

# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>7</b>
1.1	Rationale and Purpose .....	8
1.2	Scope.....	8
1.3	Structure of this Guide .....	9
<b>2</b>	<b>Material Handling .....</b>	<b>11</b>
2.1	Introduction .....	11
2.2	Storage Conditions .....	14
2.3	Container Type.....	16
2.4	Container Features .....	17
2.5	Mechanical Flow Aids .....	19
2.6	Milling and Screening.....	19
2.7	Sampling and Monitoring .....	20
2.8	Pneumatic Conveying .....	21
2.9	Chutes Between Unit Operations.....	22
2.10	Cleaning.....	23
2.11	Other Considerations .....	23
<b>3</b>	<b>Feeding and Blending .....</b>	<b>25</b>
3.1	Introduction .....	25
3.2	Feeding .....	25
3.3	Blending.....	33
<b>4</b>	<b>Wet Granulation .....</b>	<b>47</b>
4.1	Introduction .....	47
4.2	Key Input Process Variables/Signals in WGD.....	48
4.3	Example Automation Interface for Fully Continuous Systems .....	55
4.4	Automation Considerations for Harmonization/Standardization .....	56
4.5	Opportunities/Scope for PAT.....	57
<b>5</b>	<b>Roller Compaction .....</b>	<b>59</b>
5.1	Introduction .....	59
5.2	Hardware Requirements for The Roller Compaction Process .....	63
5.3	Minimum Equipment Attributes .....	67
5.4	Opportunities for Advanced Process Control Using PAT and Automation .....	69
<b>6</b>	<b>Compression and Coating.....</b>	<b>73</b>
6.1	Compression.....	73
6.2	Coating.....	79
<b>7</b>	<b>Automation and PAT.....</b>	<b>85</b>
7.1	Introduction .....	85
7.2	Overview of Continuous Manufacturing Functionality.....	85
7.3	Unit Operation Modularity, Module Type Package (MTP).....	86
7.4	Process Orchestration Layer .....	89
7.5	Continuous Manufacturing Advanced Line Controls .....	93
7.6	Standard Communication Interfaces Between Unit Operations – OPC UA.....	95
7.7	Material Tracing and Tracking.....	96
7.8	Batch and Recipe Management.....	99
7.9	Process Analytical Technology (PAT).....	107
7.10	Summary.....	112

<b>8</b>	<b>Appendix 1 – Unit Operation Equipment Attributes</b> .....	<b>113</b>
8.1	Material Handling (Chapter 2).....	113
8.2	Feeding and Blending (Chapter 3).....	117
8.3	Wet Granulation (Chapter 4).....	122
8.4	Roller Compaction (Chapter 5).....	124
8.5	Compression (Chapter 6).....	127
8.6	Coating (Chapter 6).....	128
<b>9</b>	<b>Appendix 2 – References</b> .....	<b>129</b>
<b>10</b>	<b>Appendix 3 – Glossary</b> .....	<b>135</b>
10.1	Acronyms and Abbreviations .....	135
10.2	Definitions .....	137