





# WLA – *WHO Listed Authorities* e implementação do SGQ na Anvisa

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# Contextualização



Projeto Estratégico - Avaliação da Anvisa  
como WHO Listed Authority (WLA)  
2020-2023



# Contextualização



Projeto Estratégico - Avaliação da Anvisa  
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2020-2023

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

Ajudar 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



# Contextualização



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

2020-2023

**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>

# 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)



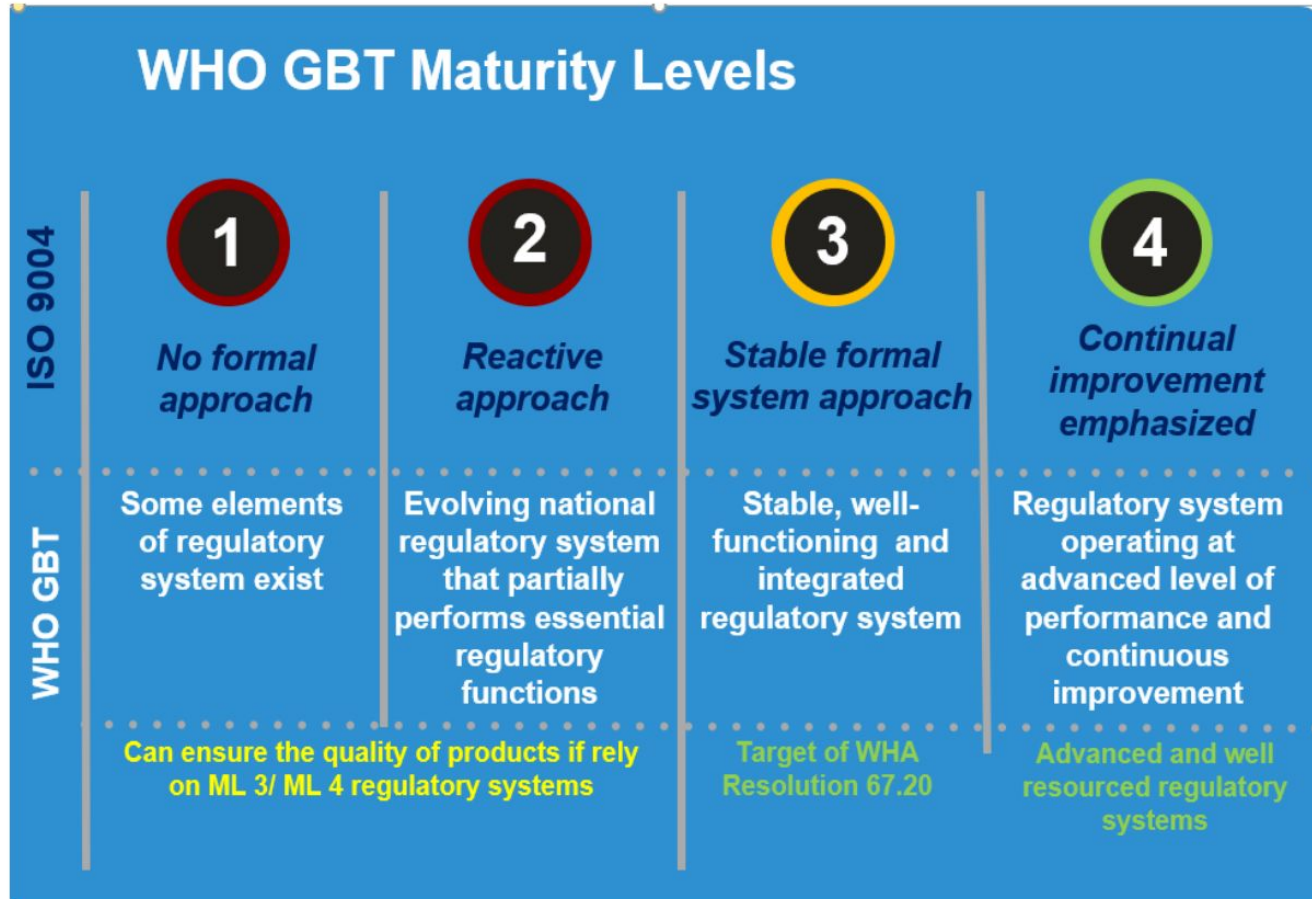
# Estrutura do GBT

<b>Function:</b>	<b>01- NATIONAL REGULATORY SYSTEM (RS)</b>
<b>Description:</b>	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.
<b>Indicator:</b>	<b>RS01 Legal provisions, regulations and guidelines required to define regulatory framework of national regulatory system (RS)</b>
<b>Objective:</b>	<p>The objective of this indicator is to ensure that the legal basis defining the regulatory framework for the national regulatory system exists.</p> <p>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.</p> <p>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.</p>
<b>Category:</b>	01. Legal provisions, regulations and guidelines
<b>Sub Indicator:</b>	<b>RS01.01: Legal provision and regulations define the medical products that should be regulated.</b>
<b>Maturity Level:</b>	1

<b>Scope:</b>	<ol style="list-style-type: none"> <li>1. Medicines</li> <li>2. Vaccines</li> <li>3. Blood Products (whole blood, blood components and plasma derived medicinal products (PDMPs))</li> </ol>
<b>Description:</b>	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.
<b>Objective:</b>	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.
<b>Requirement:</b>	Scope of regulated medical products
<b>Evidence to review:</b>	The assessor should request for and review: <ol style="list-style-type: none"> <li>1. Promulgated legal provisions and regulations that define the medical products that should be regulated.</li> </ol>
<b>References:</b>	<ol style="list-style-type: none"> <li>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), (<a href="http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf">http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf</a>)</li> <li>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), (<a href="http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf">http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf</a>)</li> <li>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), (<a href="http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf">http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf</a>)</li> <li>4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (<a href="http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf">http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf</a>)</li> </ol>
<b>Framework:</b>	Structure/Foundation/Input



# Níveis de Maturidade

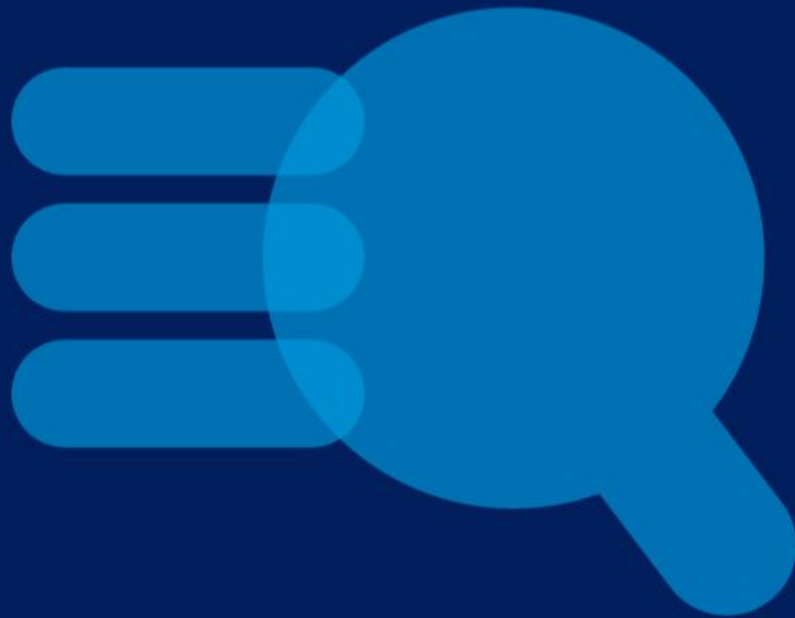


CONCEPT NOTE: A FRAMEWORK FOR EVALUATING AND PUBLICLY DESIGNATING REGULATORY AUTHORITIES AS WHO-LISTED AUTHORITIES – May 2019 – Draft for comments  
[https://www.who.int/docs/default-source/medicines/norms-and-standards/current-projects/qas19-808-who-listed-authorities.pdf?sfvrsn=e5b350f3\\_2](https://www.who.int/docs/default-source/medicines/norms-and-standards/current-projects/qas19-808-who-listed-authorities.pdf?sfvrsn=e5b350f3_2)





Operational guidance  
for evaluating and  
publicly designating  
regulatory authorities  
as WHO-listed  
authorities



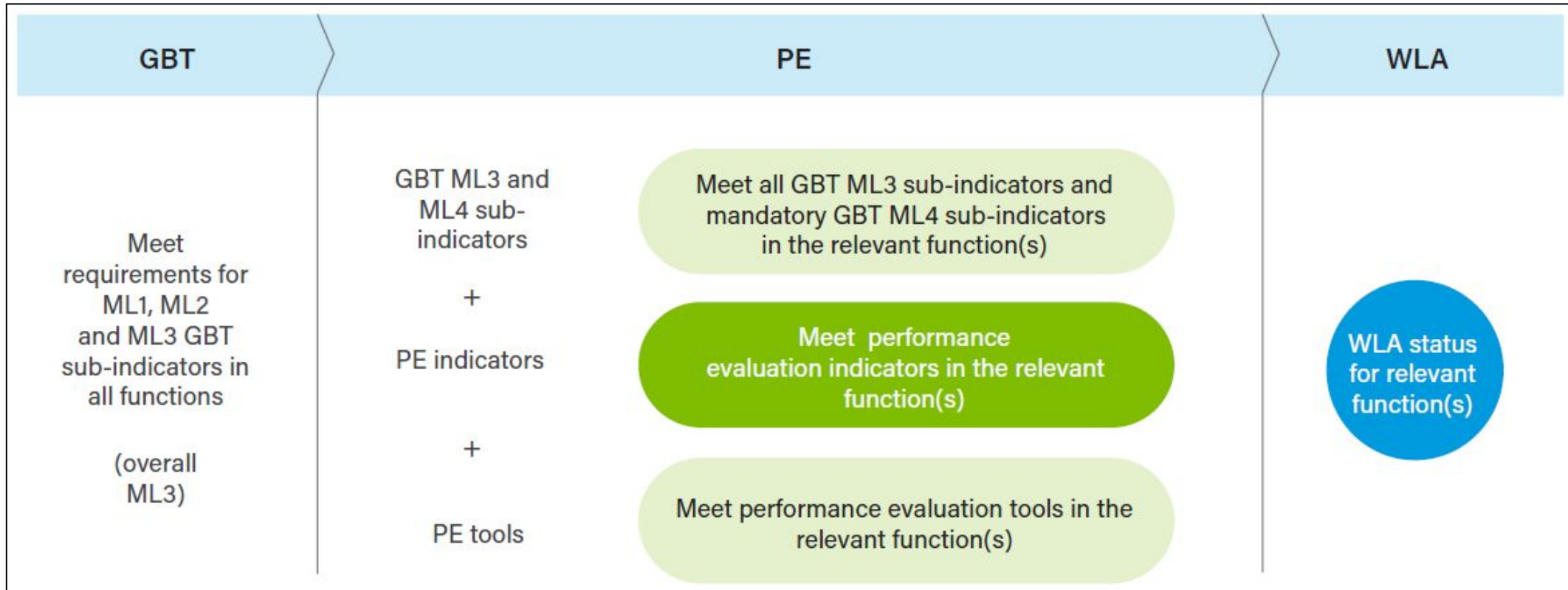
Manual for performance  
evaluation of regulatory  
authorities seeking  
designation as  
WHO-listed authorities



