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 7

Personnel

1 The manufacturer shall be obliged to have at each manufacturing or import site a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the objective of the pharmaceutical quality system.

2 The duties of the managerial and supervisory staff, including the qualified persons referred to in Article 48 of Directive 2001/83/EC, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organisation chart. Organisation charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures.

3 The staff referred to in paragraph 2 shall be given sufficient authority to discharge their responsibility correctly.

4 The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice.

5 Hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel.