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Expert workshop on setting specifications for biotech products

An Expert Workshop on Setting Specifications for Biotech Products was held at the European Medicines Agency on 9 September 2011.

Setting specifications is an area of great interest to both the regulatory agencies and industry particularly as our knowledge of product and process continuously evolves. More experience in manufacture of recombinant proteins is being gained, with the use of these types of products, and the correlation of potential safety concerns with product variants and impurities. Analytical techniques are constantly being improved and products are becoming better characterised.

What to control is one of the key questions to consider for each product in establishing the specification. Information about the critical quality attributes (CQAs) is defined during development. The criticality of controlling these in routine production should be assessed, but consideration should also be given to life cycle maintenance of specifications.

The **basis for setting acceptance criteria** for the release and in-process control (IPC) specifications must also be considered. How will it be possible to ensure that the variability in the production process is covered by the specification with the limited number of manufacturing scale lots that are available at the time of submission? Are these criteria reflected in the clinical experience with the product, or are the limits based on process performance alone?

The selection of the most suitable **statistical models** to define the acceptance criteria for different types of assays is another topic for discussion, but equally important is the understanding of the source of variability and the contribution not only from the process but also from the variability from the analytical methods.

With new and improved analytical technologies and techniques becoming available on an ongoing basis, the question of **how and where to control** process performance and product quality is also key. How is the link between methods and CQAs best established, are specific tests best performed as an IPC or, as a component of final release testing. How can alert and action limits be utilized in controlling the process that would result in a suitable product quality?

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The aim of the Workshop was to address some of the key topics on Setting Specifications from a regulatory and an industry perspective with the intention of fostering a discussion on these issues and, if possible, to arrive at a consensus view. For each session the topic was presented by a regulator and an industry speaker. The Workshop was intended to bring together experts in the area. The sessions were interactive with the aim of drawing upon the experience of the participants during the discussions. The output from the Workshop will be published and it is hoped that this will provide a useful reference source for future regulatory guidelines.