

# ISO 15378:2017-09 (E)

## Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)

---

| <b>Contents</b>     |  | <b>Page</b> |
|---------------------|--|-------------|
| <b>Foreword</b>     |  | <b>v</b>    |
| <b>Introduction</b> |  | <b>vi</b>   |
| <b>1</b>            | <b>Scope</b>   | <b>1</b>    |
| <b>2</b>            | <b>Normative references</b>  | <b>1</b>    |
| <b>3</b>            | <b>Terms and definitions</b>                                       | <b>2</b>    |
|                     | 3.1 Terms related to organization                                  | 2           |
|                     | 3.2 Terms related to activity                                      | 3           |
|                     | 3.3 Terms related to system  | 4           |
|                     | 3.4 Terms related to requirement                                   | 5           |
|                     | 3.5 Terms related to process                                       | 6           |
|                     | 3.6 Terms related to results                                       | 7           |
|                     | 3.7 Terms related to data, information and document                | 8           |
|                     | 3.8 Terms related to action  | 9           |
|                     | 3.9 Terms related to characteristic                                | 10          |
|                     | 3.10 Terms related to determination                                | 10          |
|                     | 3.11 Terms relating to risk management                             | 11          |
| <b>4</b>            | <b>Context of the organization</b>                                 | <b>12</b>   |
|                     | 4.1 Understanding the organization and its context                 | 12          |
|                     | 4.2 Understanding the needs and expectations of interested parties | 12          |
|                     | 4.3 Determining the scope of the quality management system         | 13          |
|                     | 4.4 Quality management system and its processes                    | 13          |
| <b>5</b>            | <b>Leadership</b>  | <b>14</b>   |
|                     | 5.1 Leadership and commitment                                      | 14          |
|                     | 5.1.1 General  | 14          |
|                     | 5.1.2 Customer focus   | 15          |
|                     | 5.1.3 Customer audits  | 15          |
|                     | 5.2 Policy   | 15          |
|                     | 5.3 Organizational roles, responsibilities and authorities         | 16          |
| <b>6</b>            | <b>Planning</b>  | <b>17</b>   |
|                     | 6.1 Actions to address risks and opportunities                     | 17          |
|                     | 6.2 Quality objectives and planning to achieve them                | 18          |
|                     | 6.3 Planning of changes  | 19          |
| <b>7</b>            | <b>Support</b>   | <b>19</b>   |
|                     | 7.1 Resources  | 19          |
|                     | 7.1.1 General  | 19          |
|                     | 7.1.2 People   | 19          |
|                     | 7.1.3 Infrastructure   | 20          |
|                     | 7.1.4 Environment for the operation of processes                   | 21          |
|                     | 7.1.5 Monitoring and measuring resources                           | 23          |
|                     | 7.1.6 Organizational knowledge                                     | 24          |
|                     | 7.2 Competence   | 24          |
|                     | 7.2.1 General  | 24          |
|                     | 7.2.2 GMP-training   | 24          |
|                     | 7.3 Awareness  | 25          |
|                     | 7.4 Communication  | 25          |
|                     | 7.5 Documented information   | 26          |

|  |  |           |
|--|--|-----------|
| 7.5.1  | General.....   | 26        |
| 7.5.2  | Creating and updating.....   | 26        |
| 7.5.3  | Control of documented information.....                               | 27        |
| 7.5.4  | Administration of IT systems and data.....                           | 28        |
| <b>8</b>   | <b>Operation.....</b>  | <b>29</b> |
| 8.1  | Operational planning and control.....                                | 29        |
| 8.2  | Requirements for products and services.....                          | 30        |
| 8.2.1  | Customer communication.....  | 30        |
| 8.2.2  | Determining the requirements for products and services.....          | 31        |
| 8.2.3  | Review of the requirements for products and services.....            | 31        |
| 8.2.4  | Changes to requirements for products and services.....               | 32        |
| 8.3  | Design and development of products and services.....                 | 32        |
| 8.3.1  | General.....   | 32        |
| 8.3.2  | Design and development planning.....                                 | 32        |
| 8.3.3  | Design and development inputs.....                                   | 33        |
| 8.3.4  | Design and development controls.....                                 | 33        |
| 8.3.5  | Design and development outputs.....                                  | 34        |
| 8.3.6  | Design and development changes.....                                  | 34        |
| 8.4  | Control of externally provided processes, products and services..... | 35        |
| 8.4.1  | General.....   | 35        |
| 8.4.2  | Type and extent of control.....                                      | 36        |
| 8.4.3  | Information for external providers.....                              | 37        |
| 8.5  | Production and service provision.....                                | 38        |
| 8.5.1  | Control of production and service provision.....                     | 38        |
| 8.5.2  | Identification and traceability.....                                 | 41        |
| 8.5.3  | Property belonging to customers or external providers.....           | 42        |
| 8.5.4  | Preservation.....  | 42        |
| 8.5.5  | Post-delivery activities.....  | 43        |
| 8.5.6  | Control of changes.....  | 43        |
| 8.6  | Release of products and services.....                                | 44        |
| 8.7  | Control of nonconforming outputs.....                                | 44        |
| <b>9</b>   | <b>Performance evaluation.....</b>                                   | <b>45</b> |
| 9.1  | Monitoring, measurement, analysis and evaluation.....                | 45        |
| 9.1.1  | General.....   | 45        |
| 9.1.2  | Customer satisfaction.....   | 45        |
| 9.1.3  | Analysis and evaluation.....   | 46        |
| 9.2  | Internal audit.....  | 48        |
| 9.3  | Management review.....   | 48        |
| 9.3.1  | General.....   | 48        |
| 9.3.2  | Management review inputs.....  | 49        |
| 9.3.3  | Management review outputs.....                                       | 49        |
| <b>10</b>  | <b>Improvement.....</b>  | <b>50</b> |
| 10.1   | General.....   | 50        |
| 10.2   | Nonconformity and corrective action.....                             | 50        |
| 10.3   | Continual improvement.....   | 51        |
| <b>Annex A (informative) Clarification of new structure, terminology and concepts.....</b>   |  | <b>52</b> |
| <b>Annex B (informative) Other International Standards on quality management and quality management systems developed by ISO/TC 176.....</b> |  | <b>56</b> |
| <b>Annex C (normative) GMP requirements for printed primary packaging materials.....</b>   |  | <b>60</b> |
| <b>Annex D (informative) Guidance on verification, qualification and validation requirements for primary packaging materials.....</b>        |  | <b>64</b> |
| <b>Bibliography.....</b>   |  | <b>75</b> |
| <b>Alphabetical index of defined terms used in this document.....</b>  |  | <b>78</b> |