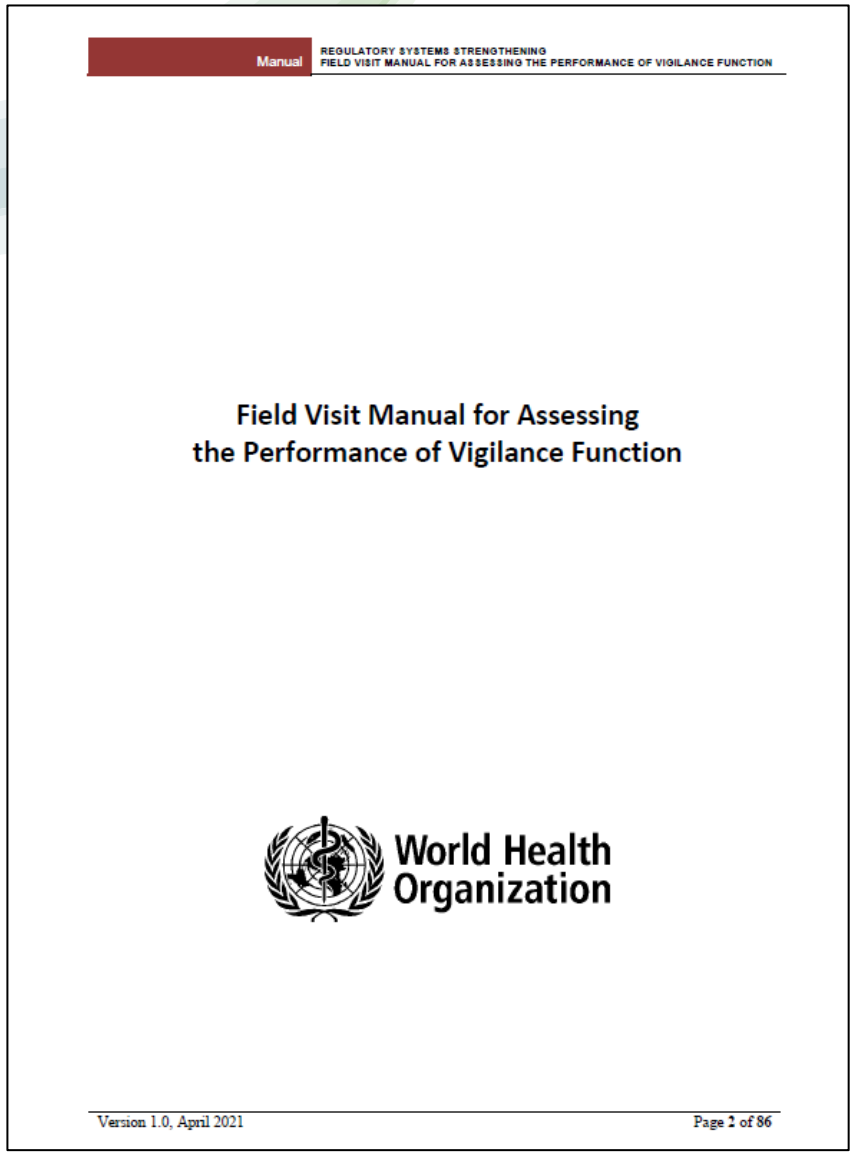
Critérios do PE para Farmacovigilância

7 indicadores de desempenho

1. Número total de notificações de reações adversas recebidas nos últimos três anos.
2. Percentual de relatórios anuais concluídos satisfatoriamente e apresentados ao centro nacional de vigilância nos últimos três anos.
3. Número de ações regulatórias tomadas nos últimos três anos como consequência de atividades nacionais de vigilância.
4. Percentual de produtos médicos registrados com plano de vigilância e/ou estratégia de gerenciamento de risco dos detentores de registro.
5. Percentual de produtos médicos registrados para os quais relatórios periódicos de atualização de segurança foram enviados e avaliados pela AR.
6. Número de produtos médicos registrados para os quais foram requeridos e avaliados estudos de segurança ou eficácia pós-comercialização nos últimos três anos.
7. Número de inspeções regulatórias de boas práticas de vigilância nos últimos três anos.

Evolução em números

Critérios do PE para 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)

Obrigada!

Coordenação do Sistema de Gestão da Qualidade da Anvisa

CSGQA/GADIP

csgqa@anvisa.gov.br