

# Contents

Professional group members .....	2
Foreword .....	3
<b>1 Industrial hygiene – a key part of the cosmetics manufacturing process (U. Eigener, E.-M. Köhler) .....</b>	<b>7</b>
<b>1.1 Hygiene – part of the quality system .....</b>	<b>8</b>
<b>1.2 Implementing hygiene requirements .....</b>	<b>11</b>
<b>1.3 Training and control measures .....</b>	<b>13</b>
<b>1.4 Monitoring hygiene in relation to external service providers, suppliers and contractors .....</b>	<b>16</b>
<b>1.5 Literature .....</b>	<b>17</b>
<b>2 Structural requirements (E.-M. Köhler, U. Eigener) .....</b>	<b>19</b>
<b>2.1 General building requirements – room specification sheets .....</b>	<b>19</b>
<b>2.2 Site requirements .....</b>	<b>22</b>
<b>2.3 Planning principles .....</b>	<b>22</b>
<b>2.4 Building areas .....</b>	<b>23</b>
<b>2.5 Literature .....</b>	<b>28</b>
<b>3 System design and system hygiene (W.J. Beckermann, C. Koch) .....</b>	<b>33</b>
<b>3.1 System design .....</b>	<b>33</b>
<b>3.2 System hygiene .....</b>	<b>49</b>
<b>3.3 Literature .....</b>	<b>57</b>
<b>4 System design and system hygiene for water (W.J. Beckermann, U. Eigener, H. Simon) .....</b>	<b>63</b>
<b>4.1 Microbiological quality of the product water used .....</b>	<b>63</b>
<b>4.2 Biofilm .....</b>	<b>64</b>
<b>4.3 General diagrams for process water .....</b>	<b>65</b>
<b>4.4 Basic pretreatment of incoming water .....</b>	<b>67</b>
<b>4.5 Microbiological treatment of town water .....</b>	<b>70</b>
<b>4.6 Chemical/physical treatment of incoming water .....</b>	<b>76</b>
<b>4.7 Storing treated process water and closed circular pipelines .....</b>	<b>82</b>
<b>4.8 Design for hot process water .....</b>	<b>86</b>
<b>4.9 Taking samples to determine microbial burden .....</b>	<b>88</b>
<b>4.10 Disinfecting the system .....</b>	<b>89</b>
<b>4.11 Common technical and hygienic errors .....</b>	<b>93</b>
<b>4.12 Literature .....</b>	<b>94</b>

<b>5</b>	<b>Room hygiene (S. Deyhle, C. Wunderlich)</b> .....	<b>95</b>
	<i>5.1 Cleaning and disinfection</i> .....	95
	<i>5.2 Hygiene schedule (for cleaning and disinfecting rooms subject to the good manufacturing practice requirements)</i> .....	98
	<i>5.3 Personnel movements and material flows</i> .....	102
	<i>5.4 Ventilation</i> .....	103
	<i>5.5 Literature</i> .....	103
	<i>5.6 Sample documents</i> .....	104
<b>6</b>	<b>Personnel hygiene (S. Deyhle, R. Müller)</b> .....	<b>109</b>
	<i>6.1 Integration into the hygiene areas concept</i> .....	110
	<i>6.2 Employee conduct</i> .....	111
	<i>6.3 Hand hygiene</i> .....	112
	<i>6.4 Clothing</i> .....	115
	<i>6.5 Health</i> .....	116
	<i>6.6 Visitors and external personnel</i> .....	117
	<i>6.7 Employee training</i> .....	117
	<i>6.8 Checks</i> .....	118
	<i>6.9 Documentation</i> .....	119
	<i>6.10 Miscellaneous</i> .....	119
	<i>6.11 Literature</i> .....	119
<b>7</b>	<b>Material transportation and storage (R. Müller, L. Neumayr)</b> .....	<b>121</b>
	<i>7.1 General conditions</i> .....	121
	<i>7.2 Storerooms</i> .....	124
	<i>7.3 Systems and containers</i> .....	125
	<i>7.4 Creating bulk goods ("compounding")</i> .....	126
	<i>7.5 Using packaging and tissue materials</i> .....	127
	<i>7.6 Handling semi-finished (bulk) and finished goods</i> .....	129
	<i>7.7 Guidance values and checks</i> .....	130
	<i>7.8 Literature</i> .....	133
<b>8</b>	<b>Pest control and waste disposal (C. Wunderlich)</b> .....	<b>135</b>
	<i>8.1 Pest control</i> .....	135
	<i>8.2 Waste disposal</i> .....	139
	<i>8.3 Literature</i> .....	141
<b>9</b>	<b>Microbiological checks (D. Ochs, J. Kolar)</b> .....	<b>143</b>
	<i>9.1 Sampling</i> .....	143
	<i>9.2 Process checks (raw materials – packaging – preparation vessels – storage – filling – packing)</i> .....	148
	<i>9.3 Methods</i> .....	152
	<i>9.4 Alternative methods</i> .....	162

<b>9.5 Organising and evaluating microbiological checks</b> .....	166
<b>9.6 Literature</b> .....	167
<b>10 Hygiene monitoring (D. Ochs)</b> .....	169
<b>10.1 Methods</b> .....	171
<b>10.2 Organising and implementing hygiene checks</b> .....	178
<b>10.3 Hygiene check schedules</b> .....	186
<b>10.4 Guidance values</b> .....	187
<b>10.5 Documentation</b> .....	189
<b>10.6 Literature</b> .....	190
<b>11 Reacting to positive microbiological findings</b> (L. Neumayr, U. Eigener) .....	191
<b>11.1 Basic requirements, official microbiological         limits and internal company specifications</b> .....	191
<b>11.2 Microbiological analyses and resultant decisions</b> .....	193
<b>11.3 Basic considerations and validation measures</b> .....	197
<b>11.4 Root cause analysis and quality assurance measures</b> .....	200
<b>11.5 Literature</b> .....	202
<b>Index</b> .....	203