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



# Processo de Avaliação

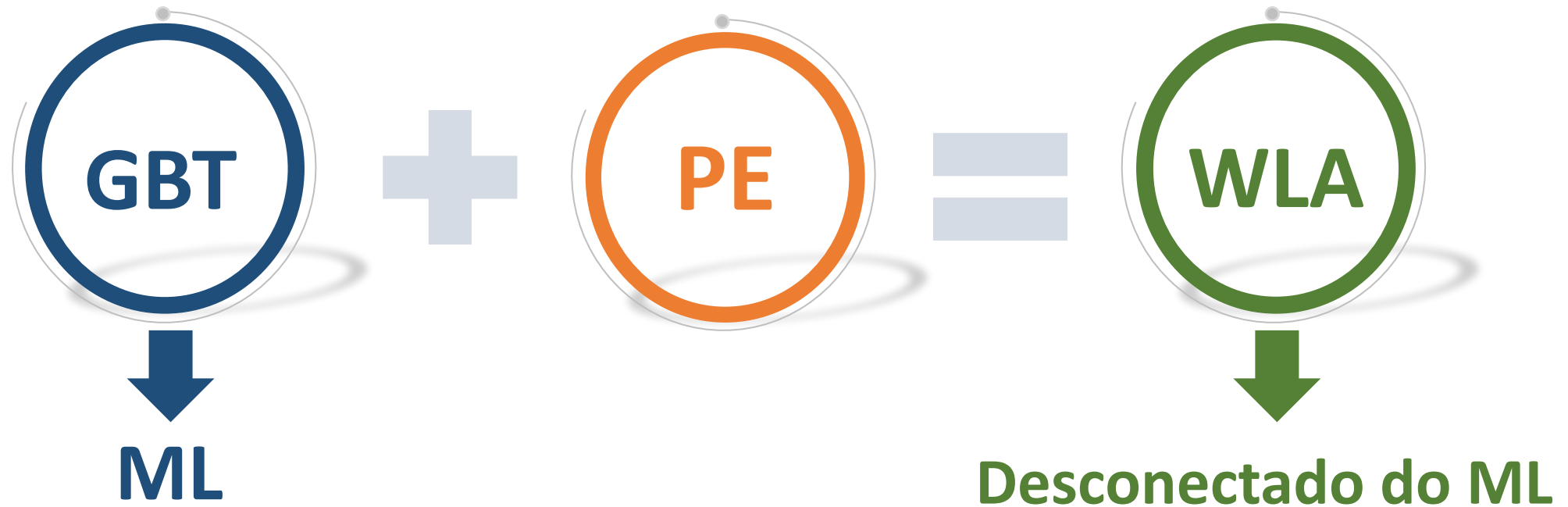


# Critérios de avaliação

Assessment category	Number of:		
	mandatory ML4 GBT sub-indicators	PE indicators	PE tools
Regulatory system (RS) <sup>a</sup>	14	4	-
Registration and marketing authorization (MA)	3	3	1
Vigilance (VL)	4	7	1
Market surveillance and control (MC) <sup>b</sup>	2	2	-
Licensing establishments (LI) <sup>c</sup>	2	-	-
Regulatory inspection (RI) <sup>d</sup>	5	-	1
Laboratory testing (LT)	3	1	1
Clinical trials oversight (CT)	2	3	1
Lot release (vaccines) (LR) <sup>e</sup>	1	-	-



