A quality management system operates behind all functions of an organisation. It's functions have a direct impact to the quality of the products and services offered by the organization. Quality management systems are required for example when a company wants to improve it's processes, make the quality of the products more stable and get an edge in the competition. The quality management system defines the procedures of the company for each of the levels and areas of its operation. It effects on every process, person and practice of the organization.

The thesis investigates design and implementation processes of a quality management system in a software company. The system is based on two standards which are ISO 9001, the quality management system's standard, and ISO 13485, the medical device's standard. Different organizations relating to the quality management and standardization are reviewed in the thesis as well as standards ISO 9001 and ISO 13485 are discussed in detail. The thesis is divided into two main chapters which are theoretical examination of quality management systems and practical part that concentrates on the implementation of a quality management system for a software company. In the third chapter the overall project is analysed and conclusions are made about it's success.

Implementing a quality management system according to international standards helps customers to identify that the company fulfils the common quality management criterion and thus quality management systems of different organizations are compatible with each other. That's why implementation of a quality management system gives an edge on competition for a software company. When a company implements a quality management system it usually encounters several problems which are discussed in the thesis. One of these problems is how the development of the processes of the quality management system works in the continuous pressure caused by the normal invoicing projects. As a result of the system's implementation, a quality manual is created. There the quality policy of the company is described in a general level, and also is presented what information the quality manual will contain, how and where it is collected and how it is represented.

Key words: Quality management system, Quality assurance project, ISO 9001, ISO 13485.