

# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>9</b>
1.1	Background.....	9
1.2	Purpose and Objectives.....	9
1.3	Scope.....	9
1.4	Benefits.....	10
1.5	Summary of Revisions.....	11
1.6	Key Concepts and Terms.....	11
<b>2</b>	<b>Purpose of HVAC in Pharmaceutical Facilities (Basic Concepts) .....</b>	<b>19</b>
2.1	Regulations.....	19
2.2	Product Quality.....	19
2.3	Cleanroom Classification – ISO 14644 versus GMP Regulation.....	21
2.4	Environmental Classification and Monitoring: Occupancy States.....	24
2.5	Contamination Control.....	30
2.6	Airlocks.....	32
<b>3</b>	<b>Specification and Design Qualification Process.....</b>	<b>39</b>
3.1	Introduction.....	39
3.2	Quality by Design (QbD).....	40
3.3	Concept Design.....	42
3.4	User Requirements Specification.....	42
3.5	Identification of HVAC CPPs and SPPs.....	44
3.6	Basis of Design.....	48
3.7	Detailed Design.....	48
3.8	Design Review and Risk Assessment.....	52
<b>4</b>	<b>System Design Configuration and Components.....</b>	<b>59</b>
4.1	Equipment Specification.....	59
4.2	Fans.....	62
4.3	Motors and Drives.....	67
4.4	Airflow Control Devices.....	68
4.5	Control Valves.....	73
4.6	Coils.....	76
4.7	Additional Equipment.....	79
4.8	Sound Attenuators.....	83
4.9	Air Filters.....	85
4.10	HVAC System Configuration.....	94
4.11	Pressure Control Strategies.....	101
4.12	AFDs and AFIDs.....	104
<b>5</b>	<b>Energy and Environment.....</b>	<b>107</b>
5.1	Introduction.....	107
5.2	Energy Demand Reduction.....	107
5.3	Waste Energy Recovery.....	109
5.4	Energy-Efficient Design.....	113
5.5	Measure/Verify/Optimize.....	114
5.6	Refrigerants.....	115
5.7	Water Use Reduction.....	115
5.8	Lifecycle Cost Considerations.....	116
5.9	Building Rating Systems.....	116
5.10	Sustainable Design for HVAC Systems.....	119

<b>6</b>	<b>Design Considerations.....</b>	<b>123</b>
6.1	Introduction .....	123
6.2	General Design Considerations .....	124
6.3	AHU and Control Considerations.....	127
6.4	Airflow Diagrams by Facility Type .....	131
6.5	Process Equipment Integration.....	156
<b>7</b>	<b>Controls/BMS/EMS .....</b>	<b>161</b>
7.1	Introduction .....	161
<b>8</b>	<b>Commissioning and Qualification (C&amp;Q).....</b>	<b>179</b>
8.1	Equipment Installation and Startup.....	179
8.2	Commissioning and Qualification Planning.....	187
8.3	Commissioning and Qualification of HVAC Systems .....	193
<b>9</b>	<b>Lifecycle Documents – Documentation Requirements .....</b>	<b>207</b>
9.1	Introduction .....	207
9.2	Engineering Document Life Cycle.....	207
<b>10</b>	<b>Equipment Operation and Maintenance .....</b>	<b>211</b>
10.1	Introduction .....	211
10.2	Air Handling Units .....	211
10.3	Fans.....	212
10.4	Heating and Cooling Coils .....	213
10.5	Steam Humidifiers.....	214
10.6	Desiccant Dehumidifier .....	214
10.7	Air Filtration [60].....	215
10.8	Ductwork .....	216
10.9	Dampers and Louvers.....	217
10.10	Diffusers and Registers.....	217
10.11	Ultraviolet Lights .....	217
10.12	Fume Exhaust/Extraction Systems.....	217
10.13	Building .....	217
10.14	Air Balancing.....	217
10.15	Spare Parts.....	218
<b>11</b>	<b>Appendix 1 – Psychrometrics.....</b>	<b>219</b>
11.1	Introduction .....	219
11.2	Dry-Bulb Temperature .....	221
11.3	Wet-Bulb Temperature .....	221
11.4	Dew Point Temperature .....	222
11.5	Relative Humidity (Percentage of Saturation).....	223
11.6	Barometric or Total Pressure .....	223
11.7	Specific Enthalpy .....	224
11.8	Specific Volume .....	224
11.9	Humidity Ratio or Specific Humidity.....	225
11.10	Vapor Pressure .....	226
11.11	Eight Fundamental Vectors.....	227
11.12	System Mapping .....	228

<b>12 Appendix 2 – System Risk Assessment.....</b>	<b>229</b>
12.1 Suggested Approach for the Classification of HVAC/Facility Monitoring Instruments.....	229
12.2 SRA for an HVAC System – with the System Boundary including the HVAC System and Final HEPA Filter .....	230
12.3 SRA for a Room – with the System Boundary including the Room and Final HEPA Filter .....	232
<b>13 Appendix 3 – Design Review and Design Qualification Examples .....</b>	<b>235</b>
13.1 Design Review Process .....	235
<b>14 Appendix 4 – Sample Test and Balance Report .....</b>	<b>241</b>
<b>15 Appendix 5 – Continuous Dilution Modeling for Air Change Rates in Non-Unidirectional Cleanrooms .....</b>	<b>247</b>
15.1 Introduction .....	247
15.2 Assumptions .....	247
15.3 Example Input Data .....	248
15.4 Solution .....	249
15.5 Conclusion .....	251
15.6 Discussion.....	251
<b>16 Appendix 6 – References .....</b>	<b>253</b>
<b>17 Appendix 7 – Glossary .....</b>	<b>259</b>
17.1 Acronyms and Abbreviations .....	259
17.2 Definitions .....	263