

## Enhance *regulatory success*

Empower regulatory affairs specialists, drug development professionals and clinical researchers with easy access to regulatory precedents for effective regulatory planning throughout the drug life cycle.

### An AI tool trained on:

- FDA approval packages since 1938
- EMA approval documents since 1995
- FDA Advisory Committee documents since 1981
- Meyler's Side Effects of Drugs 16th edition



### How it works



Ask your questions



Interprets the question and rephrases to improve response quality



Retrieves and ranks all relevant snippets across millions of documents



LLM processes top 10 snippets



Provides summary response with in-line references



# Gathering *regulatory insights* has never been easier

The screenshot displays the PharmaPendium AI interface with a workflow of six steps:

- 1. Ask a question:** A user asks in Japanese, "米国でUCに対するアダリムマブの承認前に審査官からどのような反対意見があったか (表形式)".
- 2. Interpretation:** The system interprets the question as: "What were the objections raised by the reviewers before the approval of Adalimumab for Ulcerative Colitis in the United States?".
- 3. Response:** The system provides a table summarizing objections and references to the original document.
- 4. Table:**

Objection	Details	Source
<b>Safety Concerns</b>	Serious infections and malignancies were highlighted, including tuberculosis, bacterial sepsis, invasive fungal infections, hepatosplenic T-cell lymphoma, and other lymphomas and malignancies. There were also warnings about hypersensitivity reactions, Hepatitis B virus reactivation, demyelinating disease, cytopenias, heart failure, autoimmunity, use with live vaccines, and use with abatacept.	[1]
<b>Efficacy Concerns</b>	The efficacy of adalimumab in patients who stopped responding to or could not tolerate TNF-blocker medicines was questioned.	[2]
<b>Regulatory History</b>	The regulatory history of ulcerative colitis in the United States was discussed, including the clinical development program and study designs.	[3]
- 5. Reference:** A link to the original document is provided: "1. Approval Package 125057/S-232 Part 07, 28-Sep-2012 | FDA approval packages".
- 6. Follow-up:** A button labeled "Ask a follow-up question" is shown.

## Intuitive experience

1. Ask natural language questions in multiple languages including English, Japanese, Korean, French and Spanish.
2. Request responses in a variety of formats including table, free text, bullet points and CSV.
3. Easily search through previous responses within your history.

## Transparent searching

4. Review how a question was interpreted to gain clarity and improve responses.
5. Provides in-line references to allow users to dive into the original regulatory document and verify the response.
6. Ask follow-up questions to refine your search and gather more regulatory insights.

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