1

Is it safe and how has safety been verified?

Ensure the ingredient is supported by safety data published in a peer-reviewed journal and has been reviewed by the appropriate leading regulatory agencies.

2

Has the mechanism of action been explained, defined, or published?

Studies should be conducted in a manner that demonstrates the mechanism of action as measured by its effect on the immune system.
•

3

Is the ingredient an immune stimulator or immune modulator?

Look for ingredients that have a demonstrated ability to help strengthen the body's natural immune mechanisms or maintain immune system balance, and can be taken year-round. 4

What is the quality and quantity of the clinical research?

Look for multiple peer-reviewed, published, high-quality clinical studies with consistent outcomes.

5

How was the clinical study designed?

Study designs that are doubleblind and placebo-controlled are the gold standard.

10 QUESTIONS TO ASK

when evaluating an immune health ingredient.



When evaluating an immune health ingredient, focus on the research. Quality research is the key to understanding and communicating the safety of an ingredient, how it works, and its benefits – all of which help deliver products consumers can trust and value.

6

Was the research conducted on the actual ingredient?

Efficacy of a functional ingredient is affected by its chemical structure, which varies by biological strain. It is inaccurate to generalize results conducted on a different strain or non-identical ingredient.



What kind of outcomes were described in the study?

Primary outcomes of scientific and regulatory interest relate to biomarkers and physical health. The results of human clinical studies should show a demonstrable positive benefit in humans.



Is the ingredient well-characterized?

Ingredient characterization allows for consistency in manufacturing, stability, and shelf-life testing. It also provides confidence that the ingredient's efficacy and stability is the same from batch-to-batch.



How is serving size determined?

Ensure that the ingredient's serving size response data supports the recommended daily serving.

10

What are the formulation characteristics?

It is critical that appropriate analytical methods be available to quantify the amount of the ingredient present in a finished product after processing and at the end of the projected shelf life of the product.

