of both the product and the manufacturing process. Therefore, process control, product and process understanding are key elements of QbD. The main QbD steps are summarized below:

1. Identification of the critical quality attributes of the target drug product;
2. Design and development of drug formulation and manufacturing process;
3. Determination of critical process parameters and sources of variability;
4. Control of the manufacturing process to produce consistent quality over time.

The QbD implementation in the pharmaceutical and biopharmaceutical industries is based on four elements as shown in Figure 9.1:

1. Multivariate tools for design, data acquisition and analysis;
2. Process analysers;
3. Process control tools;
4. Continuous improvement and knowledge management tools.

The first element deals with the use of multivariate mathematical approaches – statistical design of experiments, response surface methodologies, process simulation, and pattern recognition algorithms – to understand multi-factorial relationships between process, formulation and quality. Process analysers include on- and in-line equipment that allows obtaining

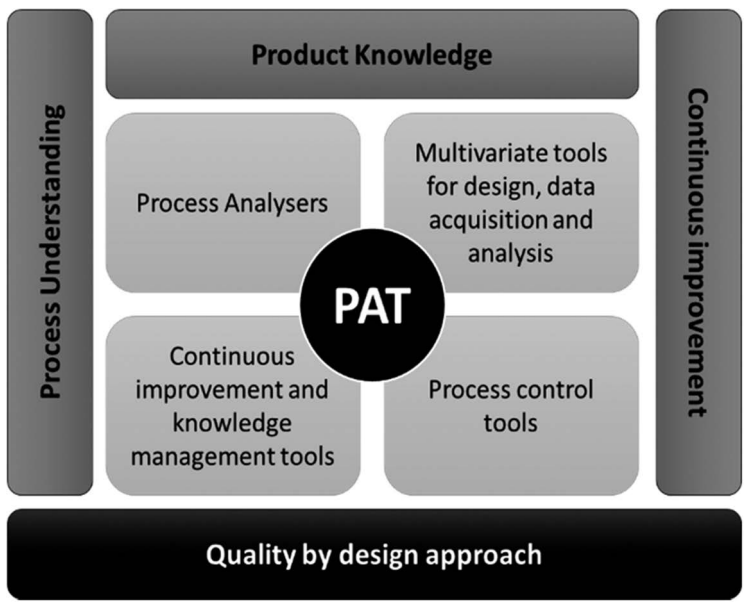

Figure 9.1 The PAT concepts based QbD framework.