

Regulatory 101: The Basics Of New Drug Application Submissions In Major Markets

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Table 1. Regulatory Acronyms, Defined First, for this discussion, the major markets are defined as those countries with health authorities that were either foundational to the creation and first adoption of ICH guidelines or countries that quickly followed on to adopt ICH protocols. Specifically discussed are United States, Canada, the European Union (additional note about United Kingdom in post-Brexit), Switzerland, and Japan. The names of the corresponding health authorities are noted for reference. Second, it is important to understand that each of the major markets adhere to and require that...

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