

# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>7</b>
1.1	Objectives .....	7
1.2	Scope .....	7
1.3	Benefits .....	8
1.4	Key Concepts .....	9
1.5	Definitions .....	9
1.6	Guidance Structure .....	10
<b>2</b>	<b>Variability and Sampling .....</b>	<b>11</b>
2.1	Variability .....	11
2.2	Sampling .....	16
<b>3</b>	<b>Establishment and Application of a Process Performance and Product Quality Monitoring System.....</b>	<b>17</b>
3.1	Introduction .....	17
3.2	Establishment and Implementation of a Control Strategy as a Basis for a PP&PQMS .....	19
3.3	Provide the Tools for Measurement and Analysis of Parameters and Attributes .....	19
3.4	Analysis of Parameters and Attributes .....	27
3.5	Identify Sources of Variation .....	28
3.6	Include Feedback on Product Quality from both Internal and External Sources .....	32
3.7	Provide Knowledge to Enhance Process Understanding .....	36
<b>4</b>	<b>Roles and Responsibilities of Quality Stewards .....</b>	<b>43</b>
4.1	Introduction .....	43
4.2	Quality Steward Role .....	43
<b>5</b>	<b>Appendix 1 – Considerations for Analytical Procedures and Data.....</b>	<b>49</b>
<b>6</b>	<b>Appendix 2 – General Considerations for Establishing a Control Strategy.....</b>	<b>57</b>
<b>7</b>	<b>Appendix 3 – Analytical Procedures Potentially Used in a PP&amp;PQMS.....</b>	<b>62</b>
<b>8</b>	<b>Appendix 4 – References .....</b>	<b>67</b>
<b>9</b>	<b>Appendix 5 – Glossary .....</b>	<b>71</b>
9.1	Acronyms .....	72
9.2	Definitions .....	74