# Como ser autoridade referência?



# Contextualização



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2020-2023



Diagnóstico da Anvisa - GBT  
2021

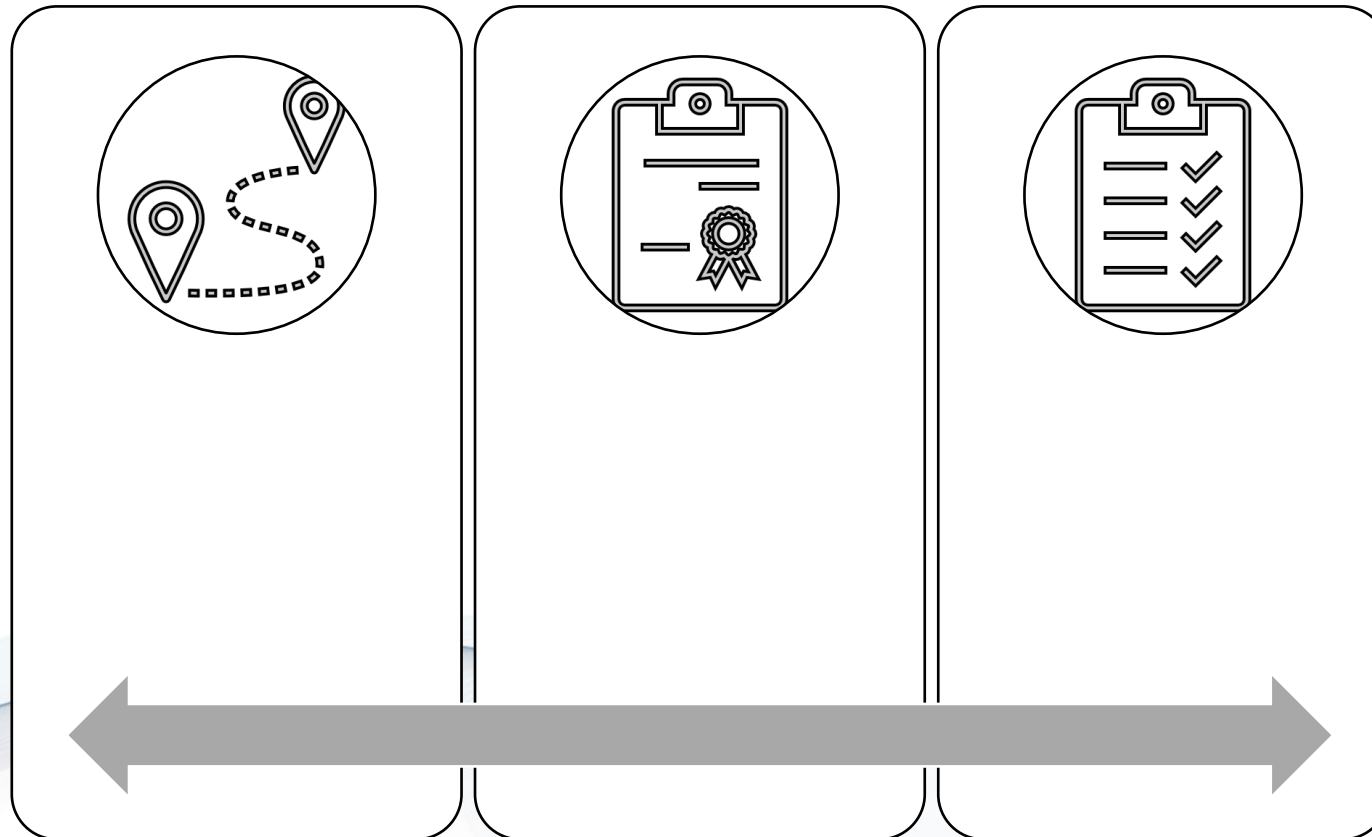


# Contextualização



Diagnóstico da Anvisa - GBT  
2021

## Considerações do GT



# Contextualização



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como WHO Listed Authority (WLA)  
2020-2023



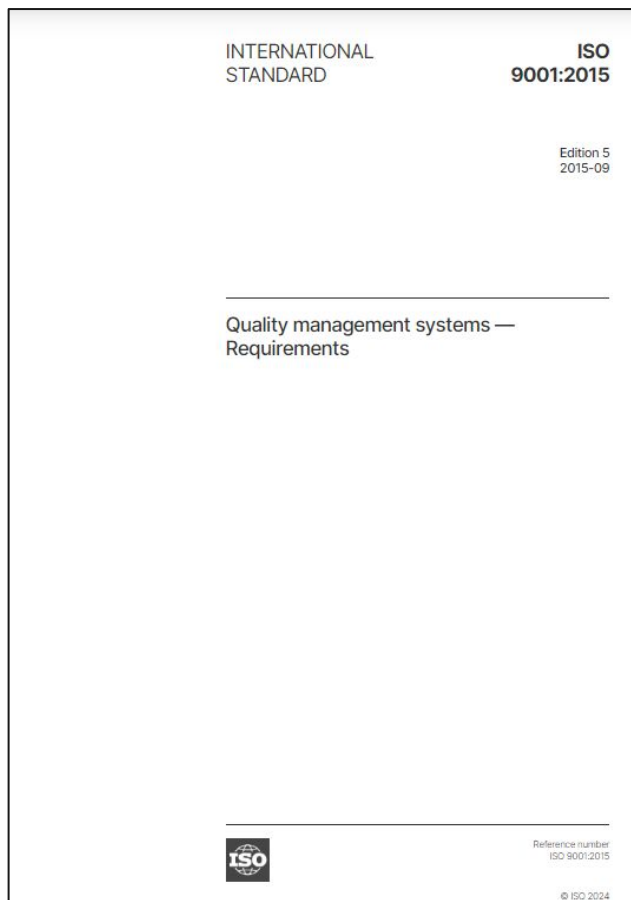
Diagnóstico da Anvisa - GBT  
2021



Criação da CSGQA  
Jun/2022



# Base para a estruturação do SGQ/Anvisa



## Annex 13

### WHO guideline on the implementation of quality management systems for national regulatory authorities

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Implementing quality management systems in national regulatory authorities:

Examples and practices

Guia para Implantação de Sistema de Gestão da Qualidade em Unidades do Sistema Nacional de Vigilância Sanitária

