Download Eu Requirements For A Quality Manual

The requirements for the Manufacturer’s Quality Management System (QMS) are contained in Article 10, 9. Those familiar with the EU’s medical device QMS standard, EN ISO 13485:2016, should immediately recognise the similarities with Article 10, 9.All the previous versions of ISO 9001 (ISO 9001:2000, ISO 9001:2008, etc) required a Quality manual as the first level of documentation in a Quality Management System. O rganizations would combine the Quality Manual and Procedures into one manual, and refer to it as a quality manual.Quality: (not defined in EU GMP Guidances) degree to which a set of inherent properties (of a product, system, or process) fulfills requirements [ISO 9000 / ICH Q9 and Q10] Pharmaceutical Quality Assurance: the total sum of the organised arrangements made with the object of ensuring that medicinal products are of the quality required for theirenvironment and financial resources. The resource requirements for the implementation, management, control and continual improvement of the quality management system, and activities necessary to enhance customer satisfaction, are defined in our operational procedures, work instructions and the following sections of this quality manual: 1.