

Analysis and Case Study Review: FDA Warning Letter To Tismor Health and Wellness



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By

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On 5 December 2019, the US FDA issued a Warning Letter (320-20-10) to the Australian firm Tismor Health and Wellness Pty Limited, following an inspection conducted on May 20 to 24, 2019. The source of this Warning Letter is: Warning Letter to Tismor Health and Wellness Pty., dated December 5, 2019 OBSERVATION This US FDA observation is related to 21 CFR Part 211.68(b). This section in the CGMP manufacturing of drug and finished pharmaceuticals is associated with the automatic systems performing CGMP functions. 211.68(b) regulation, related to e-records integrity, provides the following principles: Access...

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