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Quality Manual EU GMP Yes (Chapter 4) Yes
(Chapter 1) PIC/S GMP version 11 (2017) Yes
(Chapter 4) Yes (Chapter 1) WHO GDRP (2016)
No Yes EU and PIC/S SMF guidance document Yes
No specific requirement ISO 9001 (2015) No
Yes (2013), No (2015) now more general ICH
Q10 No Yes Adapted from Tang, S. 2013.

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