



sindus*farma*

Navigating Complexity: PGMP Implementation  
for Sterile Medicines During the Pandemic

# Agenda

- 1 Opening - Framing the Context
- 2 Background - What is PGMP?
- 3 The Challenge - Why Sterile Medicines?
- 4 Our PGMP Implementation Journey
- 5 Results and Regulatory Impact
- 6 Closing - Key Messages



# 1. Opening - Framing the Context

- Introduction and thanks
- Importance of regulatory agility during the pandemic
- Why PGMP matters for sterile medicines

# 2. Background - What is PGMP<sup>1</sup>?

- Regulatory tool aligned with ICH Q12 principles
- Enables pre-defined management of post-approval changes
- ANVISA is a Standing Regulatory Member of ICH
- RDC 690/22 (2022) established PGMP pilot for synthetic and semi-synthetic APIs
- Brazil's initiative reflects global alignment in change management

<sup>1</sup> - PGMP (Brazil) - Protocolo de Gerenciamento de Mudanças Pós-Registro  
PACMP (ICH) - Post-Approval Change Management Protocol

# 3. The Challenge - Why Sterile Medicines?

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- Stringent aseptic processes and validated sterile conditions
- Limited flexibility for post-approval changes without prior ANVISA approval
- Global shortage of sterilizing filters due to COVID-19 vaccine production
- Proactive engagement with ANVISA via Sindusfarma to define risk-based, temporary measures

# 4. Our PGMP Implementation Journey

- Step 1 Protocol: waiver of specific tests, risk mitigation, commitment to HMP\*
- Risk assessment: included compatibility, adsorption, extractables, and sterility support
- Step 2 Protocol: product-specific evidence submission; rapid coordination between production, QC and validation process
- Outcome: successful implementation of the new filter across 26 products

\* HMP - (Brazil) - *Histórico de Mudança de Produto* - *Product Change History*

# 5. Results and Regulatory Impact

- Ensured product supply and prevented shortages during the crisis
- Strengthened internal change management processes
- Improved regulatory communication and alignment
- For ANVISA: reduced number of protocols, faster reviews, maintained product quality and minimized market shortages



# 6. Closing - Key Messages

- PGMP enables efficiency and regulatory predictability
- Collaboration with ANVISA and Sindusfarma was key to success
- The pandemic accelerated sustainable regulatory innovation





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Thank you!