OSWALDO CRUZ ANVISA PROADESUS INSTITUTO FEDERAL DE GOV. FEDERAL





# Base para a estruturação do SGQ/Anvisa

## Iniciativas existentes

Política de Governança Organizacional

SGQ implantado na Gerência-Geral de Inspeção

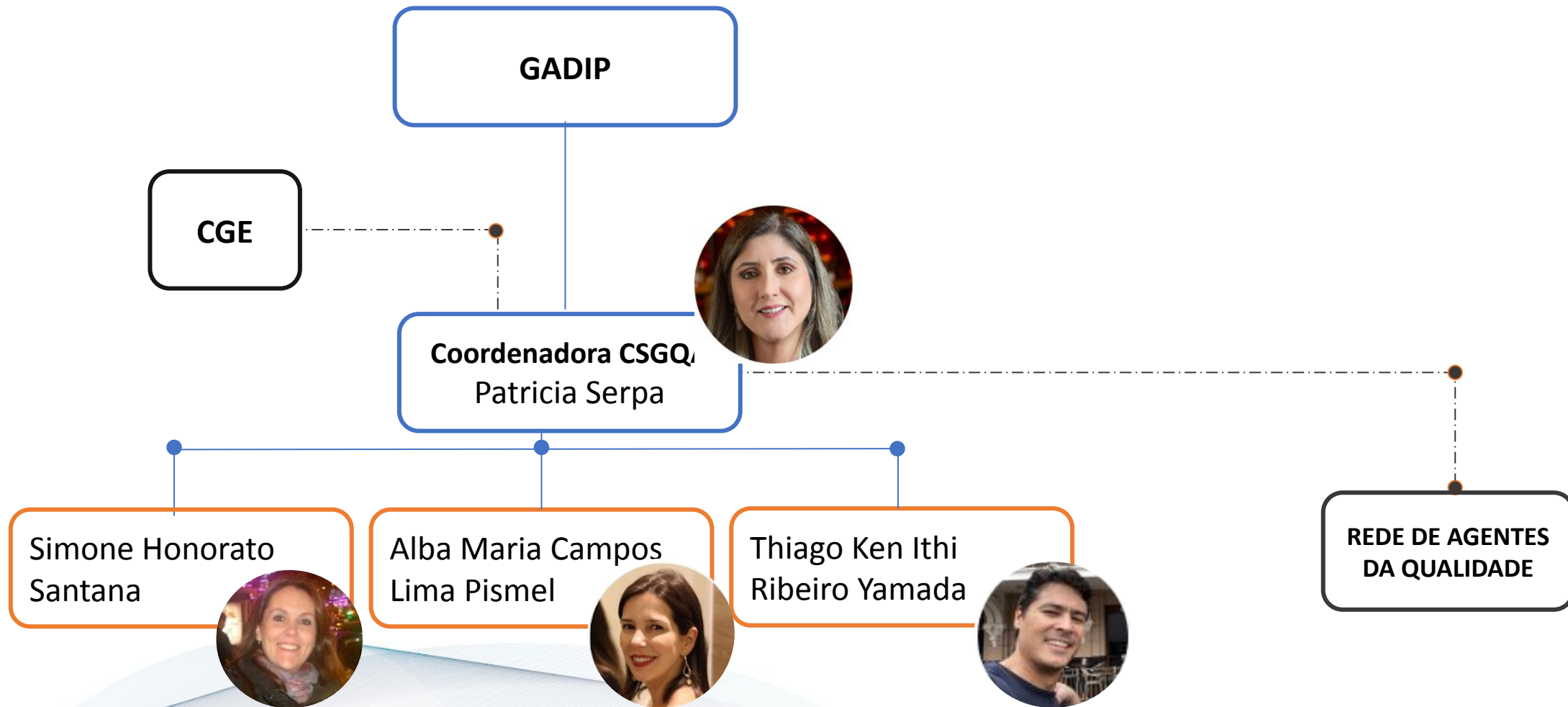
Estrutura de documentação em diversas unidades

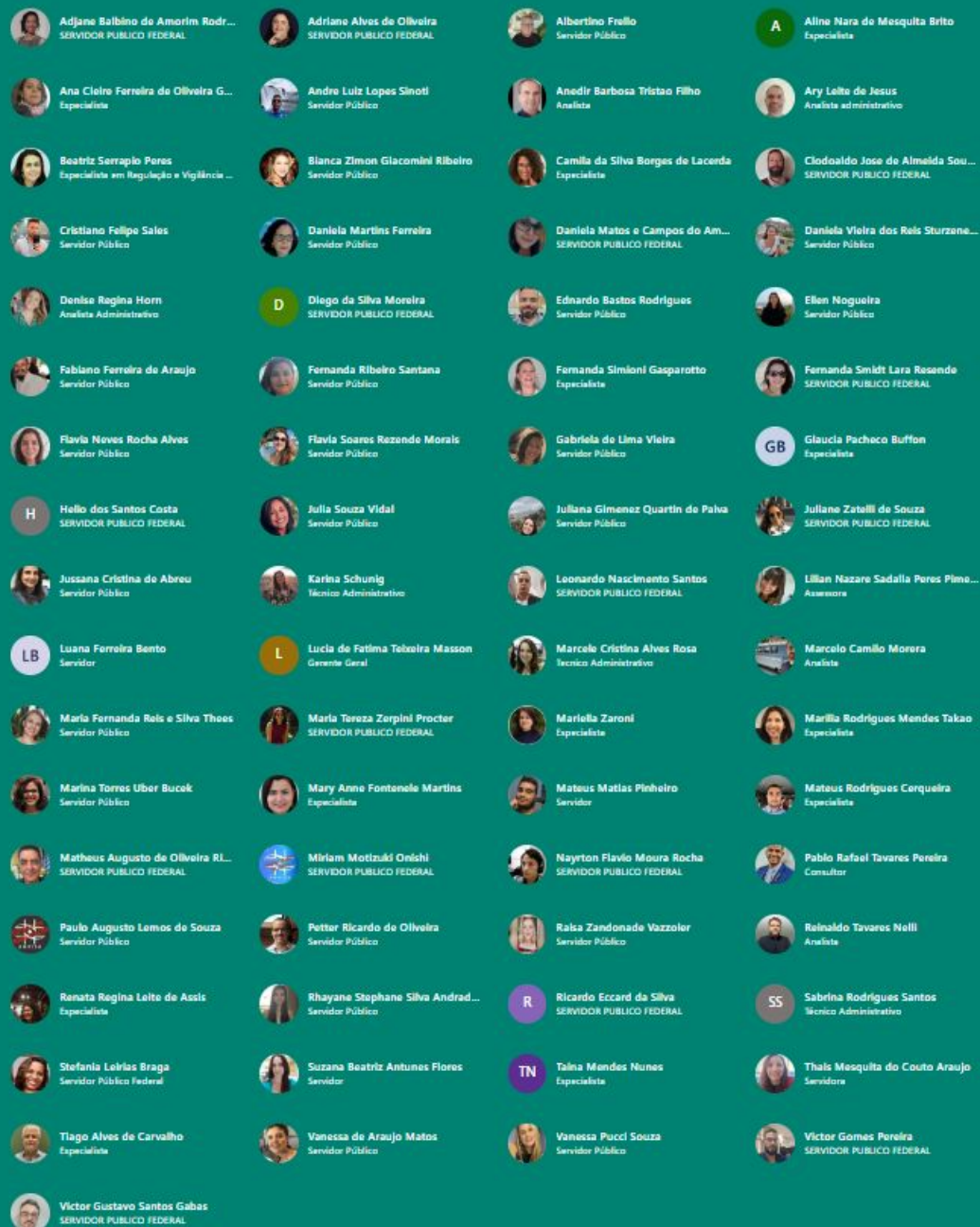
Cadeia de valor estruturada

Unidade especializada em mapeamento e melhoria de processos (CQUAL/Aplan)



# Estruturação da Área





# Estrutura da Qualidade

## REDE DE AGENTES DA QUALIDADE

PORTARIA 607/ANVISA – 05/08/22

Art. 3º São atribuições dos agentes da qualidade:

- I - promover a implantação local do SGQ;
- II - fornecer informações à CSGQA quanto à implementação do SGQ na unidade;
- III - participar dos cursos de capacitação promovidos pela CSGQA sobre SGQ;
- IV - auxiliar o gestor, com o apoio e supervisão da CSGQA, na operacionalização do SGQ na rotina da sua unidade;
- V - Desenvolver outras atribuições a serem definidas ao longo da implantação visando estabelecer e consolidar o SGQ.

# Escopo Inicial

CRITÉRIOS DO GBT & CADEIA DE VALOR  
105 PROCESSOS ENTRE 3º E 5º NÍVEL

## CADEIA DE VALOR INTEGRADA

Agência Nacional de Vigilância Sanitária

**MISSÃO**  
INSTITUCIONAL

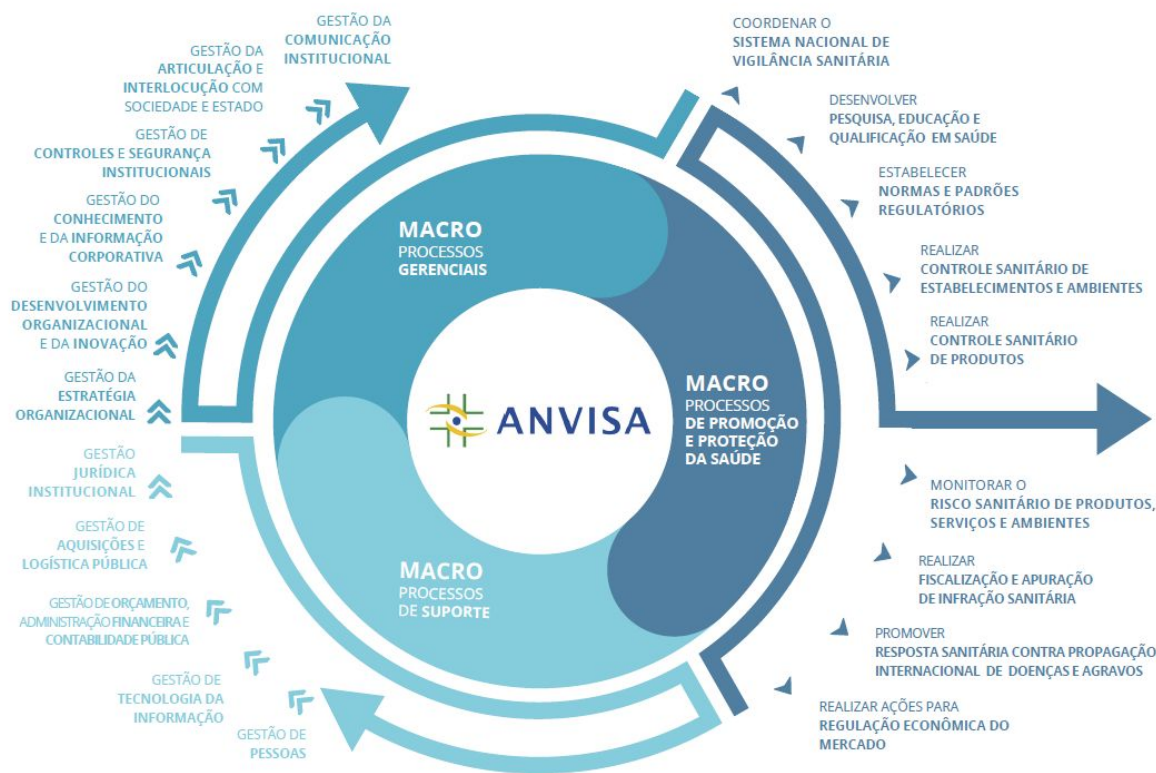
Proteger e promover a saúde da população, mediante a intervenção nos riscos decorrentes da produção e do uso de produtos e serviços sujeitos à vigilância sanitária, em ação coordenada e integrada no âmbito do Sistema Único de Saúde

