

Packaging

EU Part I	All operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product. Note. Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not finally packaged, primary containers.
EU Part II	-
21 CFR 210/211	-

Packaging material

EU Part I	Any material employed in the packaging of a medicinal product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
EU Part II	Any material intended to protect an intermediate or API during storage and transport.
21 CFR 210/211	-

Procedure(s)

EU Part I	Description of the operations to be carried out, the precautions to be taken and measures to be applied directly or indirectly related to the manufacture of a medicinal product.
EU Part II	A documented description of the operations to be performed, the precautions to be taken and measures to be applied directly or indirectly related to the manufacture of an intermediate or API.
21 CFR 210/211	-
ISO 9000	Specified way to carry out an activity or a process.

Process Aids

EU Part I	-
EU Part II	Materials, excluding solvents, used as an aid in the manufacture of an intermediate or API that do not themselves participate in a chemical or biological reaction (e.g. filter aid, activated carbon, etc).
21 CFR 210/211	-

Production

EU Part I	All operations involved in the preparation of a medicinal product, from receipt of materials, through processing and packaging, to its completion as a finished product.
EU Part II	All operations involved in the preparation of an API from receipt of materials through processing and packaging of the API.
21 CFR 210/211	-

Qualification

EU Part I	Action of proving that any equipment works correctly and actually leads to the expected results. The word validation is sometimes widened to incorporate the concept of qualification.
EU Part II	Action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation.
21 CFR 210/211	-
ISO9000	Process to demonstrate the ability to fulfill specified requirements.

Quality Assurance

EU Part I	-
EU Part II	Den totala summan av de organiserade aktiviteter som görs i syfte att säkerställa att alla API har den kvalitet som behövs för avsedd användning samt att kvalitetssystemen vidmakthålles.
21 CFR 210/211	-
ISO9000	Part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality Control

EU Part I	-
EU Part II	Checking or testing that specifications are met.
21 CFR 210/211	-
ISO9000	Part of quality management (3.2.8) focused on fulfilling quality requirements.