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Japan represents the third largest pharmaceutical market in the world. Developing a new biopharmaceutical drug product for the Japanese market is a top business priority for global pharmaceutical companies while aligning with ethical drivers to treat more patients in need. Understanding Japan-specific key regulatory requirements is essential to achieve successful approvals. Understanding the full context of Japan-specific regulatory requirements/expectations is challenging to global pharmaceutical companies due to differences in language and culture. This article summarizes key Japan-specific regulatory aspects/requirements/expectations applicable to new drug development, approval, and postapproval phases. Formulation excipients should meet Japan compendial requirements with respect to the type of excipient, excipient grade, and excipient concentration. Preclinical safety assessments needed to support clinical phases I, II, and III development are summarized. Japanese regulatory authorities have taken appropriate steps to consider foreign clinical data, thereby enabling accelerated drug development and approval in Japan. Other important topics summarized in this article include: Japan new drug application-specific bracketing strategies for critical and noncritical aspects of the manufacturing process, regulatory requirements related to stability studies, release specifications and testing methods, standard processes involved in pre- and postapproval inspections, management of postapproval changes, and Japan regulatory authority's consultation services available to global pharmaceutical companies.

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Digestive tract tumors are among the most common and deadliest malignancies worldwide, mainly due to late diagnosis and lack of efficient therapeutics. Current treatments essentially rely on surgery associated with (neo)adjuvant chemotherapy agents. Despite an upfront response, conventional drugs often fail to eliminate highly aggressive clones endowed with chemoresistant properties, which are responsible for tumor recurrence and disease dissemination. Synthetic drugs also present severe adverse systemic effects, hampering the administration of biologically effective dosages. Nanoencapsulation of chemotherapeutic agents within biocompatible polymeric or lipid matrices holds great potential to improve the pharmacokinetics and efficacy of conventional chemotherapy while reducing systemic toxicity. Tagging nanoparticle surfaces with specific ligands for cancer cells, namely monoclonal antibodies or antibody fragments, has provided means to target more aggressive clones, further improving the selectivity and efficacy of nanodelivery vehicles. In fact, over the past twenty years, significant research has translated into a wide array of guided nanoparticles, providing the molecular background for a new generation of intelligent and more effective anticancer agents. Attempting to bring awareness among the medical community to emerging targeted nanopharmaceuticals and foster advances in the field, we have conducted a systematic review about this matter. Emphasis was set on ongoing preclinical and clinical trials for liver, colorectal, gastric, and pancreatic cancers. To the best of our knowledge this is the first systematic and integrated overview on this field. Using a specific query, 433 abstracts were gathered and narrowed to 47 manuscripts when matched against inclusion/exclusion criteria. All studies