**VISÃO**  
DE FUTURO

Ser uma instituição promotora da saúde, cidadania e desenvolvimento, que atua de forma ágil, eficiente e transparente, consolidando-se como protagonista no campo da regulação e do controle sanitário nacional e internacionalmente

**NOSSOS VALORES**

- Visão sistêmica
- Transparência e diálogo
- Ação articulada e integrada no SNVS
- Conhecimento como fonte de ação
- Excelência na prestação de serviços à sociedade



**VALORES PÚBLICOS**  
PARA A SOCIEDADE

**SEGURANÇA**  
SANITÁRIA

**ACESSO**  
A SERVIÇOS E PRODUTOS DE SAÚDE DE QUALIDADE

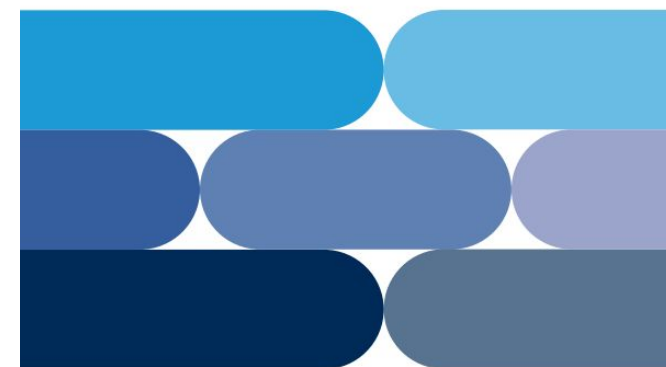
**CONFIANÇA** E PREVISIBILIDADE NO AMBIENTE REGULATÓRIO

**INFORMAÇÃO**  
PARA AUTONOMIA E CIDADANIA EM SAÚDE

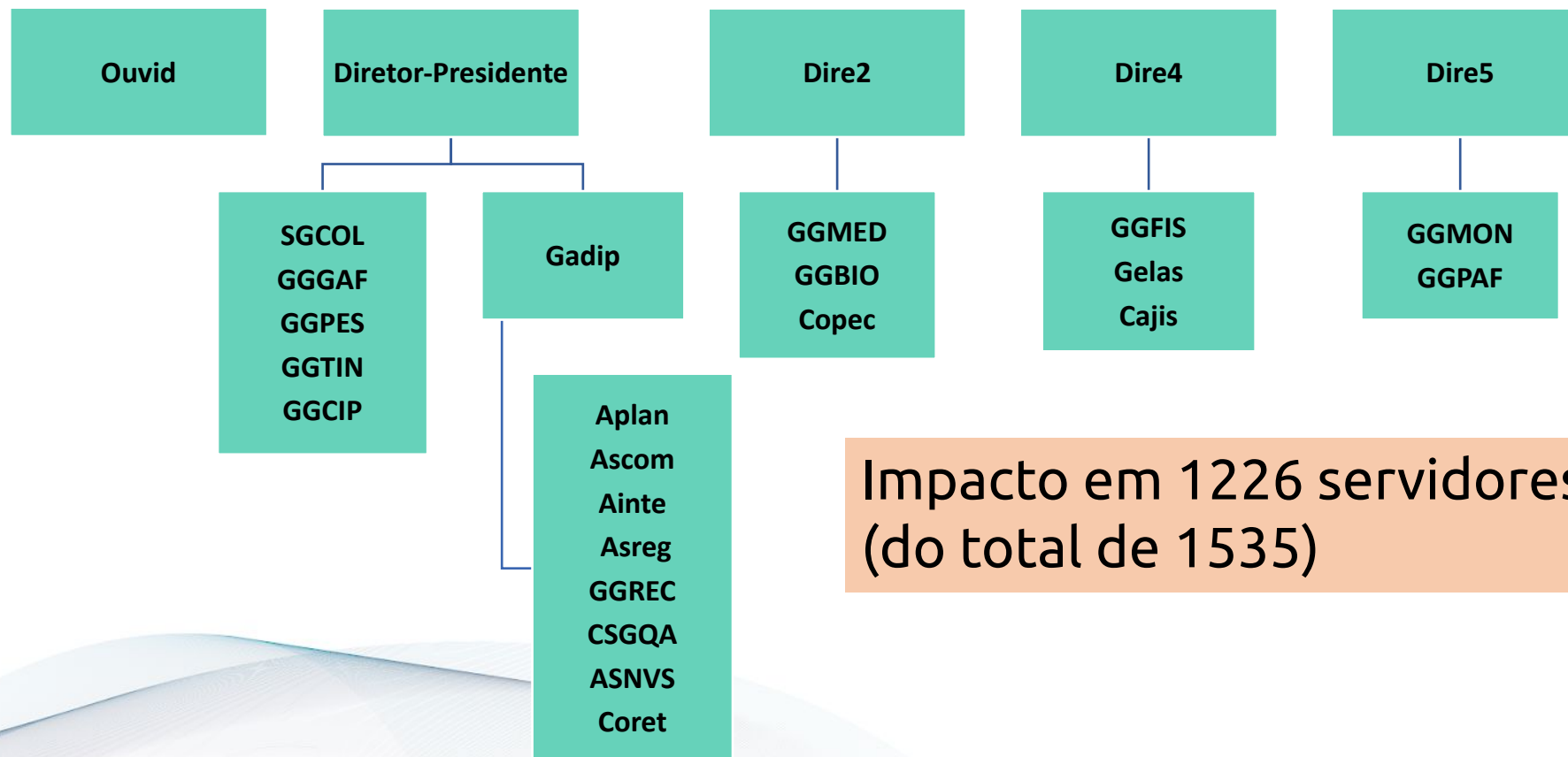
## WHO Global Benchmarking Tool (GBT)

