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REGULATORY · FIRST-IN-HUMAN DOSE

The first human dose, informed by a QSP model.

What FDA's new QSP draft guidance asks sponsors to show.

SWIPE →

QSP for the starting dose.

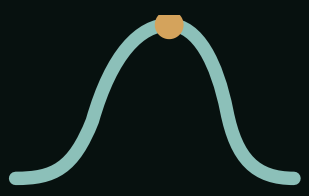
CDER draft guidance, June 2026, part of FDA's push to speed development from IND to pivotal trial. Where MABEL applies, a QSP model can inform the first-in-human dose, together with all other available data.

The ICH M15 way.

- The question of interest and the context of use
- A model risk assessment
- Validation, sensitivity and uncertainty analyses

In life-threatening disease, a higher start may be justified.

MABEL is a low-end dose. In some cases, a QSP model can help find a minimal active dose above it. For novel targets without precedent, if estimates disagree, FDA asks for the lowest.



Find the faster path through drug development.

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