Trends and brands

3. Medicines for advanced therapies: scientific approaches to validate quality, safety and efficacy

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References

44. The International Conference on Harmonisation (2011). Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (S6(R1)).

47. The International Conference on Harmonisation (2004). Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process (Q5E).