PUBLIC SCIENTIFIC DOCUMENT

Technical documentation: from client brief to manufacturing readiness

What a development partner should generate, control and hand over.

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Educational and business-development publication. It does not replace product-specific development, risk assessment, current official guidance, regulatory review, validated methods, stability data or professional clinical judgement.

ΕΛΛΗΝΙΚΗ ΕΚΔΟΣΗ

Ο ρόλος του brief

Ένα καλό brief δεν είναι εμπορική περιγραφή. Ορίζει intended use, target population, market, dosage form, strength, route, pack, target shelf life, claims/positioning, constraints, reference products, target batch size και decision owners. Όσα παραμένουν ασαφή καταγράφονται ως assumptions ή open questions.

Development knowledge package

Κατά την ανάπτυξη πρέπει να δημιουργείται controlled body of knowledge και όχι μόνο μία συνταγή. Περιλαμβάνει formula versions, rationale επιλογής υλών, supplier/grade decisions, risk assessments, development trials, failures, observations, analytical results, compatibility, packaging selection και stability protocol/results.

Analytical development

Η αναλυτική στρατηγική πρέπει να είναι κατάλληλη για το στάδιο του έργου. Τα methods εξελίσσονται από fit-for-purpose development methods σε transferred/validated ή verified methods σύμφωνα με την κατηγορία προϊόντος και τις απαιτήσεις του project. Τα specifications δεν πρέπει να αντιγράφονται μηχανικά από γενικές πηγές.

Manufacturing readiness

Πριν από το industrial batch απαιτούνται frozen ή ελεγχόμενα formula inputs, εγκεκριμένες πρώτες ύλες/grades, equipment assessment, process instructions, IPCs, sampling, theoretical yield, reconciliation, packaging components, cleaning approach, line clearance και deviation/escalation rules.

Διασύνδεση με RA/MAH

Ο contract development/manufacturing partner παράγει τεχνικά δεδομένα και documentation που υποστηρίζουν τον φάκελο και τη μεταβολή παραγωγού. Η regulatory strategy και η ευθύνη της κατάθεσης παραμένουν στο RA/MAH σχήμα που έχει ορίσει ο πελάτης. Η συνεργασία πρέπει να ξεκινά νωρίς ώστε development, dossier και manufacturing να μη diverge.

Handover και lifecycle

Η ολοκλήρωση δεν είναι η αποστολή ενός PDF. Είναι controlled handover με version status, approvals, open commitments, stability follow-up, change control, knowledge retention και ορισμό δεδομένων που θα επιστρέφουν από commercial batches στο product/process knowledge.

ENGLISH VERSION

The role of the brief

A sound brief is not a marketing description. It defines intended use, target population, market, dosage form, strength, route, pack, target shelf life, claims/positioning, constraints, reference products, target batch size and decision owners. Unresolved matters are recorded as assumptions or open questions.

Development knowledge package

Development should create a controlled body of knowledge, not just a formula. It includes formula versions, raw-material and supplier rationale, risk assessments, development trials, failures, observations, analytical results, compatibility, packaging selection and stability protocols/results.

Analytical development

The analytical strategy must fit the project stage. Methods evolve from fit-for-purpose development methods to transferred, validated or verified methods according to product category and project requirements. Specifications should not be copied mechanically from generic sources.

Manufacturing readiness

Before an industrial batch, controlled formula inputs, approved grades, equipment assessment, process instructions, IPCs, sampling, theoretical yield, reconciliation, packaging components, cleaning approach, line clearance and deviation/escalation rules are needed.

Interface with RA/MAH

A contract development/manufacturing partner generates technical data and documentation that support the dossier and manufacturing-site changes. Regulatory strategy and submission responsibility remain with the client-appointed RA/MAH structure. Early collaboration prevents divergence between development, dossier and manufacturing.

Handover and lifecycle

Completion is not the delivery of one PDF. It is a controlled handover with version status, approvals, open commitments, stability follow-up, change control, knowledge retention and a defined feedback loop from commercial batches.

Selected references and standards

ICH Q8(R2), Pharmaceutical Development, International Council for Harmonisation.

ICH Q9(R1), Quality Risk Management, International Council for Harmonisation.

ICH Q10, Pharmaceutical Quality System, International Council for Harmonisation.

European Commission, EudraLex Volume 4, EU Guidelines for Good Manufacturing Practice.

EU GMP Annex 15, Qualification and Validation.

FIP/WHO, Joint Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services.