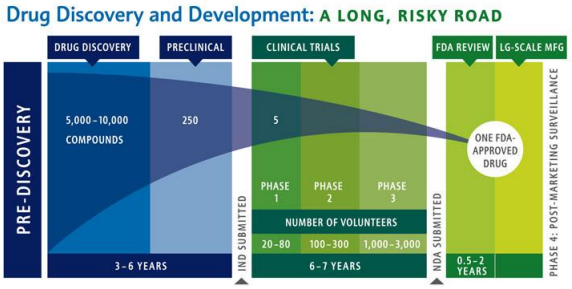
QbD | ANALYTICAL AND PROCESS DEVELOPMENT FACTSHEET

What for…?

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified. It includes pre-clinical research, clinical trials and analytical/process development through filing of the drug application to the regulatory authorities. This process can last more than 10 years, but it is necessary to fully evaluate the safety and efficacy of the new pharmaceutical drug.
By applying Quality by Design (QbD) during drug development in combination with the use of project management tools the "time-to-market" can be substantially shortened.

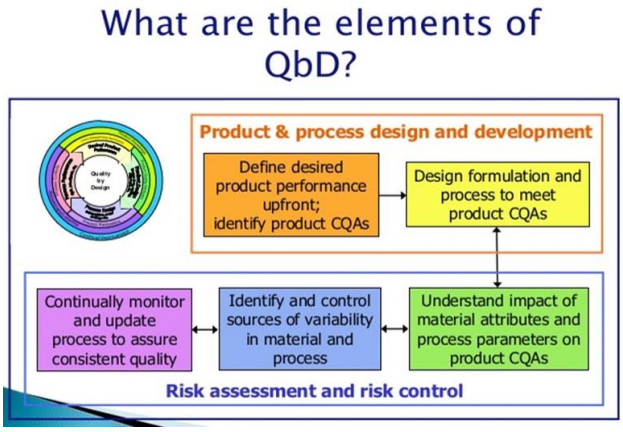


Source: Pharmaceutical Research and Manufacturers of America

Quality by Design

Quality by Design (QbD) is a systemic approach to pharmaceutical drug development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. In addition, a thorough product and process knowledge will lead to a robust process with less batch failure ("right-first-time"). Important QbD elements during development are:

- ✓ Target Product Profile (TPP) describes Labelled use-focus on safety, efficacy and quality
- ✓ Quality Target Product Profile (QTPP) that identifies the Critical Quality Attributes (CQAs) of the drug product
- ✓ Product design and understanding including identification of Critical Material Attributes (CMAs)
- ✓ Process design and understanding including identification of Critical Process Parameters (CPPs), linking CMAs and CPPs to CQAs
- ✓ Control strategy that includes specifications for the drug substance(s), excipient(s), and drug product as well as controls for each step of the manufacturing process
- ✓ Process capability and continual improvement



Facing the challenge…!

Applying QbD during drug development is more and more expected by regulatory authorities and the use of QbD elements is required by the FDA and the EMA since respectively 2011 and 2012. It will enable the review of a new drug application into a science-based pharmaceutical quality assessment.
Implementation of QbD in analytical, product and process development requires the collaboration of research, development, manufacturing, QA, QC and RA at an early stage.

Process Development

Process development comprises the early development at laboratory scale through late development at commercial manufacturing scale. Knowing this will take up to 10 years it is important to archive the gained knowledge in a structural manner. This can be achieved by writing development files which contain a summary of the development work such as development research results, process changes during (pre-)clinical phases and justifications.

Applying QbD in combination with project management tools can support an efficient process development. An experienced CMC project leader is a must have to be able to achieve drug approval by the regulatory authorities and thereby reduce the "time to market" as much as possible.

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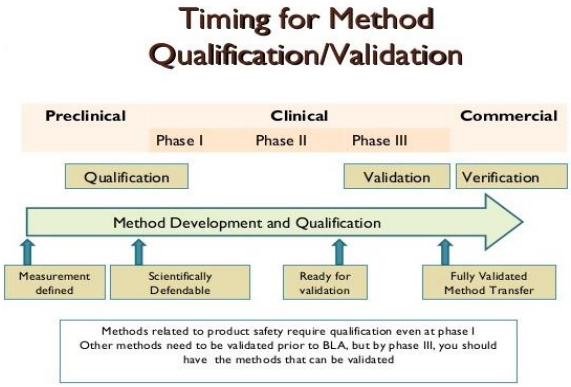
Analytical Development including Stability Studies

Analytic method development is a key element of any pharmaceutical drug development program. Reliable and reproducible analytical methods are essential. Method development is a continuous process that progresses in parallel with the drug development.

The goal and purpose of the method should reflect the phase of drug development.



How can we support you during Analytical and/or Process Development?

Progress-PME has a wide expertise in process and analytical development using the QbD approach. We can help you with design, implementation and/or execution of:

- ✓ QbD methodology for product and process and analytical development including DoE studies
- ✓ Process development including relevant process steps such as USP, DSP, formulation, filling and freeze-drying
- ✓ Product and Analytical development including design of stability studies
- ✓ Translation of research processes into pilot and subsequently commercial scale processes which fulfill GMP requirement
- ✓ Translating development knowledge into a strong validation program
- ✓ Development of a scientific based control strategy
- ✓ Knowledge management which comprises the available analytical/product/process information from early development phase through validation phase

Track record and facts

This is a selection of our main Quality by Design / Analytical and Process development experience:

- ✓ We have provided interim managers to lead both Analytical and Process development teams
- ✓ Our project managers have lead and supported several analytical and process development project teams in both early and late stage development projects
- ✓ We have given (in-house) QbD and DoE workshops and supported organisations implementing QbD methodology
- ✓ We have built a QTTP/CQA/CPP control strategy documentation package for legacy products
- ✓ We have supported organisations in gap analysis and mitigation strategies for FDA stage I and/or stage II process validation
- ✓ We have developed several tools and templates to facilitate the QbD methodology

Who are we….?

Progress-PME is an independent project management and consultancy company with customers in life science, (bio)pharmaceutical, medical device and healthcare industries.

The company was founded in 1999, operates internationally and provides support throughout the entire range of process development to commercial production.

Progress-PME provide services in the field of project and interim management, and Consultancy.

Fields of expertise: CMC, Quality (cGxP), Validation, Engineering, LEAN Six Sigma.