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Drug-Device Combinations for Chronic Diseases

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Guidance is provided on dossier requirements for drug-device combinations (DDCs) in the context of a regulatory submission (marketing authorisation application and post-authorisation application). The types of DDCs within the scope of this guideline are medical devices that are integral to the medicinal product, co-packaged with the medicinal product or referenced in the medicinal product ...

Quality requirements for drug-device combinations ...

Combination Products Therapeutic and diagnostic products that combine drugs, devices, and/or biological products.

Combination Products | FDA

Drug combinations that target critical pathways are a mainstay of cancer care. To improve current approaches to combination treatment of chronic lymphocytic leukemia (CLL) and gain insights into ...

Survey of ex vivo drug combination effects in chronic ...

A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug ...

Frequently Asked Questions About Combination Products | FDA

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Drug/Device & Device/Drug Combinations in the EU and USA ...

In some combination drug products that include an antihypertensive agent, the endpoint targeted by each component is different, such as the combination of amlodipine, a dihydropyridine CCB that lowers BP, and atorvastatin, an HMG-CoA reductase inhibitor that lowers cholesterol.

Combination Drug - an overview | ScienceDirect Topics

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Synchrony Labs conducts non-GLP and GLP-compliant preclinical studies for medical devices and drug-device or cell-device combination products. As needed, assistance with model selection, study design and study protocol development is also provided to meet our client's research needs.

Preclinical Services for Medical Devices and Combination ...

Devices have long been used to improve drug therapy. Tablets, capsules, oral liquid syringes, eye drops, nose drops, syringes for intravenous, subcutaneous, or intramuscular injection, and catheters are classical drug delivery devices.

Modern Drug-Medical Device Combination Products ...

There are ways to combat chronic pain without pills, though, and a Boston-area technology company called NeuroMetrix is trying to bring drug-free pain relief to the masses, no prescription required.

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