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Quality Manual Template www.iso9001help.co.uk ISO 9001:2015 Quality Management System Document Ref. Page 8 of 51 4 Context of the Organization 4.1 Organizational Context Your organization is committed to defining our position in the marketplace and understanding how relevant

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Regulation or Standard Site Master File 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.

Quality Manual – DCVMN

This Manual is the property of Jet Precision Metal, Inc. It may not be reproduced or disclosed in whole or in part. When printed this document is uncontrolled. Page 6 of 12 5.4 Management Review - Management reviews the quality system to ensure its continuing suitability, adequacy and effectiveness.

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5.1.1 General 13 5.1.2 Customer Focus 13 5.2 Policy 14 5.2.1 Developing the Quality Policy 15 ... This quality manual defines the policies and principles applied against each of the requirements of ISO 9001:2008 and relates to all activities carried out in the company that determine quality, and lays down ...