

Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use (Text with EEA relevance)

*Article 10*

**Production**

- 1 The Member States shall ensure that the manufacturers carry out the different production operations in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available by the manufacturer for the in-process controls. All process deviations and product defects shall be documented and thoroughly investigated.
- 2 The manufacturers shall be required to take appropriate technical and organisational measures to avoid cross contamination and mix-ups.
- 3 Any new manufacturing or important modification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly revalidated.