PUBLIC SCIENTIFIC DOCUMENT

Two-site development and manufacturing platform

How complementary facilities can support development, scale-up and capacity planning.

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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

Πλαίσιο

Η Sikalias Pharmaceutical Laboratories λειτουργεί δύο συμπληρωματικές εγκαταστάσεις στο Περιστέρι. Το Site 0 στην Κυκλαμίνων 7 διαθέτει GMP certificate για το εγκεκριμένο πεδίο μη στείρων φαρμακευτικών προϊόντων ανθρώπινης χρήσης και υπό έρευνα. Το Site 1 στη Στυλιανού Γονατά 3-5 διαθέτει άδεια δυνατότητας παραγωγής ΕΟΦ για ευρύτερο εύρος μη στείρων μορφών. Η ακριβής δημόσια διατύπωση πρέπει να επικαιροποιηθεί όταν εκδοθεί και ανασκοπηθεί το ξεχωριστό GMP certificate του Site 1.

Development-to-manufacturing flow

Το operating model συνδέει client brief, formulation development, analytical work, stability, pilot/engineering work, scale-up, technical documentation και manufacturing. Το regulatory office/MAH που έχει ορίσει ο πελάτης διατηρεί τη regulatory strategy και submission responsibility.

Τεχνική ευελιξία

Οι εγκαταστάσεις υποστηρίζουν liquid, semi-solid και επιλεγμένες solid dosage-form εφαρμογές ανάλογα με το αδειοδοτημένο scope, τον εξοπλισμό και την project-specific readiness. Οι δυνατότητες χαμηλής υγρασίας, αυτοματοποίησης, ελεγχόμενου handling και χρήσης αζώτου μπορούν να αποτελέσουν σημαντικά process tools όταν δικαιολογούνται από το συγκεκριμένο formulation.

Continuity planning

Δύο sites ενισχύουν capacity planning, batch-size flexibility και operational resilience. Δεν αποτελούν αυτομάτως validated back-up για κάθε προϊόν. Η εναλλακτική παραγωγή συγκεκριμένου προϊόντος απαιτεί αδειοδότηση, dossier alignment, qualified equipment, validation και approved change control.

Quality framework

Η δημόσια τεκμηρίωση πρέπει να διαχωρίζει GMP certificates, manufacturing authorisations και management-system certificates. Τα ISO 9001:2015, ISO 13485:2016 και ISO 22716:2007 υποστηρίζουν το ευρύτερο quality framework, αλλά δεν αντικαθιστούν το product/site-specific GMP scope.

ENGLISH VERSION

Framework

Sikalias Pharmaceutical Laboratories operates two complementary facilities in Peristeri. Site 0 at 7 Kyklaminon holds a GMP certificate for its approved scope of non-sterile human and investigational medicinal products. Site 1 at 3-5 Stylianou Gonata holds an EOF production-capability authorisation for a broader range of non-sterile dosage forms. Public wording should be updated when the separate Site 1 GMP certificate is issued and reviewed.

Development-to-manufacturing flow

The operating model connects client brief, formulation development, analytical work, stability, pilot/engineering work, scale-up, technical documentation and manufacturing. The client-appointed regulatory office/MAH retains regulatory strategy and submission responsibility.

Technical flexibility

The facilities support liquid, semi-solid and selected solid dosage-form applications according to authorised scope, equipment and project-specific readiness. Low-humidity capability, automation, controlled handling and nitrogen may be valuable process tools when justified by the formulation.

Continuity planning

Two sites strengthen capacity planning, batch-size flexibility and operational resilience. They are not automatically validated back-up sites for every product. Alternative production requires authorisation, dossier alignment, qualified equipment, validation and approved change control.

Quality framework

Public documentation should distinguish GMP certificates, manufacturing authorisations and management-system certificates. ISO 9001:2015, ISO 13485:2016 and ISO 22716:2007 support the broader quality framework but do not replace product/site-specific GMP scope.

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.