

# WHO PQ Variations Assistant

**AI-powered chatbot to navigate WHO Prequalification variations  
guidance  
(FAQ Variation Document)**

# The problem & opportunity

## The problem

The WHO FAQ Variation document provides additional guidance addressing context and situations not covered by the main variation guideline (WHO TRS 981 annex 3) and reflecting current practices based on experience gained. It is designed to be regularly updated for use by both applicants and dossier assessors.

- WHO PQ variation FAQ is **lengthy and technical**, making navigation difficult.
- Manual searching leads to **delays and inconsistent interpretations**.
- Growing need for **real-time, accurate guidance** for global stakeholders.

## The opportunity

- Streamline access to WHO guidelines (TRS 981 Annex 3) and FAQs through the development of **WHO PQ Variation Assistant Chatbot**

The WHO PQ Variations Assistant is an intelligent, interactive chatbot designed to streamline access to guidance on variations to prequalified pharmaceutical products. Its core mission is to support applicants and assessors by providing instant, accurate, and context-aware responses based on the WHO Prequalification Programme's FAQ document and related guidelines (TRS 981 Annex 3).

# Solution & workflow

- **Solution: WHO PQ Variations Assistant**
  - Intelligent chatbot hosted on Botpress
  - Provides instant, context-aware answers aligned with WHO Variation FAQ document
  - Links to relevant WHO resources, templates and forms
  - Tone tailored to WHO: professional, clear, helpful
- **Workflow (high level)**
  - User asks a regulatory question (e.g., variation classification.. “Is variation 28c minor or major?”)
  - NLU interprets intent & entities; maps to FAQ/guidance sections
  - Retrieval & reasoning generate a tailored, compliant response
  - Feedback captured to improve future answers; content updated as FAQs change

# Key features & AI tools used

- **AI & platform components**
  - Botpress as the conversational platform
  - LLM-powered understanding and response generation
  - Retrieval over the WHO PQ Variations FAQ document
  - Entity recognition and intent classification
  - Analytics for usage insights and content gaps

# Demonstration

AI Support Assistant

Share

2025-10-31

I'm not sure how to classify a change in the manufacturing process of my FPP. It's not listed in the guideline.

If a change in the manufacturing process of your Finished Pharmaceutical Product (FPP) is not listed in the WHO guideline, it can be categorized with the suffix "u" within the most relevant classification. For example, if the change does not meet the conditions of existing categories like #31a or #31b, it may be submitted as #31u, which could be a major change by default, or an unclassified minor variation if you believe the change will not significantly affect the safety, efficacy, and quality of the product.

Today

Is variation 28c minor or major?

Delivered

Variation 28c is classified as a minor variation [Vmin].

Type your message...



Try Botpress

<https://cdn.botpress.cloud/webchat/v3.3/shareable.html?configUrl=https://files.bpcontent.cloud/2025/10/30/22/20251030223104-W707Z6GK.json>

# Current limitations & opportunities

- **Current limitations**
  - Dependent on FAQ completeness and update cadence
  - Not a substitute for official decisions or legal interpretation
  - Edge cases/Complex queries may require human intervention
  - Multilingual support contingent on validated translations
  - Requires governance for versioning and change control
  - Limited integration with external WHO systems for real-time validation.
- **Opportunities for improvement**
  - Deeper integration with WHO templates and submission portals
  - Human-in-the-loop review workflows for complex scenarios
  - Expanded coverage to other WHO guidance documents
  - Enable voice interaction for accessibility.
  - Proactive ‘what changed’ notifications when FAQs update
  - Continuous evaluation and user feedback loops

# Impact at a glance

- Faster, more consistent answers for applicants and assessors
- Reduced workload for WHO teams; better-quality submissions
- Scalable, update-ready assistant aligned to WHO expectations