Assay & Quality Control

GreyRigge Associates Ltd.

1. Product Critical Quality Attributes (CQAs)

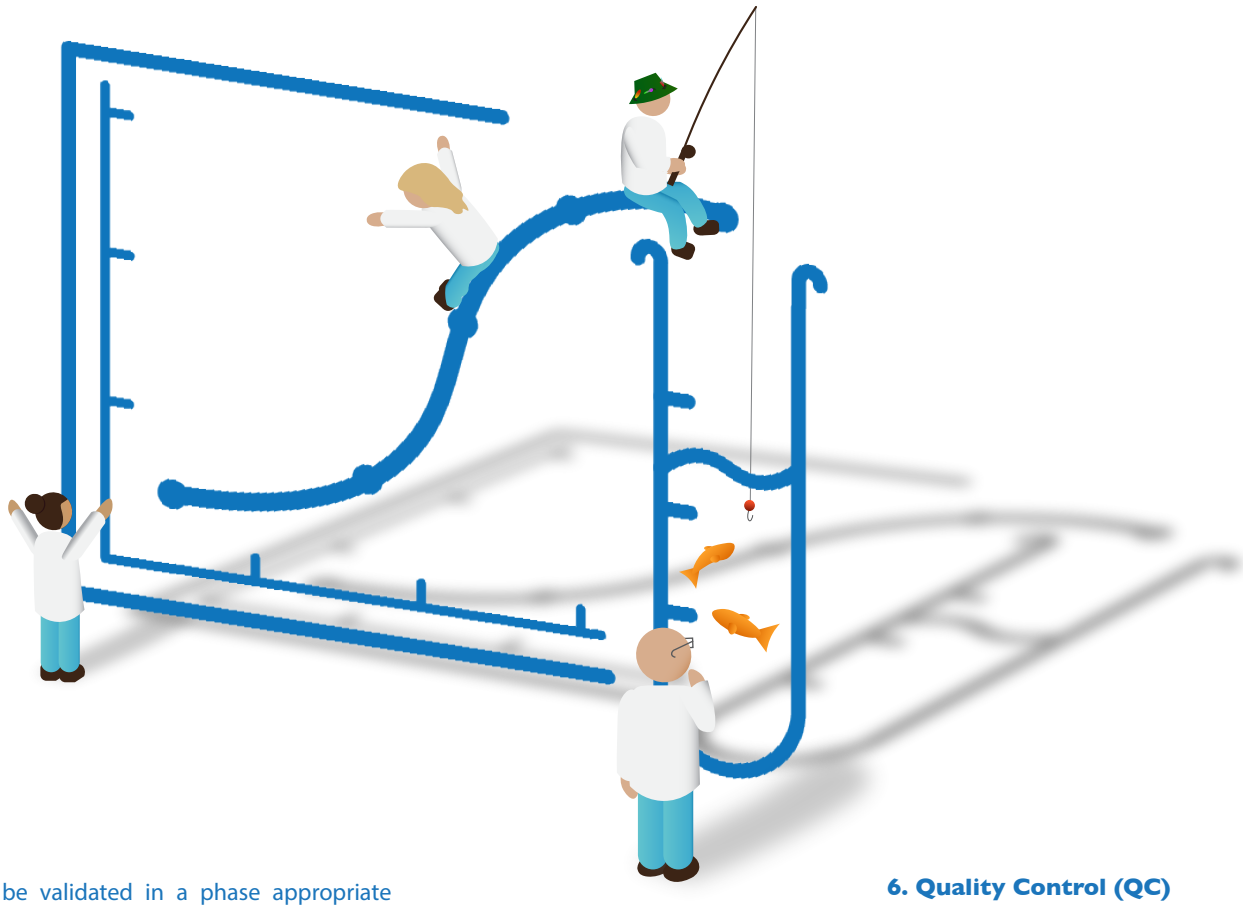
The Critical Quality Attributes (CQAs) of a product are essential information, with methods specifically developed to measure these. The product's specifications lay out what is to be measured, containing ranges and pass/fail criteria on which product is released.

2. Analytical Development

Analytical methods must be rigorously developed that can help measure a product's identity, content, potency and impurities. Ultimately these methods are used by Quality Control (QC) to test the product.

3. Method Optimisation

Methods must be optimised to ensure that they are both robust and rugged. ICH Q14 provides detailed guidance and best practice for developers. Quality by Design principles can be applied, included Design of Experiments (DoE) approaches to systematically build reliable methods.



4. Validated

Methods need to be validated in a phase appropriate manner. This requires alignment with ICH Q2 regulatory guidance to ensure the method is fit for purpose. This includes specificity, accuary, linearity, precision and range.

5. Reference Preparations

Preparation of references to use as standards and controls, both positive & negative, are essential to ensure method control. Routinely testing controls during method use allows the analyst to be confident that the method is performing as expected and that the results generated at the time are valid.

6. Quality Control (QC)

Developed methods are routinely used to test products produced in manufacturing facilities working to Good Manufacturing Practice (cGMP) guidelines. QC methods are critical for ensuring that the integrity and quality of the biopharmaceutical throughout their development lifecycle.