Could the EU SoHO Regulation affect your development pathway?

A first screen for products and processes involving material collected from the human body — for medicinal product, ATMP, medical device and microbiota-based developers.

7 August 2024
Entered into force

7 August 2027
Applies. The Blood and Tissues & Cells Directives are repealed.

7 August 2028
An extra year for certain provisions and transitional arrangements.

THE POINT MOST DEVELOPERS MISS

Even where the final product is regulated as a medicinal product, ATMP or medical device, SoHO requirements may still apply **upstream** — to collection, testing, processing, storage and distribution of the human-derived material, up to its supply to the manufacturer.

FIVE SCREENING QUESTIONS

Tick what applies. Screens 02–04 take more than one answer.

01 Does the product or manufacturing process involve material collected from the human body?

SoHO means any substance collected from the human body — cells or no cells, living or not — including preparations made from it.

☐ **Yes** ☐ **No** If no, the Regulation is unlikely to apply — unless human-derived material enters the process later.

IN SCOPE, FOR EXAMPLE
Blood and blood components, cells and tissues, reproductive cells, donated or banked human milk, intestinal microbiota — and anything processed from these.

OUTSIDE SCOPE
Solid organs for transplantation (Directive 2010/53/EU); breast milk fed only to the donor's own child, unprocessed by a SoHO entity. Cells or tissues taken from an organ stay in scope.

02 What is that material intended for?

- ☐ **Direct human application** — infusion, transfusion, transplantation, implantation, assisted reproduction, ingestion
- ☐ **Production of a SoHO preparation** — processing human-derived material for release and human application
- ☐ **Manufacture of a medicinal product, ATMP, investigational medicinal product or medical device** — as starting, source or ancillary material

This decides which framework governs the finished product — and where SoHO requirements continue to apply alongside it. Cell-based products may be ATMPs or SoHO preparations; classification turns on manipulation and intended function.

03 Which SoHO activities happen in your supply chain?

- ☐ Donor registration and evaluation
- ☐ Donor testing
- ☐ Collection
- ☐ Processing
- ☐ Quality control
- ☐ Storage
- ☐ Release
- ☐ Distribution to a manufacturer
- ☐ Import or export
- ☐ Human application
- ☐ Clinical-outcome registration

04 Who performs them?

- ☐ A SoHO entity
- ☐ A SoHO establishment
- ☐ A hospital or clinic
- ☐ An importer or distributor
- ☐ A CDMO or service provider
- ☐ A tissue, cell, milk or microbiota bank
- ☐ Your own organization

Obligations attach to whoever performs the activity — they may sit with suppliers, while the manufacturer maintains oversight of those activities.

05 Is the regulatory status or the interface between frameworks uncertain?

☐ **Yes** ☐ **No** Borderline cases can require case-by-case coordination between SoHO, medicinal-product, ATMP and device authorities.

READ-OUT

Five screens to a first view

Tick what applies. The read-out builds up as you go.

0/5 SCREENS

Working with human-derived materials?

Early assessment shows where SoHO enters your pathway — sourcing, CMC, traceability. VCLS supports applicability assessment, readiness and transition planning, and development strategy.

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A first screen, not a regulatory determination.