for Evaluation of National Regulatory System of Medical Products

Revision VI

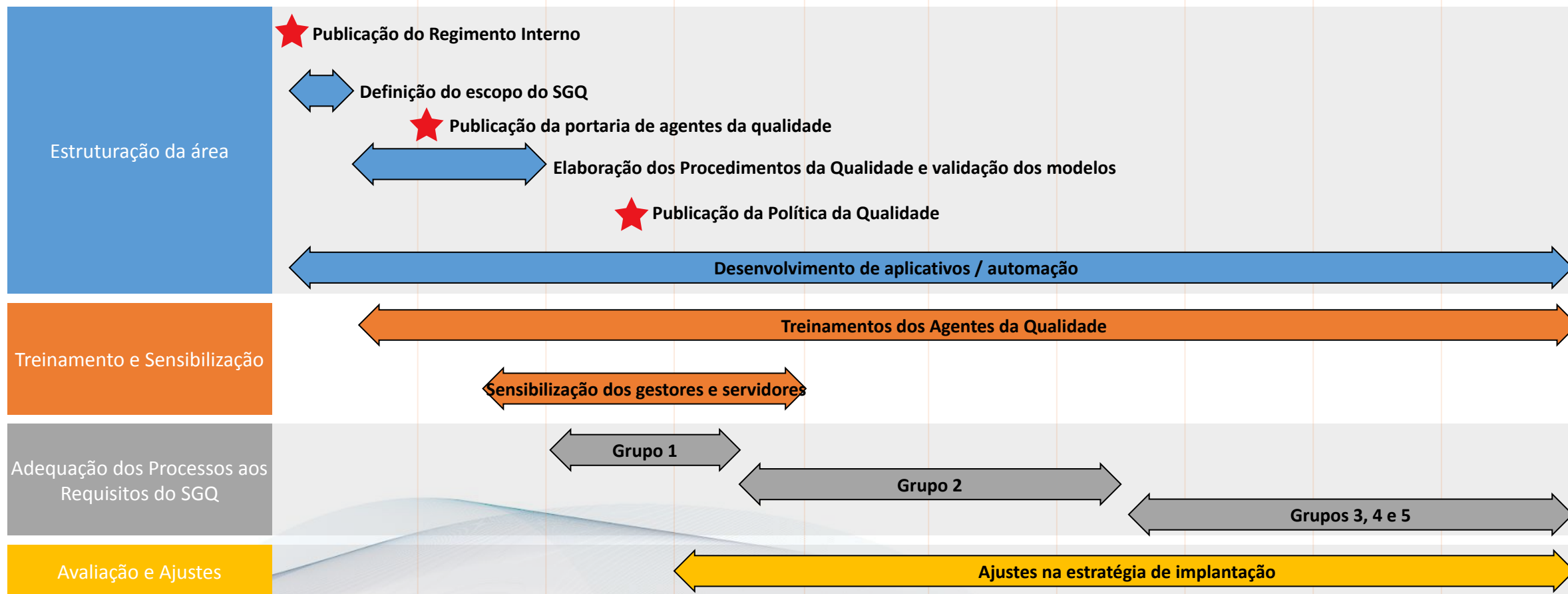


# Escopo Inicial

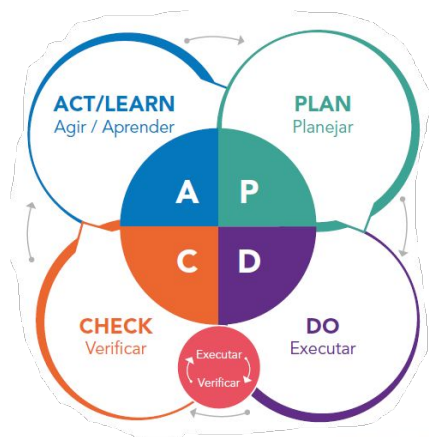


# Plano de Implantação

Ju	Aug	Out	De	Fe	Ap	Ju	Aug	Out	De
Q	Q	Q	Q	Q	Q	Q	Q	Q	Q
202	3	4	202	2	3	4	202	4	4



Tendência natural de acomodação:  
“mudança de “prioridades e foco gerencial”  
comum nas alternâncias de governos,  
rotatividades de gestores e lideranças nos  
cargos de direção, mudanças nas equipes  
técnicas, “crises” políticas institucionais ou  
orçamentárias, e a força de hábitos e rotinas  
antigas.”



# Manutenção e Expansão do SGQ

## • Compromisso ANVISA

### Plano Plurianual 2024-2027

- Incluir 90% dos processos de terceiro nível finalísticos da cadeia de valor da Anvisa no Sistema de Gestão da Qualidade.
- Atender 100% dos critérios de auditoria utilizados pela Organização Mundial da Saúde para auditar as autoridades sanitárias nacionais





**OBRIGADA!**