

QUALITY GUIDE

Quality System Scope and Batch Consistency

A restrained overview of quality-system, batch-consistency and document-review questions for material qualification.

Technical reading for preliminary material evaluation. This article does not describe a measured Kannrybio batch, certify a production site or establish suitability for a finished medical device.

01 Define the scope before relying on a certificate

ISO 13485:2016 is a quality management system standard for medical devices. When reviewing any certificate, check the named legal entity, site address, certified activities, issuing body and validity. A certificate from one location does not establish the status of another location.

02 Trace the material, not just the label

Ask how raw materials, manufacturing records, inspection results and the finished lot are linked. Determine which characteristics are release tests and which are development or reference measurements. Confirm the grade and lot on every record.

03 Compare batches on the same basis

A trend is interpretable only when sampling, methods and acceptance criteria are comparable. For α/β phase or a silicate polymorph, retain the phase name and analysis method; for PSD, retain the dispersant and measurement basis. A single typical value cannot demonstrate batch consistency.

04 Agree on changes

For a regulated development program, clarify how changes to manufacturing site, process, source material or test method will be evaluated and communicated. The device manufacturer remains responsible for its own qualification and regulatory decision.

FURTHER READING

ISO 13485:2016, ISO